MIPLC Studies 3

Andrew Law

Patents and Public Health

Legalising the Policy Thoughts in the Doha TRIPS Declaration of 14 November 2001

Nomos

MIPLC Munich Intellectual Property Law Center
Augsburg München Washington DC

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For Silke and Noah

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Hanover, September 2008 Andrew Law

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List of Abbreviations

ACP	African, Caribbean and Pacific Group
AER	American Economic Review
AGOA	African Growth and Opportunity Act
AJIL	American Journal of International Law
AJPH	American Journal of Public Health
Art	Article
BGH	German Federal Supreme Court
BPatG	German Federal Patent Court
BSE	Bovine spongiform encephalopathy
BVerfG	German Federal Constitutional Court
CAFTA	US/Central American and Dominican Republic Free Trade Agreement
CEO	Chief Executive Officer
Chi. J. Intl. L.	Chicago Journal of International Law
CIPO	Canadian Intellectual Property Office
CIPR	UK Commission on Intellectual Property Rights
CPTech	Consumer Project on Technology
CSGTSD	Centre for Study of Global Trade System and Development
CUP	Cambridge University Press
DG	Director General
DSB	Dispute Settlement Body
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
EC	European Communities
ECJ	European Court of Justice
ed(s)	Editor(s)
edn	Edition
EFTA	European Free Trade Association
EGBGB	Einführungsgesetz zum Bürgerlichen Gesetzbuch
EJAIB	Eubios Journal of Asian and International Bioethics
EJIL	European Journal of International Law
ELDB	European Legal Developments Bulletin
EMEA	European Medicines Agency
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union

FDA	US Food and Drug Administration
FDI	Foreign direct investment
Food Drug L.J.	Food and Drug Law Journal
FTA	Free trade agreement
FTAA	Free Trade Agreement of the Americas
FTC	Federal Trade Commission
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GSP	Generalised System of Preferences
GRUR	Gewerblicher Rechtschutz und Urheberrecht
GRURInt	Gewerblicher Rechtschutz und Urheberrecht, Internationaler Teil
ICCPR	International Convent on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICJ	International Court of Justice
IFDA	International Foundation for Development Alternatives
IGE	Eidgenössisches Institut für Geistiges Eigentum
IIC	International Review of Industrial Property and Copyright Law
IIE	International Institute for Economics
IntCl	International Patent Classification
Int. J. Health Serv.	International Journal of Health Services
IntTLR	International Trade Law and Regulation
IPC	Intellectual Property Committee
IPGRI	International Plant Genetic Resources Institute
IPR	Intellectual property right
ITO	International Trade Organisation
IYHR	Israel Yearbook on Human Rights
JIEL	Journal of International Economic Law
J.Intell.Prop.L	Journal of Intellectual Property Law
JIPLP	Journal of Intellectual Property Law and Practice
JPHP	Journal of Public Health Policy
JPO	Japan Patent Office
JPTOS	Journal of the Patent and Trademark Office Society
JWIP	Journal of World Intellectual Property
LDC	Least-developed country
LMU	Ludwig-Maximilians-Universität (Munich)

MFN	Most-favoured nation
Mich.J.Int'l.L	Michigan Journal of International Law
Mich.L.Rev.	Michigan Law Review
MLU	Martin-Luther-Universität Halle-Wittenberg
MPI	Max Planck Institute
MSF	Médecins sans Frontières
NAFTA	North American Free Trade Agreement
NIH	US National Institutes of Health
NGO	Non-governmental organisation
NZZ	Neue Züricher Zeitung
OAPI	Organisation Africaine de la Propriété Intellectuelle
OHCHR	Office of the High Commissioner for Human Rights
OJEPO	Official Journal of the European Patent Office
OUP	Oxford University Press
p	Page(s)
Para	Paragraph
PCIJ	Permanent Court of International Justice
PhRMA	Pharmaceutical Research and Manufacturers Association
PMA	Pharmaceutical Manufacturers Association
QUNO	Quaker United Nations Office
SACU	Southern African Customs Union
SCID	Studies in Comparative International Development
sec	Section(s)
SPS	Sanitary and Phytosanitary Measures
TBT	Agreement on Technical Barriers to Trade
TIFA	Trade and investment framework agreement
TPD	Transvaal Provisional Division of the South African High Court
TPRM	Trade Policy Review Mechanism
TRALAC	Trade Law Centre for Southern Africa
TRIMS	Trade-Related Investment Measures
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNCHR	United Nations Commission on Human Rights
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNGA	United Nations General Assembly

UNHDI	United Nations Human Development Index
UNICEF	United Nations International Children's Emergency Fund
UNTS	United Nations Treaty Series
US	United States of America
USC	Unites States Code
USTR	US Trade Representative
WBER	World Bank Economic Review
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WSJ	Wall Street Journal
WTO	World Trade Organisation
WVK	Wiener Vertragsrechtkonvention
ZaöRV	Zeitschrift für ausländisches öffentliches Recht und Völkerrecht
ZEuS	Zeitschrift für Europarechtliche Studien

Chapter 1 Introduction

One of the three pillars of the World Trade Organisation ('WTO') is the Agreement on trade-related aspects of intellectual property rights.[1] The agreement, known as the TRIPS Agree-ment, requires its Member States to enact a system of intellectual property rights that has no comparison in the international arena. What sets the TRIPS Agreement apart from other international intellectual property rights treaties is its comprehensiveness. Not only does it dictate a minimum level of intellectual property protection from all WTO Member States but it also creates a judicial body to adjudicate and sanction those states abiding by its rules.[2] The combination of a minimum standard of intellectual property protection and a compliance body has made the TRIPS Agreement a formidable tool for the globalisation of intellectual property rights.

Parallel to the expansion of global intellectual property standards has been the spread of the HIV/AIDS virus. The toll this and other epidemics have taken has become a cause for national and international concern. Those countries worst affected by these epidemics, mostly developing countries, lacked the financial resources to provide meaningful treatment or adequate access to the necessary pharmaceuticals. Rightly or wrongly, the affected countries and non-governmental organisations identified patent protection as a barrier to providing access to the needed medicines. The WTO Member States reacted to the conflict of 'patent rights vs. patient rights' with the adoption of the Declaration on the TRIPS Agreement and Public Health (the 'Public Health Declaration').[3] By adopting the Public Health Declaration the WTO Member States presupposed three things: Firstly, that the TRIPS Agreement lacked the legal ability to address those policy thoughts contained in the Public Health Declaration; secondly, that the contents of the Public Health Declaration would rectify the problem, or at least point the direction to a resolution; and lastly that a solution would rectify the alleged weaknesses in the TRIPS Agreement.

These presuppositions arise principally out of the lack of a shared understanding of the scope and application of the TRIPS Agreement. It is only within the context of a legal evaluation of the TRIPS Agreement that the policy thoughts of the Public Health Declaration can be evaluated. Hence, it is the intention and purpose of this

1 Agreement on the Trade-Related Aspects of Intellectual Property Rights Annex 1C to the Agreement Establishing the World Trade Organisation. Cf. *Straus*, TRIPS, TRIPS-plus oder TRIPS-minus – Zur Zukunft des internationalen Schutzes des Geistigen Eigentums in: *Ohly et al* (eds) Perspektiven des Geistigen Eigentums und Wettbewerbsrechts (CH Beck Munich 2005) p. 197.

2 The TRIPS Agreement does however provide for the transitional implementation of the agreement in favour of developing and least-developed Member States.

3 Declaration on the TRIPS Agreement and Public Health, 14.11.2001, WT/MIN(01)/DEC/2 (Annex I hereto).

dissertation to conduct a legal appraisal of the scope and application of the TRIPS Agreement and the Public Health Declaration. In doing so this dissertation elucidates what measures are legally tenable under the TRIPS Agreement thus enabling an accurate appraisal of the necessity and applicability of the Public Health Declaration and, ultimately, the correctness of the criticisms levelled at the TRIPS Agreement.

In order to bring light into the TRIPS Agreement, this dissertation analyses the TRIPS Agreement from a neutral, pre-Public Health Declaration situation. Thereafter, the scope and effect of the Public Health Declaration is extensively addressed. Thereafter this dissertation then examines the international and domestic consequences that flowed from the Public Health Declaration.

The legal examination of the TRIPS Agreement alone would be incomplete without put-ting the exercise into a social and political context. This is done immediately below. Firstly, the relationship between patents and society is addressed and, secondly, the political events preceding the Public Health Declaration is described.

Chapter 2 Patents and society

There cannot be any doubt that it is noble for any country to pursue a policy which stimulates and rewards innovative elements in society, especially when these creations lead to advantages which society as a whole can reap. Although this may provide the originally intended purpose for the intellectual property regime,[4] the ensuing exclusive rights possess the ability to restrict free trade which can, in certain circumstances, even burden society. This negative effect of intellectual property rights can even lead to situations whereby elements of society are hindered from gaining benefits that would relieve their discomfort, illness and/or harm. The intellectual property regime, in particular the patent system, would thus appear to be paradoxical in nature. This however is not the case. The basic tenet of an open market is that free (unencumbered) trade increases economic growth and raises standards of living.[5] Patents form an exception to this rule in that they intentionally restrict trade yet also have the effect that society gains knowledge and efficiency from the invention, thus bringing with it an enrichment to society.[6] The balance between the interest of the society as a whole and that of the inventor rests on the condition that exclusive rights may only be granted for a limited period and when the inventor creates something that is new, non-obvious, useful and discloses the way in which to recreate the invention.[7] This relationship between the patent and the government-granted exclusive rights reflects a type of reciprocal pact in which both parties (the inventor and the government representing society) pay a 'price' in exchange for exclusive rights on the one hand and the creation and diffusion of knowledge and efficiency on the other hand.[8] It is upon this bargain that the patent system is based and justified.[9]

4 *May*, EIPR 1 (2003) p. 2.

5 *Beier*, 11 IIC 5 (1982) p. 548-549.

6 *Templeman*, 1 JIEL 4 (1998) p. 603, *Gervais*, 1 JIPLP 4 (2006) p. 252. *Maskus* makes an analogy between intellectual property rights and exclusive rights to property and notes that both are potentially growth-enhancing. *Maskus*, Intellectual Property Rights in the Global Economy (IIE Washington DC 2000) p. 145-146. Early commentators on free trade also did not oppose the patent system. *Beier* also notes that patent rights were, from their beginning, a natural partner of the free market economy. Cf. *Beier*, 11 IIC 5 (1982) p. 549.

7 As early back as 1848 *Mill* was able to make the following clear defence of the patent system: 'Because it leaves nothing to any one's discretion; because the reward conferred by it depends on the invention's being useful, and the greater reward; and because it is paid by the very persons to whom the service is rendered, the consumers of the commodity', Quoted in *Beier*, 94 GRUR 4 (1992) p. 231.

8 *CIPR*, (2002), p. 32, *May*, EIPR 1 (2003) p. 2.

9 An attempt to adequately address either the numerous theories justifying patents or the social, political and legal arguments in favour or against the intellectual property regime would however unnecessarily divert the purpose of this dissertation. As such, the societal justification of

Is the price society pays for the patent too high? This may indeed be the case when one looks at individual patents. Looking at the patent system on a whole it is important to realise that the creation of and the access to knowledge forms the fundamental driving powers behind the development of mankind. Accordingly, the wealth of new and useful information that the patent system brings is, in itself a means whereby society is able to develop.[10] It is almost impossible to quantify the benefit mankind has received through the patent system however patented inventions like the light bulb,[11] the telephone[12] and the four-stroke/Otto cycle engine[13] have themselves brought incalculable benefits to society. This benefit of the patent system was recognised from the very beginning and used as a measure for countries to improve their competitiveness and level of development.[14]

It was also early on in the development of the patent system that governments noticed that exclusive rights could also be abused and misused. As a result and in order that the patent system does not hamper development in an unjustifiable manner, safeguards were introduced to counter the potential misuse or abuse of the patent system.[15] Hence, it can be said that the patent system is there to add to society's wealth – where it fails to do so, the patent system allows society the means to remove the harmful and infringing elements that prevent this. At least in theory, it can therefore be said that there is a balance of rights and obligations within the patent system.

Again from a theoretical perspective, the territorial nature of patent rights further ensures that the benefits can be reaped by all countries, both rich and poor. The reason for this is that the patent exclusivity is limited to the country in which the patent rights are granted. Hence, in each and every country where the inventor acquires patent protection that country has a 'sufficiently clear and complete' description of how the invention works.[16] In other words, in exchange for granting of the patent rights that country has enriched its knowledge base. The countries, in which the inventor decides not (or is not able) to seek patent protection, also benefit because the invention, the existence and operation of which is already fallen into the public do-

intellectual property rights, in particular patent rights, is dealt with briefly and from a current standpoint.

10 *Maskus*, Intellectual Property Rights in the Global Economy (IIE Washington DC 2000) p. 150.

11 *Edison* applied for a patent for the 'Improvement in the Electric Lights' in 1878.

12 *Bell* was granted a patent in 1875 for 'Transmitters and Receivers of Electric Telegraphs' (US Patent 161,173).

13 *Barsanti* and *Matteucci* obtained the first patent for the four-stroke/Otto cycle engine in 1854.

14 *Granstand* notes that intellectual property rights are even older that capitalism. Cf. *Granstand*, The Economics and Management of Intellectual Property (Edward Elgar Cheltenham 1999) p. 5, 27-41.

15 The most famous example is the 1623 English Statute of Monopolies. The statute made reference to situations whereby the patented would be rendered void, for example price rises, injury to trade, inconvenience. Cf. *Davenport*, The United Kingdom Patent System: A Brief History (Mason London 1979) p. 20.

16 TRIPS Agreement Art 29.1.

main, can then be freely used by third parties.[17] In practice, however, not all countries are able to reap these rewards. Blaming the patent system for this would be wrong. This inability is due to market factors and insufficient resources; not all countries have the willpower or capacity to produce products domestically – it is often more affordable to import products instead of producing them locally.[18] Regardless of the reason for not making use of the invention (either on or off patent), the 'blame' for not doing so is economical or political; rarely is it the patent system itself that can be held responsible for the lack of access.

Criticism of the patent system also originates in the expectations individuals and countries have developed. The patent system is not one that will magically turn all countries adopting it into first-world nations.[19] The patent system only is one of many governmental measures and it alone cannot guarantee a country financial prosperity.[20] It may create an added incentive for an inventor to register its patent but it does not mean that the patent will be successfully exploited in that country, if at all.[21] Despite the neutral effect[22] a patent will *ipso facto* have on a country *Straus* has shown that the adoption of a patent system does not in itself bring less prosperity to a country.[23] In fact, it is a positive indication for a country when inventors increasingly seek patent protection for their inventions. The reason for this is that an inventor will be more willing to apply for a patent, thus paying the application fees and most likely also undertaking a degree of investment in a country that can give the inventor a likelihood of it capitalising on its invention.[24] The more inventors a country is able to attract the more knowledge it is able to accumulate and the more

17 A 1997 study of the Indian pharmaceutical market showed that local generic producers were quick to manufacture generic versions of the original product (patented elsewhere). Cf. *Lanjouw* referred to in *Maskus*, Intellectual Property Rights in the Global Economy (IIE Washington DC 2000) p. 162.

18 *Maskus* provides examples of how open markets were most able to profit, *inter alia*, from intellectual property markets. Cf. *Maskus*, Intellectual Property Rights in the Global Economy (IIE Washington DC 2000) p. 169.

19 *CIPR*, (2002), p. 39.

20 *Kongolo*, 33 IIC 2 (2002) p. 208-209.

21 For a discussion on the role of patent rights in national development see *Granstand*, The Economics and Management of Intellectual Property (Edward Elgar Cheltenham 1999) p. 41-45.

22 *Blakeney*, A critical analysis of the TRIPS agreement in: *Pugatch* (ed) The Intellectual Property Debate (Edward Elgar Cheltenham 2006) p. 19.

23 *Straus*, 6 J. Marshall Rev. Intell. Prop. L 1(2006) p. 1-16. It would however be amiss to draw the conclusion that the intellectual property rights had themselves solely lead to the economic growth in India and China. Such a conclusion ignores the complex macro and micro economic factors that affect the economic growth of a country. Compare *Gervais*, 1 JIPLP 4 (2006) p. 252-253, *Ullrich*, Transformations in IPR, in *Brunn* (ed) Intellectual Property Beyond Rights (WSOY Helsinki 2005) p. 4-5.

24 *Abbott*, 1 JIEL 4 (1998) p. 506. *Abbot* also acknowledges other positive factors that may derive from an intellectual property regime, such as added legal security and domestic innovation stimulations.

investment it is also able to count on.[25] This in turn increases market efficiency and competitiveness. The more efficient a country is, the more its wealth is effectively utilised. The sum of all these factors is that the country becomes more attractive for investment and more developed.[26] Innovation has hence become the mainspring of economic growth.[27] Despite this it would be wrong to state that a patent regime would bring short-term benefits.[28] Its true value can only truly be reaped in the long-term; and even then only as one part of a comprehensive domestic strategy.[29]

As mentioned at the beginning of this chapter, critics of the patent system suggest that it could be a barrier to obtaining access to certain essential and life-saving medicines. Critics suggest that patented medicines are higher in cost than similar non-patented medicines (or equivalent generic versions of the patented medicine).[30] This accusation is, in some instances true.[31] Seldom will one find a patented medicine trading at the same or lower price of a generic version thereof. However this accusation has little to do with a misuse or abuse of the patent rights.[32] Quite simply the patent period is a period of exclusivity designed to allow the patent holder the chance to recoup the resources invested into the creation of the pharma-ceutical and,

25 *Lippoldt*, Can stronger intellectual property rights boost trade, foreign direct investment and licensing in developing countries? in: *Pugatch* (ed) The Intellectual Property Debate (Edward Elgar Cheltenham 2006) p. 58-59. Contrast *Blakeney*, A critical analysis of the TRIPS agreement in: *Pugatch* (ed) The Intellectual Property Debate (Edward Elgar Cheltenham 2006) p. 23.

26 In summing up recent studies on the effect of intellectual property *Gervais* concludes that 'sufficient intellectual property protection is an essential component of increased FDI and trade flows … for countries above a certain economic development threshold'. Cf. *Gervais*, 1 JIPLP 4 (2006) p. 252-253. *Maskus* states that the lack of intellectual property protection hindered research and development and led to poor product quality production. Cf. *Maskus*, Intellectual Property Rights in the Global Economy (IIE Washington DC 2000) p. 150. *Imam* also indicates that stronger intellectual property rights could attract FDI to developing countries. Cf. *Imam*, 37 IIC 3 (2006) p. 259.

27 --, Innovation and the economy: The good, the bad and the ugly, The Economist (04.08.2007) p. 29.

28 *Imam* notes that development in itself is a gradual process and that intellectual properties can be used as a tool for economic development. Cf. *Imam*, 37 IIC 3 (2006) p. 259.

29 *Gervais*, 1 JIPLP 4 (2006) p. 252, 254-255.

30 *CIPR*, (2002), p. 36.

31 Although confirming this point, *Maskus* does however note that 'such fears may be overstated'. Notwithstanding this, the higher price for patented pharmaceuticals can and is set-off by: the benefits deriving from increased transfers of technology through trade, FDI and licensing; the improved likelihood of innovative enterprises placing newer products on that market and; a lower price impact where the market is already a competitive market economy. *Maskus*, Intellectual Property Rights in the Global Economy (IIE Washington DC 2000) p. 159-160, 162. *Imam* also states that an appropriate intellectual property regime could aid technology transfers and help reduce the academic brain-drain in some countries by giving innovative scientists an economic incentive to remain. Cf. *Imam*, 37 IIC 3 (2006) p. 253, 259.

32 There are numerous other factors that affect pharmaceutical prices: market structure, demand elasticity, pricing regulations and competition policies. Cf. *Maskus*, Intellectual Property Rights in the Global Economy (IIE Washington DC 2000) p. 160-161, *CIPR*, (2002), p. 34-39.

where possible, to make a profit.[33] As pharmaceutical companies and other inventors are principally profit-driven they not only have a right to make money but also a need to do so in order to ensure the health of the company and to invest in new research and development.[34] Expecting pharmaceutical inventors to behave otherwise would be short-sighted and ultimately lead to less research and development and, in turn, to fewer new medicines.

Patents are also accused of creating a monopoly that inhibits subsequent development in this field. It is correct to say that a patent prevents a third party from exploiting the patent for the duration of the patent. It does not, however, prevent the third party from creating an in-vention which competes with the first patent. More often than not it is the patented invention that competes with existing unencumbered products on the market. Only when the patented invention is able to show that it is better will consumers migrate to the new product – this is especially the case when the patented invention costs more than the existing products on the market. This added competition inspires other producers in the market to update or even develop novel inventions themselves in that field.[35] It is seldom that a patent holder is able to create an invention that corners an entire market and prevents competitors from interacting on the market without its consent. In the past where such patented inventions have indeed cornered a market the result has been that the competition stagnates and, possibly, that the patent holder misuses this situation to its advantage. Where this is the case governments are able to use the safeguards in the patent system to redress the imbalance, allowing, *inter alia*, third parties to exploit the patent without the patent holder's consent by way of a compulsory license. In addition hereto, competition law is also able to provide remedies.[36]

The increasingly global character of patent rights has also been criticised as requiring a common standard of intellectual property rights for countries regardless of their different financial, social and market characteristics. The basis for this criticism stems from the TRIPS Agreement which sets a minimum patent standard for all Member States to implement.[37] Although this is clearly the intention of the TRIPS Agreement, currently one cannot speak of a universal obligation on all WTO Member States.[38] Full implementation for all WTO Member States of the TRIPS obliga-

33 *CIPR*, (2002), p. 34.

34 The *CIPR* correctly reminds critics of the intellectual property regime that pharmaceutical companies are commercially driven. Cf. *CIPR*, (2002), p. 32.

35 *Maskus*, Intellectual Property Rights in the Global Economy (IIE Washington DC 2000) p. 147.

36 *Anderson*, 1 JIEL 4 (1998) p. 655-675, for a European perspective *Manley and Wray*, 1 JIPLP 4 (2006) p. 266; for an Italian perspective *Coco and Nebbia*, 2 JIPLP 7 (2007) p. 452-452.

37 It is also interesting to note that the patent system was close to being disbanded in the late 18th to late 19th century in Europe. Objections were raised on the basis of free-trade and anti-monopolistic principles. Cf. *Granstand*, The Economics and Management of Intellectual Property (Edward Elgar Cheltenham 1999) p. 35.

38 *May*, EIPR 1 (2003) p. 2, 4.

tions was initially only required in 2006.[39] This has since been extended to 2016 for pharmaceutical patents[40] and can, by means of an application, be extended on a case-by-case basis.[41] Notwithstanding this, implementing an intellectual property regime in accordance with the TRIPS Agreement need be done in a manner that balances the interests of innovators and those of the society as a whole. It is not only a matter of creating a legal framework but also a social and political awareness on how to use intellectual property rights in a manner that will suit that country itself.[42] No country is the same and neither are the social and welfare pressures on the budget. Each country needs to decide for itself how it is to make effective use of the intellectual property regime.[43]

All taken into account, *Granstand* makes a poignant remark:

> '… although the patent system has often been found to be deficient, it has been better than nothing, and there has been no better incentive system for technical progress in the commercial sector'[44]

This quote reflects my opinion. The intellectual property regime imposed by the TRIPS Agreement is fundamentally good and has the potential to benefit all countries who subscribe to it.[45] The reason for this lies in the TRIPS Agreement itself. It can be interpreted and implemented in ways that allow Member States to better structure it to suit their own domestic situations.[46] Understanding what the TRIPS Agreement actually requires is thus essential to ensuring the patent system has a positive effect on the country implementing it. This goal, the understanding of the TRIPS Agreement, is critically investigated in this dissertation. Further the effects of

39 TRIPS Agreement Art 65.

40 Public Health Declaration para 7, *Gervais*, 1 JIPLP 4 (2006) p. 250.

41 TRIPS Agreement Art 66.1.

42 *Maskus*, Intellectual Property Rights in the Global Economy (IIE Washington DC 2000) p. 143-170. *Maskus* provides the Japanese patent system between 1960 and 1993 as an example of how the patent system was used to enhance development. Compare *Kongolo*, 33 IIC 2 (2002) p. 208-209.

43 *Straus* and *Hindley* both come to the conclusion that it is not the obligations required by the TRIPS Agreement that require rebalancing but rather that the WTO balance between concessions made in respect to goods, services and intellectual property that requires rebalancing. Cf. *Straus*, 6 J. Marshall Rev. Intell. Prop. L 1(2006) p. 16, *Hindley*, The TRIPS agreement: the damage to the WTO in: *Pugatch* (ed) The Intellectual Property Debate (Edward Elgar Cheltenham 2006) p. 41. *Imam* further notes that countries should adapt the intellectual property regime to suite their own techno-economic development. Cf. *Imam*, 37 IIC 3 (2006) p. 259.

44 *Granstand*, The Economics and Management of Intellectual Property (Edward Elgar Cheltenham 1999) p. 44-45.

45 Other authors have been arguing in favour of a intellectual property regime that can be adjusted according to social needs of the country implementing the regime. Cf. *May*, EIPR 1 (2003) p. 4-5.

46 *Gervais* speaks of the TRIPS Agreement's 'built-in normative elasticity'. Cf. *Gervais*, 1 JIPLP 4 (2006) p. 255.

the Public Health Declaration and the subsequent agreements on this understanding are also critically assessed.[47]

47 Interpreting and implementing the TRIPS Agreement will pose difficult policy decisions for countries seeking to adopt or adjust their domestic intellectual property regime. The advantages or disadvantages of such choices or their socio-economic effects are not dealt with here. This dissertation seeks to create a better understanding of what choices are legally tenable under the auspices of the TRIPS Agreement and also addresses the legal effects that the Public Health Declaration may have had on the interpretation of the TRIPS Agreement.

Chapter 3 The legalising policy thoughts in the Public Health Declaration

The title of this dissertation identifies two principal elements that are central to determining the importance and influence of the Public Health Declaration. Firstly, the title directs the readers' attention to the policy elements contained in the Public Health Declaration. Secondly, it recognises the intention of the WTO Member States to formalise or 'legitimise' these policies. Whereas the latter forms the main focus of this dissertation, the former requires a brief examination in order to provide a context for this dissertation.

A 'policy' is best described as:

> 'a definitive course or method of action selected (as by a government, institution, group or individual) from among alternatives and in the light of given conditions to guide and [usually] determine present or future decisions'.[48]

As such a policy is a 'blueprint' or guiding principle to bring about a desired state of affairs. The Public Health Declaration exhibits such features.[49] It identifies what is 'wrong', what the solution should incorporate and which routes should be taken to bring about the solution. These points, which will be addressed below, were the result of intense negotiations between government representatives within the realm of an international body. As such, they reflect a common understanding and can be said to constitute policies within the auspices of the WTO.

The problems identified by the Ministers at the Doha Ministerial Conference in 2001 fall under the scope of TRIPS Agreement and public health. More accurately stated, the problems stem from the perceived effects of intellectual property rights have on the measures taken by Member States to protect the public health. Within the debates preceding the Public Health Declaration it was clear that the main focus lay on patent rights. The problems caused by the obligations that flow from these rights were felt to impinge upon the Member States' measures to address their public's health. Whereas public health may refer to any and all measures taken by a government to improve or protect their citizens' wellbeing,[50] the problem in the TRIPS Agreement centre's on the access to medicines that are patented.[51] The prob-

48 Webster's Third New International Dictionary (Merriam Chicago 1971) p. 1754.

49 The WTO itself refers to the 'important guidance' the Public Health Declaration provides to Member States and the DSB. Cf. *WTO*, (Undated).

50 Public health is defined as 'the art and science of preventing disease, promoting health, and extending life through the organised efforts of society'. Cf. *McMichael and Beaglehole*, Lancet 365 (2000) p. 495.

51 The Public Health Declaration was initially titled 'Draft Declaration on Intellectual Property and [Access to Medicines] [Public Health]'. The importance of access to medicines is reflected in para 4 of the Public Health Declaration.

lem of access to medicines derives from the intention of certain Member States to 'break' a patent (i.e. to use it without the patent holder's consent) and allow the generic production[52] of the medicine. It was hoped that the generic production of patented medicines would lower their prices and thus be affordable to more people suffering from illnesses. The Public Health Declaration indirectly notes that the desire to make medicines more affordable was critical to treating epidemics, in particular HIV/AIDS, tuberculosis and malaria. The Public Health Declaration acknowledged these problems and expressly stated that the TRIPS Agreement does not and should not prevent Member States from taking measures to protect the public health. This recognition forms the key policy issue that resulted from the negotiations in Doha.

A second key policy issue reiterated in the Public Health Declaration is the importance of intellectual property rights, in particular their role in furthering future health treatments.[53] The Public Health Declaration confirms the policy that the compliance with the TRIPS provisions will assist in the protection of the public health. This somewhat conjectural policy was nevertheless accepted by all.

The result of these two key policies is that whereas the Member States are free to take measures to protect the public health, the TRIPS Agreement must be complied with.[54] Phrased in another way, Member States must comply with their TRIPS obligations but may do so in a manner that facilitates their health protection measures. The realisation of these policies was identified by the Member States in a number of ways. Firstly, the Member States should be able to use the flexibilities in the TRIPS Agreement to the full. In other words, where a provision permits two or more means to comply, a Member States is free to choose the means to do so.[55] Secondly, the interpretation of the TRIPS Agreement should be done so in a manner that supports public health protection. Hence, where the meaning of a TRIPS provision is unclear, it should be interpreted in a health-friendly manner. Thirdly, there was a commitment to resolve the problem certain Member States have in making effective use of compulsory license system because of inadequate domestic manufacturing facilities. Lastly, the Public Health Declaration identified the special position LDC Member States have within the WTO and pledged to take measures to ease and assist their application and implementation of intellectual property rights and obligations.[56]

52 'Generic' and 'generics' are used within the scope of this dissertation as referring to pharmaceuticals that are bioequivalent to the original patented pharmaceutical, whether they are produced after the expiry of the patent rights or during the patent life with the permission of a body authorised to allow its production (but without the patent holders consent).

53 To this effect the Public Health Declaration noted the exceptions available to patent protection, e.g. compulsory rights, and the flexible interpretations of the TRIPS provisions.

54 The USTR refers to the relationship as 'dual objectives … meeting the needs of poor countries without the resources to pay for cutting edge pharmaceuticals and … ensuring that the patent rights system continues to promote the development and creation of new lifesaving drugs'. Cf. *USTR*, Special 301 Report (2006) p. 10.

55 Four flexibilities were expressly noted in para 5 of the Public Health Declaration.

56 Compare *CIPR*, (2002) p. 39.

Of the four policies, the policy pertaining to the use of the flexibilities, in particular compulsory licenses, stood out as being the key way for Member States to promote access to affordable medicines. Although compulsory licenses are expressly permitted in the TRIPS Agreement, their use was subject to political and legal opposition. The precise scope and extent of the TRIPS provisions on compulsory licenses was not clear. The Public Health Declaration's reference to the compulsory licenses serve as a policy measure as it identifies the compulsory license system as a viable tool within the patent system, especially when addressing the issue of access to affordable medicines.

The codification of these policies represented the first formal step to realising their goals. Their realisation, and the necessity of their realisation, must be seen within the light of the developments leading up to the Public Health Declaration and TRIPS Agreement as a whole.

Chapter 4 The circumstances leading up to the Public Health Declaration

A. Introduction

On the 14th of November 2001 the WTO Ministerial Conference adopted the Public Health Declaration. Contrary to the public perception, this decision was neither the beginning nor the end of a long period of political and legal uncertainty as to the meaning and role of the TRIPS Agreement.

The Public Health Declaration marked a convergence of a number of political, social and legal conflicts. These clashes of interest insured a high degree of public awareness in the negotiations prior to the Public Health Declaration and those thereafter. The Member States, split along the so-called 'north-south divide',[57] discussed and argued over the scope and extent of intellectual property rights and the role of socio-economic interests such as the right to health as well as the understanding, interpretation and implementation of the TRIPS Agreement. The diverging positions taken by the Member States, in particular the developing countries' contention that the TRIPS Agreement was inadequate to deal with health issues, were more inspired by political uncertainty than legal necessity.[58] Despite the lack of legal merit, the issues contained and dealt with in the Public Health Declaration succeeded by virtue of its political importance. This apparent paradox represents the development of the diplomacy-based GATT system into the rules-based WTO system and the lack of faith that the rules will transcend diplomatic pressures.

If the Public Health Declaration was not legally necessary, why was there such intense political momentum to find an agreement? The answer lies in the intergovernmental relations, the domestic pressures being experienced and the Member States perceptions of the scope and nature of the TRIPS Agreement. It was upon these foundations that the Public Health Declaration was shaped.

57 A term used to distinguish the developed countries (the 'north') from the developing countries (the 'south').

58 With the exception of para 6 of the Public Health Declaration.

B. *The events preceding the Public Health Declaration*

I. The GATT system and the Uruguay Round

Towards the end of World War II the coalition parties commenced negotiations on a new world order with economic growth, stable currencies and trade liberalisation as its three pillars. The system they negotiated, known as the Bretton Woods Agreements, sought to realise these goals through the creation of three international institutions. The first two, International Monetary Fund and the International Bank for Reconstruction and Development (now part of the World Bank), were created to manage and finance the system. The third pillar, the International Trade Organisation ('ITO'), would serve to bring about trade liberalisation.[59] Domestic opposition within the US prevented the completion of the treaty process creating the ITO.[60] Although the parties were unable to formalise the ITO, they were able to salvage one treaty – the General Agreement on Tariffs and Trade (the 'GATT Agreement'). Making the most of the situation, the 23 signatory parties adopted the GATT Agreement in 1948. To ensure its development the GATT Agreement provided for the implementation of its provisions, the accession of new members and implemented a system of negotiating rounds to expand the scope of the agreement.

As the name indicates, the GATT Agreement governs the use of tariffs and similar trade measures to ensure that GATT Member States are not unreasonably affected by arbitrary or unreasonable measures taken by other Member States. The GATT Agreement recognised that certain circumstances would justify the non-compliance with these rules. To this effect the parties adopted Article XX of the GATT Agreement which allows Member States to ignore the application of the GATT provisions when, *inter alia*, they are 'necessary to protect human, animal or plant life and health'.[61] The exclusions contained in Article XX are extensive; despite this GATT Member States invoking its use have had little success under the GATT Panels.[62] Beyond tariff measures to protect the public health in accordance with Article XX(b) of the GATT Agreement, the role of health, and intellectual property rights for that matter, played little or no role.[63]

59 *Parry et al*, Encyclopaedic Dictionary of International Law (Oceana New York 1986) p. 188.

60 *Matsushita et al*, The World Trade Organization: Law, Practice, and Policy (2nd edn OUP Oxford 2006) p. 1-2.

61 GATT Agreement Art XX(b).

62 For example GATT Japan – Custom Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages – Report of the Panel (10.11.1987) L/6216 – 34S/83, GATT Thailand – Restrictions on the Importation of and Internal Taxes on Cigarettes – Report of the Panel (07.11.1990) DS10/R – 37S/200, GATT Tuna/Dolphins I – Report of the Panel 39S/155 and its successor GATT Tuna/Dolphins II – Report of the Panel.

63 With the exception of Art XX(d) of the GATT Agreement and the only two GATT disputes concerned with intellectual property protection GATT *United States – Imports of certain automobile spring assemblies* Report of the Panel (26.05.1983) L/5333 30S/107, GATT *United States – Section 337 of the Tariff Act of 1930* Report of the Panel (07.11.1989) L/6439

In 1986 the GATT Member States agreed to enter into a round of negotiations that would encompass a number of issues above and beyond tariffs and trade and ultimately lead to the formation of the WTO. The round, known as the 'Uruguay Round', contained the following mandate:

> 'In order to reduce the distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines. Negotiations shall aim to develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods, taking into account work already undertaken in the GATT. These negotiations shall be without prejudice to other complementary initiatives that may be taken in the World Intellectual Property Organization and elsewhere to deal with these matters.'[64]

Negotiating the future TRIPS Agreement was a thorny issue. For a start it was only one agreement amongst a number that were been considered by the GATT parties. The issues under negotiation were not only tariff barriers but also non-tariff barriers. The goal of the Uruguay Round was to create a treaty-enforced harmonisation system that would extend beyond the GATT trade issues. It was clear that the expanse of the negotiations would not only result in the increased regulation of foreign trade practices but also in the limitation of the national sovereign economic policies and a dramatic shift in the internal regulatory discretion and the pre-existing balance of domestic interests.[65] In addition to the wide scope of negotiations the whole Uruguay Round negotiations were being treated as a single undertaking, i.e. the negotiating parties could only accept all of the agreements to accede to the WTO.[66] A negotiating party could not subscribe to one agreement and reject the rest. The single undertaking increased the pressure on the negotiating parties to find a mutually acceptable consensus, as whoever objected would not be a party to the WTO and thus would be unable to take advantage of its rules, opportunities and obligations.

Negotiating rights concessions under this 'all or nothing' atmosphere was taxing for the developing countries. Their lack of financial resources, manpower and technical knowledge meant that they were unable to submit meaningful proposals and responses but they were also unable meaningfully comprehend the scope and effect

36S/402. In the latter case, at para 6.1, the Panel expressly noted that their authority was limited to the US provision infringed the national treatment provisions, Art III of the GATT Agreement.

64 GATT Ministerial Declaration on the Uruguay Round (20.09.1986) MIN.DEC para D, *Chasen Ross and Wasserman*, Trade Related Aspects of Intellectual Property Rights in Stewart (ed) The GATT Uruguay Round: A negotiating History (1986-1992) (Kluwer The Hague 1993) vol II p. 2264-2265.

65 *Correa*, Health Economics: The Uruguay Round and Drugs (WHO Geneva 1997) p. 1, *UNCTAD/ICTSD*, Resource Book on TRIPS and Development (CUP New York 2005) p. 119.

66 *Gervais*, 1 JIPLP 4 (2006) p. 249.

of the issues being negotiated.[67] These shortcomings were compounded by the fact that negotiations were being conducted in several sectors simultaneously.

Added to the burdens faced within the scope of the WTO negotiations, some negotiating parties were being threatened with coercive actions should they not adopt measures to the liking of other negotiating parties. The US, itself pressed by multinational pharmaceutical companies, exerted considerable unilateral political pressure on countries to adopt additional intellectual property protection, especially in the field of pharmaceutical patent protection.[68] The extension of the US's Special 301 to intellectual property rights permitted the US to unilaterally withdraw benefits and impose sanctions on those countries it feels are providing insufficient intellectual property protection.[69] The threat and use of this system led a number of countries to adopt additional patent protection measures for pharmaceutical products.[70] This threat of unilateral measures flowing from the Special 301 also heightened the discourse at the Uruguay Round negotiations. It was, amongst other reasons, this fear of unilateral reprisals that had a curious response: it encouraged countries to support a treaty on intellectual property rights. The reason for this was the hope that a multilateral treaty would set a fixed and universal standard and prevent other signatories from claiming patent protection above and beyond what was required by the treaty. Where conflicts could not be prevented the treaty, as envisaged by the Uruguay Round, would channel disputes through the multilateral dispute resolution process. This would provide a larger degree of security and, more importantly, impartiality.

67 *Gervais*, 1 JIPLP 4 (2006) p. 249-250.

68 The US was itself lobbied by large US multinational pharmaceutical and agro-chemical businesses. A group of 13 large US businesses formed the Intellectual Property Committee ('IPC') in 1983 in order to 'help convince the US officials that we need to take a tough stance on intellectual property issues'. According to *Pratt*, a former Pfizer CEO, advocate of the IPC and official advisor to the USTR, this pressure led the US to include intellectual property rights in the Uruguay Round of negotiations. See *Pratt*, (1995). *Straus* also notes that the US's initiatives were motivated by the lack of success in the modernisation of the Paris Convention. Cf. *Straus*, Patentschutz durch TRIPS-Abkommen – Ausnahmeregelungen und –praktiken und ihre Bedeutung, insbesondere hinsichtlich pharmazeutische Produkte in Bitburger Gespräche Jahrbuch 2003 (CH Beck Munich 2003) p. 119. *Straus* also refers to the US's 'aggressive unilateralism'. Cf. *Straus*, TRIPS, TRIPS-plus oder TRIPS-minus – Zur Zukunft des internationalen Schutzes des Geistigen Eigentums in: *Ohly et al* (eds) Perspektiven des Geistigen Eigentums und Wettbewerbsrechts (CH Beck Munich 2005) p. 198.

69 Pressure was exerted by the US primarily through the Special 301 system, introduced into the US Trade Act in 1988 by Sec 1303 of Omnibus Trade and Competitiveness Act of 1988 (23.08.1988) P.L. 100-418, 102 Stat. 1851. Cf. *Dwyer*, Trade Related Aspects of Intellectual Property Rights in Stewart (ed) The GATT Uruguay Round: A negotiating History (1986-1994) (Kluwer The Hague 1999) vol VI p. 495-508, 557-560, *Kiehl*, 10 J.Intell.Prop.L (2002) p. 149, *Matsushita et al*, The World Trade Organization: Law, Practice, and Policy (2nd edn OUP Oxford 2006) p. 135-139.

70 Bolivia, Chile, China, Columbia, Ecuador, El Salvador, Indonesia, Mexico, Peru, South Korea, Taiwan, Thailand and Venezuela have been listed as examples of countries that have succumbed to the US pressures after 1986. Cf. *Correa*, Health Economics: The Uruguay Round and Drugs (WHO Geneva 1997) p. 3-4.

Just as other negotiations on intellectual property rights before it, the central topics of the Uruguay Round negotiations on intellectual property rights, focused primarily on the rights and obligations of the rights holders.[71] The length, scope and nature of patent rights dominated discussions. Developing countries, primarily India and Brazil, were concerned about the effects of the introduction of intellectual property rights without having remedial measures to counterbalance the rights of the rights holders and prevent abuse of their monopoly rights.[72] The social and economic consequences of the introduction of intellectual property rights under the future TRIPS Agreement was never a real consideration in the negotiations.[73] There was an attempt by civil society to draw attention to the effect that intellectual property rights would have on access to pharmaceuticals, especially their prices, but this was largely ignored by the developed countries.[74]

The development of negotiations for the TRIPS Agreement does however indicate that developed countries resources were strained. The developing countries were unprepared and under qualified for such negotiations. The developed countries had on the other hand presented a common position that was comprehensive and designed to enable a fast-paced negotiation process.[75] This tactic was chosen to diminish the developing community's opportunity from putting up a competent defence or submitting counter proposals.[76]

71 The Paris Convention does not contain any specific measures for attending to health issues that conflict with intellectual property rights.

72 *Raghavan*, IFDA (1989) II, *Straus*, Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 168-170. *Straus* correctly notes that each negotiating country had to weigh up the advantages and disadvantages of being bound to the WTO rules. Whereas some provisions may have brought stricter intellectual property rules they it is unlikely that would have been agreed to without such being outweighed by the benefits that such countries would acquire in joining the WTO.

73 *Correa*, IFDA (1995), *Gregg Bloche*, 5 JIEL 4 (2002) p. 825.

74 *Singh*, UNCTAD (2003) p. 17.

75 Singh J *Wriggle Rooms: New Issues and North-South Negotiations during the Uruguay Round* presented at the Conference on Developing Countries and the Trade Negotiation Process (UNCTAD Geneva 06/07.11.2003) 16-17.

76 *Straus*, Patentschutz durch TRIPS-Abkommen – Ausnahmeregelungen und –praktiken und ihre Bedeutung, insbesondere hinsichtlich pharmazeutische Produkte in Bitburger Gespräche Jahrbuch 2003 (CH Beck Munich 2003) p. 120, *Raghavan*, IFDA (1989) I. It is also mentioned that some developing negotiators suspected that the GATT Chairman and the Secretariat came with a well-prepared programme to achieve a quick result. This suspicion was confirmed by J Enyart who stated we 'went to Geneva where we presented (our) document to the staff of the GATT Secretariat. What I have described to you is absolutely unprecedented in GATT. Industry has identified a major problem in international trade. It crafted a solution, reduced it to a concrete proposal and sold it to our own and other governments ... The industries and traders of world commerce have played simultaneously the role of patient, the diagnostician and the prescribing physician.' Cf. J Enyart, quoted in *Keayla*, Conquest by Patents. The TRIPS Agreement on patent laws: Impact on Pharmaceuticals and Health for All (CSGTSD New Delhi 1998).

Notwithstanding the pressures exerted, developing countries were not forced to accept the final act. It became clear to developing countries that the TRIPS Agreement was the lesser of the two evils; it would leave them better off than being exposed to the vigorous unilateral threats and actions of the US.[77] As a compromise for the acceptance of the future TRIPS Agreement, the developing negotiating parties were able to obtain concessions in the agricultural and textile sectors and, within the TRIPS Agreement, on compulsory licensing, patent protection for pharmaceuticals and the special needs in connection with development.[78] In addition thereto, the developed negotiating parties agreed to include additional provisions that would benefit developing countries. They included provisions providing for the transfer of technology to developing states,[79] the gradual enforcement of the provisions according to the country's level of development,[80] a sympathetic preamble with corresponding objective and principle provisions[81] and technical assistance in favour of developing countries.[82] So it was that the TRIPS Agreement was accepted and, on the 1st of January 2005, that it came into force.[83]

II. The implementation of the TRIPS Agreement

As stated above, developing Member States were able to secure a number of minor concessions. The most obvious concession was the transitional arrangements found

77 *Singh*, UNCTAD (2003) p. 11-12, *Dwyer*, Trade Related Aspects of Intellectual Property Rights in Stewart (ed) The GATT Uruguay Round: A negotiating History (1986-1994) (Kluwer The Hague 1999) vol VI p. 571-574, *Hauser and Roitinger*, 64 ZaöRV (2004) p. 642, *Straus*, TRIPS, TRIPS-plus oder TRIPS-minus – Zur Zukunft des internationalen Schutzes des Geistigen Eigentums in: *Ohly et al* (eds) Perspektiven des Geistigen Eigentums und Wettbewerbsrechts (CH Beck Munich 2005) p. 197.

78 *Straus* correctly notes that the TRIPS Agreement was part of a 'package deal' and the concessions made in respect to intellectual property are be viewed together with the gains obtained in goods and services. Cf. *Straus*, TRIPS, TRIPS-plus oder TRIPS-minus – Zur Zukunft des internationalen Schutzes des Geistigen Eigentums in: *Ohly et al* (eds) Perspektiven des Geistigen Eigentums und Wettbewerbsrechts (CH Beck Munich 2005) p. 199. See also *UNCTAD/ICTSD*, Resource Book on TRIPS and Development (CUP New York 2005) p. 4, WTO *Canada – Pharmaceuticals* p. 28, *Dwyer*, Trade Related Aspects of Intellectual Property Rights in Stewart (ed) The GATT Uruguay Round: A negotiating History (1986-1994) (Kluwer The Hague 1999) vol VI p. 525-527.

79 TRIPS Agreement Art 66.

80 TRIPS Agreement Arts 65-66, 70.

81 TRIPS Agreement Arts 7-8, *UNCTAD/ICTSD*, Resource Book on TRIPS and Development (CUP New York 2005) p. 11.

82 TRIPS Agreement Art 67.

83 *Templeman*, 1 JIEL 4 (1998) p. 604 states that the TRIPS Agreement itself was also obtained by 'the threat and reality of trade sanctions and the withdrawal of aid'.

in Articles 65 and 70 of the TRIPS Agreement.[84] The staggered implementation of the obligations found in the TRIPS Agreement permitted those Member States without corresponding intellectual property rights an extended time frame in which to adopt the provisions. Although these arrangements provided for a staggered process, they do not permit Member States to deviate from the level of patent protection based upon the development status of a country.[85] The remaining development-friendly country provisions in the TRIPS Agreement played a minor role in the early years of TRIPS implementation.

The spotlight returned to the provisions made in favour of the developing Member States with the rapid spread of the HIV/AIDS disease. In the late 1990s the developing countries slowly awoke to the extent and potential impact of the disease on their citizens. The slow reaction, especially in Africa, was due to cultural differences and ignorance on the part of politicians and the public at large.[86] The lack of manpower and financial resources in the developing world further added to the impact of HIV/AIDS. Faced with the ever increasing problem of HIV/AIDS and the realisation that the developing countries would have to take measures to prevent the collapse of their already feeble public health systems, Member States began to debate the avenues available to them.

One of the areas that gained attention was that of pharmaceutical prices and the access to affordable medicines.[87] Most of the developing countries were reliant on the importation of medication, a portion of which was from the manufacturers who held the patents to the medicines. The dependency of the developing countries on the pharmaceutical manufacturers for their pharmaceutical requirements was further cemented by domestic patent laws, which entitles the patent holder to exclude the importation of a copy of its invention. This right, entrenched in the TRIPS Agreement, was however only valid in those countries where there was patent protection for pharmaceutical products. An example of a developing country with pharmaceutical protection was South Africa.[88] South Africa has the ignominious honour of housing the largest amount of citizens infected with HIV/AIDS. To tackle the HIV/AIDS problem the South African government sought to obtain the medication necessary for the treatment of the disease from producers with lower prices. As most of the HIV/AIDS treatments were under patent protection in South Africa, the then Patent

84 Contrast USTR position in *Dwyer*, Trade Related Aspects of Intellectual Property Rights in Stewart (ed) The GATT Uruguay Round: A negotiating History (1986-1994) (Kluwer The Hague 1999) vol VI p. 509-511.

85 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 352, WTO *United Stated – Section 110(5) of the US Copyright Act* Report of the Panel (15.06.2000) WT/DS160/R p. 50.

86 *Gauri and Lieberman*, 41 SCID 3 (2006) p. 58-59. For a depiction of the HIV/AIDS epidemic and its consequences see *Kiehl*, 10 J.Intell.Prop.L (2002) p. 144-148.

87 For an overview of the disparities in pharmaceutical access see *Cohen et al*, 1 Globalization and Health 17 (2005) p. 1-2.

88 For a depiction of the extent of the HIV/AIDS epidemic in South Africa see *Kramer*, Patentschutz und Zugang zu Medikamenten (Carl Heymanns Verlag Cologne 2007) p. 7-21.

Act,[89] permitted only one way to obtain the medication from sources other than from the sources permitted by the patent holder: by way of compulsory licenses. This option was however an untested legal measure in South Africa and the limitations and compensation that would be awarded by the courts was unforeseeable. In addition to this uncertainty, the local pharmaceutical manufacturing sector in South Africa was relatively small and primarily dominated by research-based producers. To circumvent this situation the South African government decided to amend the Patent Act in order to provide for compulsory licenses that would permit the importation of the protected pharmaceuticals from countries with lower prices for these original products.[90] In terms of the proposed amendment, the:

> 'Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may –
>
> (a) notwithstanding anything to the contrary contained in the Patents Act, 1978 … determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;
>
> (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported'.[91]

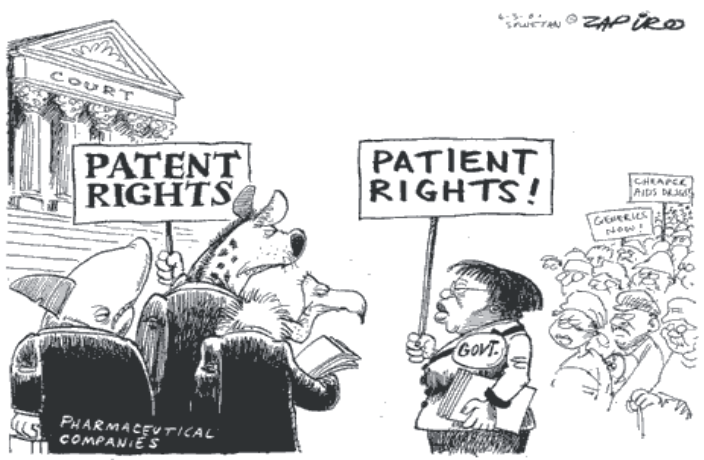
89 South African Patent Act, Act 57 of 1978.

90 For an overview of the political events surrounding the South African measures see *Bond*, 29 Int. J. Health Serv. 4 (1999) p. 765-792.

91 Medicines and Related Substances Control Amendment Act 1997 sec 15 C. For a discussion of sec 15 C and its potential consequences see *Kramer*, Patentschutz und Zugang zu Medikamenten (Carl Heymanns Verlag Cologne 2007) p. 165-177.

Prior to the passing of this Act, a group of 39 multi-national pharmaceutical companies, represented by the Pharmaceutical Manufacturers Association of South Africa (the 'PMA'), challenged the Bill on the basis that, amongst others, it constituted an infringement of the TRIPS Agreement.[92] The US itself made 'strenuous' representations to the SA government during the Bills drafting process and, in April 1998, placed South Africa on the Special 301 Watch List and suspended the granting of certain special trade preferences to South Africa.[93] The US Trade Representative (the 'USTR') stated that 'South Africa's Medicines Act appears to grant the Health Minister ill defined authority to issue compulsory licenses, authorize parallel imports, and potentially otherwise abrogate patent rights' and '[w]e call on the Government of South Africa to bring its IPR regime into full compliance with TRIPS'.[94]

Figure 1: Zapiro, 06.03.2001, published in the South African Sowetan



This PMA case was subject to significant domestic and international attention. It was portrayed in certain parts of the media as an attempt by the pharmaceutical industry to prevent a government from attending to the serious health requirements, by preventing low-cost medication reaching persons infected with HIV/AIDS. In addition to South Africa being in the sights of the US trade officials, Thailand, Argentina and Brazil were also subject to US scrutiny and pressure for similar TRIPS-related reasons.[95] The US had commenced the process of challenging aspects of the Argen-

92 Pharmaceutical Manufacturers Association et al v the President et al, TPD, 4183/98 [not published].
93 *Kiehl*, 10 J.Intell.Prop.L (2002) p. 151.
94 *USTR*, Special 301 Report (1998).
95 *Kiehl*, 10 J.Intell.Prop.L (2002) p. 151.

tinean and Brazilian patent regimes under the WTO's dispute settlement process.[96] Opposition to these actions increased and the pharmaceutical industry and, indirectly, the US were portrayed as greed ridden and inconsiderate of the suffering of those infected with HIV/AIDS.

As a result of the role the TRIPS Agreement played in the PMA case and the US actions against Argentina and Brazil, the TRIPS Agreement became synonymous with the obstructions that patent rights provide for public health and the access to affordable medicines. The public perception that the US and the pharmaceutical manufacturing sector put their financial profits and wellbeing before that of the sick and dying reverberated around the world. It mounted to such an extent that the PMA case became a public relations disaster. The PMA succumbed to the pressure and settled their court action against the South African government. In a joint statement the PMA and the government stated:

'The government of the Republic of South Africa reiterates its commitment to honour its international obligations including the Agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS). In reliance of this commitment, the referenced applicants recognize and reaffirm that the Republic of South Africa may enact national laws or regulations, including regulations implementing Act 90 of 1997 or adopt measures necessary to protect public health, and broaden access to medicines in accordance with the South African Constitution and TRIPS.'[97]

The political backlash also led the US to withdraw its WTO challenges against Brazil[98] and Argentina[99] and deterred if from instituting similar proceedings against Thailand. Despite the US retreat there remained the fear for many developing countries that legal challenges could still be instituted against public interest measures that have the effect of limiting patents.

The feeling that a problem lay within the WTO arena, especially within the TRIPS Agreement, continued to spread throughout the developing Member States.[100] In order to address the TRIPS-deficiencies, within the scope of multilateral

96 WTO Brazil – Measures Affecting Patent Protection Request for Consultations by the US (08.06.2000) WT/DS 199/1, WTO Argentina. – Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals Request for Consultation by the US (10.05.1999) WT/DS 171/1.

97 Joint Statement of Understanding between the Republic of South Africa and the Applicants (19.04.2001).

98 WTO *Brazil – Measures Affecting Patent Protection* Request for Consultations by the US (19.07.2001) WT/DS 199/4.

99 WTO *Argentina – Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals* Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement (20.06.2002) WT/DS171/3.

100 *Bermudez, Oliveira and Chaves,* Intellectual Property in the Context of the WTO TRIPS Agreement: What is at Stake in Bermudez and Oliveira (eds) Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for public health (ENSP/WHO Rio de Janeiro 2004) p. 45. Compare *Straus*, TRIPS, TRIPS-plus oder TRIPS-minus – Zur Zukunft des internationalen Schutzes des Geistigen Eigentums in: *Ohly et al* (eds) Perspektiven des Geistigen Eigentums und Wettbewerbsrechts (CH Beck Munich 2005) p. 200-205.

WTO Member States began to include health issues in their topics for negotiations in the run up to the Ministerial Conference set for 1999 in Seattle.[101] The failure of the Seattle Ministerial Conference polarised the interests held by developed and developing countries. In the specific case of health and intellectual property rights, it became obvious that discussions on the issue were urgently required and a delay until the next Ministerial Conference could not be justified in light of the extent of the HIV/AIDS problem had assumed. With this thought in mind, the TRIPS Council convened a special meeting to attend to the debate. In a communication made by Brazil, on behalf of the African Group and 15 other Member States, the members made the following submission:

> 'The special discussion on TRIPS and Public Health at the TRIPS Council is not a one-off event. It should be part of a process to ensure that the TRIPS Agreement does not in any way undermine the legitimate right of WTO Members to formulate their own public health policies and implement them by adopting measures to protect public health.'[102]

The demands raised, principally by the developing nations, were ambitious; they sought a formal acknowledgement that 'nothing in the TRIPS Agreement should prevent Members from taking measures to protect public health'.[103] This point and other more concrete discussions regarding the role of compulsory licenses, exhaustion and patent exceptions were all discussed in detail in the months that preceded the Public Health Declaration.

Notwithstanding either the general issues, such as the sanctity of health measures, or the material issues concerning the use of the provisions contained in the TRIPS Agreement, an issue central to all these topics was beginning to emerge: the issue of 'flexibility'. The use of the term flexibility in the context of the WTO and TRIPS Agreement pertains to the ability a Member State has to implement the TRIPS Agreement in a manner it deems best, provided it is consistent with the contents of the provisions.[104] Its history dates back to the Uruguay Round where attaining consensus on strict and finite rules was not possible. In order to appease the multitude of negotiating parties the wording of provisions was deliberately generalised in nature. It was not that the negotiating parties wished to implement a lax treaty; it was simply that the generalised wording was the highest common denominator that was able to achieve consensus. The role of the flexible provisions was acknowledged and was so far accepted that the preamble in the TRIPS Agreement states:

101 WTO *India and others* Preparations for the 1999 Ministerial Conference (11.10.1999) WT/GC/W/354 para 27.

102 WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 p. 1.

103 WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 (29.6.2001) p. 1.

104 It is also referred to as 'normative elasticity', 'legislative leeway' or 'wiggle room'. *Watal* notes that the TRIPS Agreement has a 'plethora of legislative options' for implementing the Agreement domestically. Cf. *Watal*, Implementing the TRIPS Agreement in: Hoekman, Mattoo and English (eds) Development, Trade, and the WTO: A Handbook (World Bank Washington DC 2002) p. 363.

> 'Recognizing also the special needs of the least-developed country Members in respect of maximum *flexibility* in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base'[105] (emphasis added)

The problem flexibility posed to the Member States arose out of the relation between the preamble, Article 1 ('Nature and Scope of Obligations'), Articles 7 and 8 ('Objectives' and 'Principles') and the material provisions contained in Part II of the TRIPS Agreement. Article 1.1 of the TRIPS Agreement leaves the method of implementation of the Agreement up to the Member States to determine and states that the Member States are not required to implement a more extensive intellectual property protection regime than was provided for in the Agreement. Notwithstanding, the freedom to elect the method of implementation the actual meaning of the provisions to be implemented remained unclear. This lack of clarity is amplified by Articles 7 and 8 which recognise the importance of social-economic issues without detailing its potential influence on the material TRIPS provisions. When it came to the implementation of the TRIPS Agreement by the Member States they proceeded to implement the Agreement in a manner consistent with their understanding of the agreements and the negotiations that preceded its adoption. It became clear that their understanding as to what the TRIPS Agreement meant and what is permitted was not universally identical. The EC and the US took a stance that the TRIPS Agreement, including its exceptions, should be implemented in a formal manner that excluded national measures that readjusted the intellectual property and socio-economic balance in the TRIPS Agreement to suite national circumstances. [106] The WTO *Canada –Pharmaceuticals* case marked the first WTO Dispute Settlement Body (the 'DSB') ruling that made an award that appeared to favour of intel-lectual property rights over health policy measures.[107] In addition to favouring intellectual property rights over public health policies, the DSB set strict standards of TRIPS-com-pliancy, thus limiting the flexibilities available to Member States.[108]

The view that the TRIPS Agreement was transpiring into an ever tightening legal noose grew with each year. The year 2000 and the first 10 months of 2001 marked the beginning of the resurgence of the role of developing Member States within the WTO arena. The fear that the TRIPS Agreement could evolve into an agreement that was never intended and the increasing strain HIV/AIDS was placing on developing Member States culminated in a political standoff; the developing Member States sought clarity on the TRIPS Agreement. Through the negotiations, the influence of

105 TRIPS Agreement preamble.

106 WTO Canada – Pharmaceuticals p. 154.

107 The WTO *Canada – Pharmaceuticals* has often been used as a justification that the WTO rules restrict national health measures. Although this decision is dealt with extensively below, it is to be stated that whereas the decision may have had the effect of delaying the entry of generic pharmaceuticals after the expiry of a patent in Canada it can also be seen as a decision that confirmed that health measures may form the basis for allowing generic producers to fulfil certain market access requirements whilst the patent is still valid. See Chapter 5(C)(III)((2) below.

108 WTO Canada – Pharmaceuticals p. 153, 155.

the 11th of September 2001 terrorist attacks, the US's response to the anthrax scares and the global support for the pre-emption of health over pecuniary interests, an agreement was reached at the Doha Ministerial Conference on the 14th of November 2001, the Public Health Declaration.

Chapter 5 An analysis of the TRIPS Agreement

It is without contention that the TRIPS Agreement and the Public Health Declaration were fundamentally shaped by public perceptions and political interaction. The TRIPS Agreement is not however a mere political document, it is a binding legal document and is the subject of legal scrutiny and binding legal sanctions. The TRIPS Agreement is therefore capable of objective assessment. The meaning of the TRIPS Agreement, 'interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose'[109] not only provides for a legal understanding of the Public Health Declaration, it also establishes the framework for the future application of the Public Health Declaration and the full use of the TRIPS Agreement. In this regard the analysis of the TRIPS Agreement provisions are divided into thee main parts: the nature and scope, the object and purpose and the material provisions of the TRIPS Agreement.

A. Nature and scope of the TRIPS Agreement

The scope and purpose of the TRIPS Agreement is found in the preamble and Article 1. The determination of the scope and purpose of an agreement is essential as it sets the framework in which a treaty is to operate and the signatory parties to comply.[110] The TRIPS Agreement and its provisions form, like the remainder of the WTO Agreements, a legal instrument and bind the signatories to act in accordance with its contents. The nature of the TRIPS Agreement is, as part of the WTO Agreements, that of a treaty.[111]

The observance of a treaty implies that the signatory parties are to implement the treaty in good faith, or to 'give effect' to it. This obligation derives from the *pacta sunt servanda* obligation, codified in the Vienna Convention.[112] The operation of this rule requires the Member States to ensure that their domestic legal system comply with the TRIPS provisions.[113] The extent of the implementation and the obligations are determined by the scope of the treaty.

To determine the scope of the TRIPS Agreement one needs to consider the contents of the TRIPS Agreement in light of the preamble and Article 1. The TRIPS

109 Vienna Convention Art 31.
110 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 45.
111 Vienna Convention Art 2(1)(a).
112 Vienna Convention Art 26.
113 TRIPS Agreement Art 1.1, WTO Agreement Art XVI.4. Cf. WTO *United States – Section* 211 (panel ruling) p. 85.

Agreement, as its name states, regulates the trade-related aspects of intellectual property rights. In accordance with Article 1.2 of the TRIPS Agreement 'intellectual property' is considered to include copyright and related rights, trademarks, geographical indications, industrial designs, patents, the layout-designs of integrated circuits, undisclosed information, the anti-competitive practices in contractual licenses and any other rights that are the subject of Part II of the TRIPS Agreement.[114] These categories of intellectual property rights form the scope of the general subject matter of the TRIPS Agreement. The contents of these rights in turn form the operative provisions of the TRIPS Agreement. The contents of Part II of the TRIPS Agreement also reflect that the negotiating parties commenced their negotiations by seeking to regulate the trade-related aspects of intellectual property rights and not intellectual property rights as such. The TRIPS Agreement is however the most comprehensive treaty concerning intellectual property rights. Notwithstanding this fact, the TRIPS Agreement is characterised by trade issues and has, in certain respects, refrained from regulating all aspects of intellectual property rights. An example is Article 31 which deals with compulsory licenses. Article 31 requires that Member States abide by certain procedural elements when granting a compulsory license. It does not however prescribe the grounds for a compulsory license. Further example of this reluctance is Article 6 which has the effect of allowing Member States to elect a system of exhaustion that it deems most appropriate for its domestic needs.[115] The TRIPS Agreement does however require that the application of the exhaustion system is subject to the application of the rules on national and MFN treatment.[116]

The scope of the TRIPS Agreement further requires Member States to incorporate complex substantive legal standards into domestic law. This affirmative obligation exceeds the obligations flowing from the other WTO Agreements.[117] The rules regulating the interpretation of treaties, partially codified in the Vienna Convention, permit a contracting party to exclude the application of elements of a treaty by way of a reservation.[118] The possibility to reduce the scope of the TRIPS Agreement was expressly excluded by Article 72 of the TRIPS Agreement. As partial compliance is excluded, Member States must fully comply with each and every provision of the TRIPS Agreement. The compliance with the TRIPS Agreement does however distinguish itself from other bilateral or multilateral agreements. The first distinction is that the WTO has created its own forum and procedures for resolving disputes – the

114 This includes, for example, *sui generis* rights contained in Art 27.3(b) of the TRIPS Agreement. WTO *United States – Section* 211 (Appellate Body ruling) p. 94.

115 *Katzenberger*, TRIPS and Copyright Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 80-81.

116 TRIPS Agreement Art 6.

117 *Abbott*, WTO Dispute Settlement and the Agreement on Trade-Related Aspects of Intellectual Property Rights in: *Abbott, Cottier and Gurry* (eds), The International Intellectual Property System: Comments and Materials (Kluwer The Hague 1999) Part I p. 719.

118 Vienna Convention Arts 19-23.

'DSB'). The second distinction is that the WTO Agreements provide for a process that ultimately entitles the infringed party to penalise the infringing party. The infringement does not entitle the termination of the agreement.[119] This distinction derives from the rules-based approach that was chosen to replace the GATT diplomacy-based system. The consequence of this system is that it now has legal 'teeth'. If an infringing party is unwilling to comply with the TRIPS Agreement its sanctions extend beyond chastisement, enabling the withdrawal of trade concessions by the infringed party.[120] The renunciation by the Member State of its membership in the WTO would not necessarily lessen the severity of sanctions as non-membership would mean the forfeit of all the concessions made under the WTO Agreements and it would entitle the other states to impose unrestricted and unilateral trade barriers, either in the form of tariffs or access to markets.

The failure to give effect to TRIPS Agreement, in full compliance with its obligations, has significant repercussions for all Member States. The correct and complete implementation of the TRIPS Agreement has required that all Member States amend, in varying degrees, their intellectual property system to comply. The fear of DSB challenges and their consequences has led to levels that exceed the requirements of the TRIPS Agreement. Developed Member States, especially those with significant political presence and economic strength, have chosen to avoid WTO-compliance in certain fields and bear the financial burden instead. Such political audacity is however reserved for the political heavyweights such as the US and the EC.[121]

The implementation of the TRIPS Agreement need not however exceed what it required. Member States are only required to implement the minimum level of protection for intellectual property rights holders. Member States wishing to provide additional intellectual property protection are likewise not prohibited from doing so, provided the additional measures do not infringe any other TRIPS provision. The preamble further states that the protection need only be 'adequate' to ensure the effective protection of intellectual property rights.[122] The TRIPS Agreement does not require more of any Member State.

Whereas the *pacta sunt servanda* obligation requires the giving of effect to the agreement, the TRIPS Agreement acknowledges that the method of implementation is a national prerogative.[123] The WTO Appellate Body report stated in the *India – Patent* case that Member States 'are free to determine how best to meet their obligations under the TRIPS Agreement within the context of their own legal systems'.[124] The freedom to elect the method of implementation represents the understanding

119 Contrast Art 60 of the Vienna Convention.
120 WTO Agreement Art XV.
121 A period of over 5 years has past since the US was entitled to impose trade sanctions on the EC in the WTO *EC – Hormones* case.
122 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 10.
123 TRIPS Agreement Art 1.1 third sentence.
124 WTO India – Patent Protection I p. 18.

that no two legal systems are identical. The reluctance of the TRIPS Agreement to prescribe the manner of implementation also derives from the consensus amongst the negotiating parties to only require a minimum standard and not to bring about a harmonisation of the global intellectual property system. The use of a minimum standard as the method for the implementation of the TRIPS Agreement is significant as it permits the Member States the flexibility to implement the provisions in a manner best suited to their constitution and domestic legal system.[125] Any attempt to use the TRIPS Agreement as a means to harmonise the Member States' intellectual property system would mean that the degree of consensus amongst the negotiating parties would have been less and consequentially the extent of the TRIPS Agreement more restricted. As the 'minimum standard' was the tool of implementation, it afforded the Member States a significant ability to tailor the implementation to suit their own legal system. The element of flexibility in the 'minimum standard' method also permits Member States to elect whether they would permit, or prohibit, the direct application of the TRIPS Agreement.[126] The prerogatives afforded by the 'minimum standards' method are of special relevance to Member States that institute non-intellectual property measures that either affect or conflict with the intellectual property rights. In accordance with the preamble, the TRIPS Agreement recognises that intellectual property rights are based upon underlying public policy objectives. From the interplay of the preamble and Article 1.1 the TRIPS Agreement acknowledges that the method of implementation can be structured in a way that would further the underlying policy objectives. The preamble further notes that these public policy objectives include, *inter alia*, developmental and technological objectives. The TRIPS Agreement thus accepts that, to the extent provided for by the TRIPS provisions, Member States are able to structure their method of implementation in favour of public policy objectives.

As has been stated above, determining the 'appropriate method' for implementation of the TRIPS Agreement is the sovereign right of the Member States. The manner of giving effect to the TRIPS provisions is the prerogative of the Member States themselves. It therefore follows that the effect can be given either by way of allowing the TRIPS Agreement to be self-executing or by way of a formal transformation of the provisions into domestic law. In addition to permitting, in whatever manner, the application of the TRIPS provisions, Member States must also take measures to ensure the compliance with the provisions. This would also make the legal jurisprudence, either deriving from administrative decisions or legal courts, accountable to the TRIPS Agreement.

It follows that the Member States are obliged to implement the TRIPS Agreement in a manner that gives effect to the provisions contained therein. The scope of the

125 US submitted that Art 1.1 'emphasises flexibility'. WTO *United Stated – Section 110(5) of the US Copyright Act* Report of the Panel (15.06.2000) WT/DS160/R p. 187.

126 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 17, 24. A significant portion of the TRIPS Agreement is, because of its flexible nature and insufficient precision, unsuited for direct application.

TRIPS Agreement can be divided into three main categories: the material, procedural and organisational provisions. Rights and obligations flow from all three. The material scope of the TRIPS Agreement is defined in Article 1.2 as referring to all that intellectual property contained in Part II of the TRIPS Agreement, i.e. copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits, undisclosed information and the anti-competitive practices in contractual licenses. These provisions form both the material scope and the substantive norms of the TRIPS Agreement. Having regard to the fact that the remaining TRIPS provisions are either general in nature or seek to implement procedures for the protection of the material rights it is fair to conclude that the scope of the TRIPS Agreement is intellectual property rights.[127] Notwithstanding the widespread scope, the TRIPS Agreement does not regulate every element of intellectual property rights. The TRIPS negotiators were unable to find consensus on each and every element of the intellectual property system. It is therefore necessary when considering the scope of the TRIPS Agreement to recall that the DSB does not have the authority to rule on issues not expressly contained in these material provisions. Thus, for example, Article 31 of the TRIPS Agreement prescribes the procedural requirements for granting a compulsory license. It does not regulate the grounds for a compulsory license. The DSB and other Member States are not able to rely on the TRIPS provisions when assessing the grounds a Member States has in respect of compulsory licenses. A Member State must therefore transpose the minimum standards of all the intellectual property rights found in the TRIPS Agreement and afford the protection to the rights holders as prescribed by the provisions. In the *India – Patent* case the Appellate Body found that the freedom to elect the method of implementation did not extend to permitting a Member State to self-certify compliance with TRIPS obligations.[128]

The second sentence in Article 1.1 states that a Member State shall not be 'obliged' to implement more extensive protection than is afforded in the TRIPS Agreement. Obliged means there must be a form of coercion, in whatever form, exercised on the Member State to apply 'TRIPS-plus' standards of protection. Such circumstances may occur in bilateral trade negotiations. If this is indeed the case, it has been argued that the pressurised party could resist the implementation of the TRIPS-plus provisions on the ground that they would disturb the balance negotiated in the TRIPS Agreement and effectively constitute a bad faith implementation of the TRIPS Agreement by the opposing party.[129] This argument fails for a number of rea-

127 The scope of the TRIPS Agreement is less than that of the NAFTA Agreement. Cf. *Dwyer*, Trade Related Aspects of Intellectual Property Rights in Stewart (ed) The GATT Uruguay Round: A negotiating History (1986-1994) (Kluwer The Hague 1999) vol VI p. 560-571.

128 WTO *India – Patent Protection I* p. 18.

129 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 24-25.

sons. All modern international trade negotiations are a result of compromise.[130] If the compromises are not voluntarily made but instead have been forced upon another country, the validity of the resulting treaty will be subject to provisions of Article 52 of the Vienna Convention and may lead to the treaty being declared void. Member States must be permitted to negotiate on bilateral and multilateral forums for further intellectual property protection. If TRIPS-plus provisions were to be declared outside the scope of future negotiations, there would be less motivation to enter into further trade agreements. Lastly, Member States are free to conclude treaties, including treaties that provide for additional intellectual property protection. If the obligations concerned to be too onerous, a Member State could refuse to adopt the treaty.

To conclude, the nature of the TRIPS Agreement is that of a treaty and the consequences thereof flow from the application of customary international law and codified principles contained in, *inter alia*, the Vienna Convention. The TRIPS Agreement is part of a single undertaking and is as such to be implemented as part of the obligations flowing from the WTO Agreement. The scope of the TRIPS Agreement is the subject matter of Part II of the Agreement and includes patents, copyright and related rights and undisclosed information. This scope must however be viewed in light of the title of the Agreement and of the preamble which limits the trade-related aspects of intellectual property rights. As development and technological objectives form the underlying basis for intellectual property rights they are also to be respected.

B. The object and purpose of the TRIPS Agreement

The objectives and purposes of an agreement guide the interpretation of a treaty. The classification of the object and purpose of the TRIPS Agreement is, therefore, fundamental to determining how the TRIPS Agreement is understood and how it is to be implemented. Only when there is predictability in the TRIPS Agreement will a sense of security emerge for Member States implementing the Agreement. The DSU requires that in doing so the DSB must take customary international law into account.[131] A number of Panels and Appellate Body rulings have revealed that the Vienna Convention embodies a number of key interpretational tools of customary international law.[132] In terms of the Vienna Convention the interpretation of a treaty

130 *Straus* also notes that states concluding such agreements only do so if their 'cost-benefit' equation, on a macroeconomic level, favours the agreement. Cf. *Straus*, 6 J. Marshall Rev. Intell. Prop.L 1(2006) p. 11-12.

131 DSU Art 3.2.

132 The first Appellate Body decision to do so was the WTO *United States – Gasoline* case. Cf. WTO *United States – Gasoline* Report of the Appellate Body p. 17. See also *Abbott*, WTO Dispute Settlement and the Agreement on Trade-Related Aspects of Intellectual Property Rights in: *Abbott, Cottier and Gurry* (eds), The International Intellectual Property System:

must be made 'in light of the object and purpose'.[133] The object and purpose in the TRIPS Agreement is found, *inter alia*, in the preamble and Articles 7 and 8.[134] Further, the preamble is also characterised by object-driven terminology; 'desiring', 'recognising' and 'emphasising' are words used to reflect the goal the negotiating parties had upon conclusion of the TRIPS Agreement. The identification of the intentions of the parties, as set out in the text of the Agreement, is particularly important in the TRIPS forum as the TRIPS Agreement exhibits 'gulfs of interpretive difference regarding the meaning of many of its rules'.[135]

Articles 7 and 8 of the TRIPS Agreement are respectively identified as containing the 'objectives' and 'principles' of the Agreement. The use of this terminology would not have been lost on the negotiating parties. As it is presumed that the use of the words was not superfluous it must be concluded that it was the intention of the negotiating parties to cement their intentions in this manner.[136] Notwithstanding this, the ordinary meaning of the text does not fully confirm the titles given. Instead, Article 7 states the intended goal of the TRIPS agreement in respect to the promotion of innovation and the transfer of technology.[137] Article 8 on the other hand sets out the fixed policy or moral rule upon which Member States are to implement the TRIPS obligations. Within the auspices of the TRIPS Agreement its objectives and principles are further distinguished by the material content of the provisions themselves. They are analysed here in more detail.

I. An analysis of the preamble

The preamble of the TRIPS Agreement provides more than a mere overview of the intentions of the negotiating parties. It sets out, in addition to Articles 7 and 8, the objectives of the TRIPS Agreement.[138] As such, the preamble is not an operative provision creating rights and obligations.

A preamble in a treaty is considered to form part of the context of the treaty for the purposes of interpretation.[139] This means that within the context of the TRIPS Agreement the preamble is applied together with the ordinary meaning of an opera-

Comments and Materials (Kluwer The Hague 1999) Part I p. 517, *Ortino*, 9 JIEL 1 (2006) p. 119.

133 Vienna Convention Art 31(1).

134 WTO *Canada – Pharmaceuticals* p. 154.

135 *Abbott*, WTO Dispute Settlement and the Agreement on Trade-Related Aspects of Intellectual Property Rights in: *Abbott, Cottier and Gurry* (eds), The International Intellectual Property System: Comments and Materials (Kluwer The Hague 1999) Part I p. 719.

136 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 118.

137 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 109.

138 WTO *United States – Section* 211 (Appellate Body ruling) p. 89.

139 Vienna Convention Art 31(2).

tive TRIPS provision to determine the intention of the parties to the Agreement.[140] The preamble, as with the other provisions incorporating the objectives and purposes of the TRIPS Agreement, will only be applied when express operative provisions are ambiguous or in order to confirm an interpretation. [141] As many of the TRIPS provisions are flexible in nature and permit significant room for interpretation, the role of the preamble is potentially significant.

The preamble contains numerous references to the intention of the parties. The use of the word 'desiring' in the first paragraph of the preamble is an indication that the contents hereof form the core of the negotiating parties' intention.[142] This is confirmed by the contents thereof. The paragraph creates three pillars upon which the TRIPS Agreement is based. With the first pillar the Member States indicated their intention to use the TRIPS Agreement to reduce distortions and impediments to international trade. This intention is mirrored in the WTO and GATT Agreements and is a concept that is central to the WTO as an institution. The second pillar focuses this general concept on the field of intellectual property rights and, in doing so, forms the principal column upon which the TRIPS Agreement is based. It calls for promotion of effective and adequate protection for intellectual property rights. This is achieved through the operative provisions of the TRIPS Agreement which introduce a minimum level of intellectual property rights protection and thus, reaffirms the intention of the negotiating parties. In light of the first two pillars one would have to conclude that the intention was to introduce effective and adequate provisions that would protect intellectual property that would not distort or impede international trade. As intellectual property rights are potentially able to be applied in a manner that creates trade distortions, the negotiating parties indicated, in the third pillar, their intention that the regulation of intellectual property rights should further be regulated in such a manner that the intellectual property rights themselves do not form barriers to international trade.

The first paragraph is indeed curious as it on the one hand seeks to eliminate trade restrictions and on the other protect intellectual property rights, which are in themselves trade restrictions. The preamble ignores the theoretical debate as to the value of intellectual property rights in a free market. The fact that in reducing impediments to trade one must take 'into account' the protection of intellectual property rights indicates however that the reduction of distortions and impediments are the principal goal of the TRIPS Agreement and, indirectly, the WTO as a whole. This goal, in theory, conflicts with intellectual property rights which seek to create limited free and unencumbered trade. A patent holder is able to impede international trade by preventing the importation of the invention from countries where the product is not

140 Anheuser-Busch Inc. v. Budejovický Budvar národní podnik C-245/02 [2004] ECR I-10989.

141 WTO *United States –Shrimps* p. 42.

142 The last paragraph in the preamble also commences with the word desiring. The paragraph does not however incorporate the intention of the negotiating parties to the TRIPS Agreement as a whole, but rather it refers to the intention to create a cooperative relationship with the WIPO.

subject to patent protection. The debate as to the necessity for intellectual property rights in a society is not referred to in the TRIPS preamble. Instead it proceeds from the point where intellectual property rights are accepted as a necessary tool for the advancement of society. It must therefore be concluded that the negotiating parties were in agreement that, as a whole and as indicated in the operative TRIPS provisions, intellectual property rights are not deemed to be an impediment to trade. This acceptance of intellectual property as being an exception to the general notion of free trade was accepted as far back as 1947 where the GATT parties agreed that measures taken for the protection of patents, trade marks and copyrights were a valid general exception to the free trade.[143] It must also be concluded that as intellectual property rights are a means for reducing trade impediments and distortions, the protection of intellectual property rights is not an end in itself, but rather a means to an end.

The preamble proceeds from the first paragraph by listing the measures needed to realise the negotiating parties' intentions. The introduction of new rules providing for the application of basic GATT principles, such as national treatment, and a comprehensive spectrum of rules setting intellectual property standards and ensuring their protection and enforcement. The negotiating parties identified further principles that they deemed important for the introduction of intellectual property protection: the status of intellectual property rights as private rights, the role of public policy objectives in the intellectual property system and the additional freedoms permitted to LDCs in the implementation of the TRIPS Agreement. The role of each of these factors in determining the parties' intention is uncertain. The reason for this is that the principles identified in the preamble lead, in certain circumstances, to diverging results. An example of this is paragraph 5 in the preamble recognising the underlying policy objectives of a domestic intellectual property system. The underlying public policy objectives may, for some Member States, mean strong intellectual property rights and for others mean weak intellectual property rights. It can be argued that as Member States have differing needs, the TRIPS Agreement can be interpreted in a way that determines 'adequate' protection in relation to the public-policy needs a country exhibits. Therefore it would be possible for a Member State with a low domestic concentration of technological ability to embark on a policy of encouraging domestic industries by deter-mining 'adequate' protection restrictively.[144] The preamble does not require Member States to interpret adequate in a way that would mean maximum protection.[145] The wide scope of principles included in the preamble reflects the varying interests of the Member States and would imply that the balancing of interests, whether they be the reduction of trade impediments,

143 GATT Art XX(d).

144 The WTO Appellate Body relied heavily on the development objective found in the WTO Agreement preamble. This is, to a certain degree, mirrored in the TRIPS preamble and may carry similar weight in the interpretation of the TRIPS Agreement. See WTO *United States – Shrimps* p. 48.

145 Reaffirmed in Art 1.1 of the TRIPS Agreement.

adequate intellectual property protection or the public policy objectives of the Member States, are all to be taken into account when implementing the TRIPS Agreement and its operative provisions.

The lack of a distinct direction in which the TRIPS Agreement is intended to operate creates the potential for diverging positions as to the role of the TRIPS Agreement and its intended intention. As the Appellate Body in the WTO *US – Shrimps* dispute acknowledged, treaties often have a 'variety of different, and possibly conflicting, objects and purposes'. Taking a one-sided or overriding approach as to which single intention is to apply fails to represent the object and purpose of a treaty. It is thus in the hands of the interpreter to find a balance that implements the object and purpose of the treaty in light of the domestic concerns and needs of the country in question. To this extent, the role of the preamble should not be discounted.[146]

II. An analysis of Article 7 TRIPS

> 'Objectives
>
> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.'

Article 7 was introduced in a proposal by a number of developing countries in the Uruguay Round of Negotiations in May 1990[147] and was seen as a means to incorporate a 'developmental' aim to the body of the TRIPS agreement, thus making it indirectly a part of the operational provisions of the Agreement.[148] The incorporation of these objectives into the body of the treaty, and not in the preamble, is seen as a step that has amplified the relevance of the status of the provisions.[149] The TRIPS Agreement is however neither a health nor development aid treaty, it is a treaty set to facilitate the protection and enforcement of intellectual property rights. This is the key objective of the TRIPS agreement and is the founding component of Article 7. The scope of Article 7 is however qualified. The qualification requires that the protection and enforcement of intellectual property rights 'should' increase, or at least facilitate the increase, of technological innovation *and* the transfer and dissemination of technology. The choice of the word 'should' in the context of rules and regula-

146 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 13.
147 GATT Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay (19.05.1990) MTN.GNG/NG11/W/71.
148 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 110.
149 *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 116.

tions indicates a mandatory obligation.[150] In other words, TRIPS must facilitate the increase and dissemination of technology in and between the Member States. Failure to achieve this result would mean that the TRIPS Agreement would have failed to meet the objectives of the Member States.

Determining compliance with this provision occurs by assessing the manner and effect of the implementation of the minimum standards required by the TRIPS Agreement, i.e. Parts II to IV. Thus compliance is measured by the domestic implementation of the provision. This in turn means that each Member State is empowered and simultaneously required to give effect to the requirement that intellectual property rights, as required under the TRIPS Agreement, shall further technological innovation and transfer. Accordingly, compliance is to be determined domestically, i.e. on implementation. Hence one can also say that Member States are not only themselves required to implement this mandatory obligation but they are also required to abide by its requirements *inter partes*. Thus it would not be in 'good faith' for one Member State to call upon another to implement rules that are contrary to Article 7.

Notwithstanding being part of the operational portion of the TRIPS Agreement, Article 7 is not an operational provision in the traditional sense. A Member State could not be found in contravention of the TRIPS Agreement purely on the grounds of Article 7. Similarly a Member State cannot expect that the implementation of the TRIPS Agreement alone will automatically lead to economic growth and social improvement.[151] Article 7 cannot be seen in isolation to the remainder of the TRIPS Agreement. Likewise, the implementation of the other operational provisions that provide for the transfer and dissemination of technology or promote technological innovation must be done in a manner that reiterates the aim of Article 7. Article 7 can thus be surmised as a non-operative general provision that does not, in itself, permit Member States to limit intellectual property rights.[152] It is rather a provision that is relevant in determining if an intellectual property restriction is TRIPS-conform where the particular TRIPS provision is unclear.

Article 7 further requires that intellectual property rights be mutually advantageous to both the producers and the users of the technological knowledge.[153] Therefore the transposition of the TRIPS Agreement into national legislation must be done in a manner that benefits both the rights holder and the consumer. This requirement is further reinforced as Article 7 requires that the ensuing rights and obligations are balanced. To what extent an action is deemed to exceed the rights holder's entitlements is a matter for national determination. Notwithstanding this, Article 7 further states that the enforcement and protection of intellectual property rights should be conducive to social and economic welfare. Article 7 does not entitle a Member State

150 Webster's Third New International Dictionary.
151 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 112.
152 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 116.
153 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 126.

to renege on its TRIPS obligations where it discovers that its implementation of the TRIPS Agreement has failed to improve that country's social and economic wellbeing. It would thus be correct to state that Article 7 suggests that the TRIPS agreement can and should benefit every society in which it applies. Its success depends on the national implementation of the obligations by the Member States, not on the TRIPS agreement.

The standard used to adjudicate the domestic compliance with Article 7 differs amongst the Member States. Some Member States, in particular the US, take the view that the more extensive the protection and enforcement the more likely one is to attract persons and businesses that innovate and disseminate knowledge. Others feel that the adoption of TRIPS in its most limited form should be sufficient to lead to innovation and dissemination of knowledge.

One major consequence does however ensue from Article 7: intellectual property rights are not a means to an end. Instead they form part of a complex sum aimed to benefit society. Theoretically this provision establishes a barrier to one-sided demands to increase intellectual property protection without due consideration for its effects on other public policies. This 'justification' for limiting the extent of intellectual property rights is however a supple provision. It fails to permit Member States to take active steps to limit intellectual property rights and any limitations must be done in accordance with the scope of the applicable substantive provisions. The practical effect of Article 7 will be limited to its use as reinforcement for an action taken and permitted in other provisions. As the TRIPS Agreement is littered with interpretational nightmares, the ability to justify ones actions under Article 7 may prove sufficient to be label the measures TRIPS-compliant.

The measures regarded as being sufficiently valuable include public interest issues such as social and economic welfare, the transfer of technology and knowledge, the promotion of innovation and the protection thereof. As the relationship is dynamic, should situations require dire measures, Article 7 would not prevent such measures being taken. Such measures will be limited by the notions of reasonableness and proportionality.

III. An analysis of Article 8.1 TRIPS

> 'Principles
>
> 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.'

In implementing the TRIPS agreement, either through new legislation or the amendment of existing legislation, Article 8.1 empowers Member States with the

right to implement the provisions in a manner that protects and enhances the public interest.[154] The express referral to measures necessary to protect public health and nutrition, to promote the public interest in crucial socio-economic and technical areas of development raises the importance of these issues within the TRIPS Agreement. Deciding which measures can be taken is a Member State's prerogative. They may differ from country to country and be justified in one country and not in another. The Member State's discretion is extensive and should, provided it is identified and implemented in good faith and consistent with the remaining TRIPS provisions, be accepted by other Member States.[155] Member States wishing to challenge the public policy measures taken in connection with Article 8.1 will bear the burden of proving that it is inconsistent.[156]

The application of Article 8.1 leads to the question: is Article 8.1 a tool for the interpretation of TRIPS or is it a TRIPS flexibility? Succinctly put, Article 8.1 would be an interpretational tool if it were used to determine if an Member States action itself is permitted or not. On the other hand were Article 8.1 a flexibility, it would permit Member States to implement its contents in a number of differing, but acceptable, ways. The answer to the question is: Article 8.1 can be used as an interpretational tool as well as providing a Member States with certain flexibilities. The wording of Article 8.1 clearly indicates its intention to permit Member States to undertake certain measures. The use of the word 'may' confirms the elective nature of Article 8.1, as is also evidenced in Articles 27.2, 30 and 31. In terms of Article 8.1 Member States are entitled to elect whether to implement certain public interest measures that restrict intellectual property rights. These measures are however only permitted when consistent with the remaining TRIPS provisions. Accordingly, Article 8.1 is of limited significance as a flexibility as it does not permit any additional actions that were not already permitted under other TRIPS provisions.[157] The practical significance of Article 8.1 comes in determining to what extent other flexibilities may be exercised. As a 'principle', Article 8.1 is a 'comprehensive and fundamental' rule of conduct for the implementation of the TRIPS agreement.[158] Article 8.1 confirms the Member States ability to prefer an interpretation which potentially favours public interest issues over rights-holder interests. It needs to be recalled that a flexibility permits numerous TRIPS-compliant implementations. Having said this, the extent of each permissible action under the flexibility is not always certain and has

154 *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 121.

155 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 127.

156 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 127.

157 *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 161, *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 121.

158 Webster's Third New International Dictionary.

lead certain Member States to challenge the actions of others based upon diverging views over the ambit of a flexibility. The contents of Article 8.1 identify certain values that are held high by the Member States, in particular that of the public interest. The express mentioning of these values and their location within the agreement has ensured that they assume a key role in gauging the intention of the parties. This in turn has meant that the attributes found in Article 8.1 make it a key provision for interpreting the meaning of other provisions within the TRIPS Agreement. The interpretational role of Article 8.1, and Article 7 for that matter, comes further from assisting in creating what is regarded as the greater 'context' of the agreement.

Another peculiarity of Article 8.1 is that it seemingly permits Member States to take public policy measures to protect the wellbeing of their citizens. This 'allowance' on behalf of the TRIPS Agreement is false for three reasons. Firstly, the TRIPS Agreement desires the 'effective and adequate protection of intellectual property rights'[159] and, within the scope of the WTO, aims to eliminate discrimination in international trade.[160] Thus the scope of TRIPS does not and cannot extend beyond intellectual property rights and trade. Health and other public policy measures are inalienable from a state and any reading of TRIPS to the contrary would be an *ultra vires* interpretation and unconscionable. Secondly, Article 8.1 permits nothing that is not already permitted elsewhere in the agreement. Thirdly, the permission to take certain public interest measures does not entitle a Member States to limit or exclude the rights and/or obligations found in TRIPS.[161]

The entire provision rests on the premise that the measures taken do not conflict with the remaining operative provisions within the TRIPS Agreement. Thus, Article 8.1 does not permit an action that is not already permitted elsewhere in the TRIPS Agreement. The in-clusion of this proviso confirms the role of Article 8.1 within the TRIPS Agreement as being a general provision which does not permit measures that conflict with other TRIPS pro-visions. The use of the proviso contrasts with existing GATT practice where Article XX(b), similar in language to Article 8.1, does not require such measures to be consistent with the other GATT provisions. As this constraint requires Member States not to adopt measures that are inconsistent with the TRIPS Agreement, it can be presumed that measures taken to address public health, nutrition and matters of vital socio-economic importance are consistent with the TRIPS Agreement.[162] Thus, the burden to prove the inconsistency of the measure rests on the Member State that avers the inconsistency.[163]

159 TRIPS Preamble.

160 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 120.

161 In the WTO *Brazil – Retreaded Tyres* case the Panel stated it was not within their scope to judge on the desirability of a Member State's policy goal or its level of protection, instead it is only to decide on the WTO-compliance thereof. See WTO *Brazil – Retreaded Tyres* p. 166-169.

162 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 127.

163 A similar burden of proof applies to Art XX GATT. See WTO *Brazil – Retreaded Tyres* p. 150.

Article 8.1 requires that all actions that be 'necessary'. This obligation infers that there must be a direct connection between the measures taken and their impact on the public interest.[164]

Article 8.1 is not a once-off entitlement. It enables Member States to take public interest actions at any time. The contents of Article 8.1 limit the permissible measures to 'laws and regulations'.[165] Article 8.1 only permits two types of measures: the *protection* of public health and nutrition and the *promotion* of the public interest, provided the areas being promoted are of vital importance to the development of that Member State. Thus Article 8.1 permits health, nutritional and developmental measures, provided the latter is vitally important to that Member States.

The formulation of Article 8.1 denotes that Member States implementing health policies will be presumed to act in compliance with the TRIPS Agreement. This therefore implies that a Member State challenging the TRIPS-legitimacy will bear the burden of proving its inconsistency.[166]

The existence of Articles 7 and 8 provide support for a limitation of the provision preventing the discrimination of patents according to their 'field of technology" found in Article 27.1. Whereas a discrimination will always remain unlawful under the TRIPS Agreement, the reference to health, nutritional and developmental measures within Articles 7 and 8 increases the scope and acceptance of what will be deemed a lawful and justifiable 'discrimination' of Article 27.1; the DSU terms such limitations 'differentiations'.[167]

To conclude, Article 8.1 is an interpretive principle that entitles Member States to take public policy actions that possibly limit intellectual property rights provided they are justifiable actions and consistent with the other obligation contained within the TRIPS Agreement. Phrased in the reverse, public policy measures will fail if they exceed what is necessary to promote and protect the public interest or if they are unnecessarily trade-restrictive.

IV. An analysis of Article 8.2 TRIPS Agreement

> Article 8.2 'Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.'

Notwithstanding Article 7, which requires a balance of rights between the rights holders and the users, Article 8.2 accepts that intellectual property rights can be

164 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 119.

165 Administrative actions would therefore seem to be excluded from Article 8.1 of the TRIPS Agreement.

166 *Abbott*, Quaker Paper 7 (2001) p. 25.

167 WTO *Canada – Pharmaceuticals* p. 170-171. See Chapter 5(C)(I)(2)(c) below for a discussion on discrimination and differentiation.

abused to the detriment of the Member States, other inventors and the user or consumer. Article 8.2 expressly acknowledges that it may be necessary for Member States to take appropriate measures to prevent such abuse within their jurisdictions. In addition to preventing the abuse of the intellectual property system, Article 8.2 also permits a Member State to counter practices that stifle trade, i.e. that are anti-competitive, or negatively impact on the transfer of technology.[168] Intellectual property licensing systems are often targeted as potentially being examples of both intellectual property abuses and unreasonable restraints on trade. Article 8.2 only permits those measures taken to prevent abuse if they are 'appropriate'. This is understood to require the measures to be both adequate and proportionate in relation to the abuse.[169] The abuse must justify the measure, i.e. it must be necessary. The measure referred to in Article 8.2 needs to *prevent* an abuse, i.e. a measure can be implemented to proactively avoid even the occurrence of the abuse and the need to respond to an existing abuse. This Article 8.2 empowers Member States to implement a general policy regime regulating anti-competitive behaviour within the realm of intellectual property rights.[170] Finally, as all intellectual property rights have the potential for abuse, Article 8.2 can be applied to all potential abuses of intellectual property rights.

As the contents of Article 8.2 face the same limitations as Article 8.1, i.e. neither provisions entitle measures that are not already permitted elsewhere in the TRIPS Agreement, the legal value of the provision is limited to that of an interpretational aid whilst examining the extent of other provisions within the TRIPS Agreement. An example of the application of Article 8.2 would be the granting of a non-exclusive license by a national governmental agency enabling the third party use of a patent without the patent holder's consent in order to rectify the patent holder's anti-competitive actions. Although these actions are provided for within Article 31, Article 8.2 can be used to evaluate the extent of the actions permissible. Article 8.2 therefore introduces a legal standard – the requirement of 'reasonableness' – requiring Member States to evaluate whether certain measures to prevent competition abuse are compatible with the TRIPS Agreement.[171] Aside from providing the TRIPS provisions with a degree of legal certainty when dealing with anti-competitive behaviour, the extent of influence of Article 8.2 is hemmed by the operation of Article 40, concerning the control of anti-competitive practices in contractual licensing of intellectual property rights.

168 *Straus*, Patentschutz durch TRIPS-Abkommen – Ausnahmeregelungen und –praktiken und ihre Bedeutung, insbesondere hinsichtlich pharmazeutische Produkte in: Bitburger Gespräche Jahrbuch 2003 (CH Beck Munich 2003) p. 121.

169 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 132.

170 See further in this regard *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 133.

171 The scope of Art 8.2 of the TRIPS Agreement extends to three types of practices: abuse of rights, anti-competitive practices and acts that have a negative impact on the transfer of technology.

V. The influence of the international customary rule of interpretation on the object and purpose provisions

In adjudicating a dispute, both panel members and the Appellate Body are bound in terms of Article 3.2 to pursue the clarification of the WTO agreements in light of the '*customary rules of interpretation of public international law'*. Accordingly, WTO adjudicators are required to abide by certain basic rules of interpretations. The Vienna Convention on the Law of Treaties is considered the best collection of the customary rules of interpretation.[172] The golden rule, Article 31(1) of the Vienna Convention, requires adjudicators to give the disputed text its 'ordinary meaning'. In determining the ordinary meaning the terms must be interpreted within 'their context *and* in the light of its object and purpose' (emphasis added). This therefore means that the ordinary meaning of a treaty's provisions is not limited to the meaning of the words but instead a more comprehensive meaning has to be given, a meaning that complies with and gives effect to the object and purpose of the treaty.[173] A treaty provision cannot be interpreted on face value only. Its meaning derives from the treaty as a whole, preamble and annexes included.[174] The ordinary meaning cannot be isolated from the objects and principles of the treaty as it is often these provisions that reflect the common intention of the parties.

The objectives and principles laid down in the TRIPS Agreement, the preamble as well as Articles 7 and 8, are not merely an aid for determining a meaning of a vague term or provision; they are instead a mandatory consideration factor that must be considered when determining the ordinary meaning of the TRIPS Agreement. Developing Member States expressed their concern that the DSB was failing in this regard, thus effectively enforcing a treaty that no longer represented the common intention of the parties. In addition there was growing concern that the role of the object and purpose provisions in examining the TRIPS Agreement was being progressively sidelined. It was hoped that the express referral of certain Member States prior to the Doha Ministerial Conference to the interpretational provisions of international treaty law would serve to counter the apparent arbitrariness certain DSB

172 WTO *Japan – Alcoholic Beverages II* p. 11, WTO *United States – Gasoline* Report of the Appellate Body p. 16-17; WTO *United States – Section* 211 (Appellate Body ruling) p. 77. See also WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 p. 5, *Ehlermann and Lockhart*, 7 JIEL 3 (2004) p. 497.

173 Art 31(1) of the Vienna Convention is a compulsive provision. It states a 'treaty *shall* be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose' (emphasis added).

174 A WTO panel concluded that 'the elements referred to in Art 31 – text, context and object-and-purpose as well as good faith – are to be viewed as one holistic rule of interpretation rather than a sequence of separate tests to be applied in a hierarchical order'. WTO *United States – Sections 301-310 of the Trade Act of 1974* Report of the Panel (22.12.1999) WT/DS152/R p. 305.

panels exhibited.[175] This reminder to the DSU of their duties had a double rationale: firstly to remind TRIPS adjudicators that the interpretation of the TRIPS Agreement has rules and secondly to ensure that the adjudicators do not lose sight of the scope and purpose of the TRIPS Agreement whilst applying the agreement. By reigning in the TRIPS adjudicators, developing Member States believe that they will retain a margin of flexibility that would otherwise have been limited by conservative interpretational methods. The reminder of the application of international rules of treaty interpretation ensures that the objectives and principles, set out in the preamble and Articles 7 and 8, retain their importance of guiding the interpretation of the agreement and ensuring that its implementation is carried out in a manner 'conducive to social and economic welfare, and to a balance of rights and obligations'. [176]

In terms of Article 31(4) of the Vienna Convention, Member States may, *ex post facto*, give a particular meaning to a TRIPS provision by way of a subsequent agreement. Article IX.2 of the WTO Agreement however provides for a formal process for the Member States to secure a common interpretation of a treaty provision. It would appear that the WTO Agree-ment excludes the application of Article 31(4) of the Vienna Convention as the WTO Agree-ment states that the Ministerial Conference and the General Council shall have 'exclusive authority to adopt interpretations'. Although the customary rules of interpretation create a theoretical possibility for an interpretation without fully complying with the process, the Article IX.2 process is likely to be the sole process for providing interpretations as it does not require complete consensus.

The use of customary international laws in the interpretation of the TRIPS Agreement is not limited to the Vienna Convention. The Vienna Convention does not constitute a complete codification or closed list of customary rules of interpretation of international law.[177] The Convention itself acknowledges this and recognises that its role is amplified by the progressive development of international customary law.[178] Thus, any international custom which is generally practiced by states and accepted as law will apply to the interpretation of the TRIPS Agreement.[179] Customs are dynamic and develop as international relations develop. Trade rules between states are developing and multiplying at a significant rate. The potential exists that certain rules common to bilateral and multilateral treaties will acquire international

175 For example the Appellate Body took the following approach: 'A treaty interpreter must begin with, and focus upon, the text of the particular provision to be interpreted. It is in the words constituting that provision, read in their context, that the object and purpose of the states parties to the treaty must first be sought. Where the meaning imparted by the text itself is equivocal or inconclusive, or where confirmation of the correctness of the reading of the text itself is desired, light from the object and purpose of the treaty as a whole may usefully be sought'. WTO *United States –Shrimps* p. 42.

176 TRIPS Agreement Art 7.

177 *Brownlie*, Principles of Public International Law (6th edn OUP Oxford 2003) p. 580.

178 Vienna Convention Preamble.

179 Statute of the International Court of Justice 59 Stat. 1031 Art 38(1)(b).

law status. So to may general principles of law acquire an authoritative value.[180] Although not expressly referred to in the ICJ Statute, there is general acceptance that decisions of international bodies may potentially be a source of international law. Thus it would seem that decisions of the WTO and its Councils could potentially aid the understanding and implementation of the text of the TRIPS Agreement. The standards used to determine the existence of customary law is: 'actual practice and *opinio juris* of States'.[181] The ICJ went further and stated that 'multilateral conventions may have an important role to play in recording and defining rules deriving from custom, or indeed in developing them'.[182]

Thus, a reference to public international law reinforces the obligation adjudicators of the TRIPS Agreement have to grant due consideration for the objectives and purposes of the agreement and ensures that any subsequent agreement reached on the meaning of a TRIPS provision will have the effect of ensuring that the provision retains the meaning given to it by its signatories, whether by virtue of the original intention or by virtue of an direct or indirect meaning given *ex post facto* and by consent.

Finally, the added attention given to customary rules of interpretation of public international law by Member States benefits the role of the DSB which struggles to ensure a balance between respecting the discretions of the Member States and ensuring the 'security and predictability' of the TRIPS agreement.[183] The inclusion of references to customary public international law reaffirm that Member States desire a TRIPS Agreement that acknowledges, as a core principle, that the treaty need be interpreted and implemented in accordance with its objectives and principles.[184] The conclusion of a Ministerial Declaration on the application of provisions in the TRIPS agreement also, in terms of the Vienna Convention on the Law of Treaties, further assists the DSB as it guides the adjudicators to the intention of the Member States, towards a 'clarified' intention

VI. The role of 'flexibility' in the object and purposes of the TRIPS Agreement

Flexibility plays two roles with respect to the object and purpose of the TRIPS Agreement. Internally, the terminology and phraseology used in the preamble and Articles 7 and 8 permits numerous and often conflicting conclusions as to the intention of the parties.[185] Externally, when an interpreter seeks to determine the scope of

180 Statute of the International Court of Justice 59 Stat. 1031 Art 38(1)(c).
181 Continental Shelf Case (Libyan Arab Jamahiriya/Malta) [1985] ICJ Rep 13 p. 29.
182 Continental Shelf Case (Libyan Arab Jamahiriya/Malta) [1985] ICJ Rep 13 p. 29.
183 DSU Art 3.
184 *Ehlermann and Lockhart*, 7 JIEL 3 (2004) p. 478.
185 Flexibilities found in the TRIPS Agreement are to be distinguished from the application of the *in dubio mitius* principle. The *in dubio pro mitius* principle refers to instances where there is a burden to prove a desired interpretation and not to clauses that permit more than one interpretation. It is however noteworthy that the Appellate Body has applied the *dubio pro mi-*

the application of the flexibilities in the operative provisions of the TRIPS Agreement he will be directed to the provisions of the treaty setting out the object and purpose of the treaty.

1. The flexibilities found in the object and purposes provisions

The flexibilities residing in the object and purpose provisions recognise that the protection of intellectual property rights under the TRIPS Agreement can be tempered and directed so as to further public interest policies. This is evident not only in the preamble but also in Articles 7 and 8. The scope of these public interest policies are widespread and include the furtherance of intellectual property rights, which is assumed in itself to further the public interest as it promotes technical innovation, the dissemination of technology, public health and nutrition and socio-economic development.[186] These interests are referred to in both the preamble and part I of the TRIPS Agreement. Thus, the reference to these policy interests enables Member States interpreting the object and purpose of the TRIPS Agreement to incorporate a wide variety of public interest factors into the implementation of the TRIPS Agreement.

The preamble and Articles 7 and 8 make repeated mention of developmental objectives. This reflects the intention the negotiating parties had prior to the adoption of the TRIPS Agreement. The developed negotiating parties repeatedly inferred that intellectual property rights should and would further the development of countries – despite the lack of empirical evidence that this would occur. The developing negotiating parties, sceptical of the inference, sought to ensure that intellectual property rights would not hamper development. The parties' intention that intellectual property rights should promote development objective, or at the very least, not hamper development was thus incorporated into the objective and purpose provisions of the TRIPS Agreement. The measures that are deemed to fall within the scope of 'development' are left largely to the Member States themselves to determine. This is one of the key flexibility factors in these provisions. They are, to a certain degree, directed by Articles 7 and 8 which state that socio-economic and technical development should result from the manner of implementation. A further policy objective that permits a flexible interpretation of these provisions is the acknowledgement that a balance must exist between the rights holder and the user of the intellectual property. This objective can be interpreted to allow Member States to differ in what they consider to be a balance in the intellectual property system. As the needs or concerns

tius principle. Cf. *Matsushita et al*, The World Trade Organization: Law, Practice, and Policy (2nd edn OUP Oxford 2006) p. 85-86.

186 S 56(1) of the South African Patent Act construes public interest 'in its widest meaning, namely, the interest of the community including every class which goes to construe that body, namely, the purchasing public, the traders and manufacturers, the patentee and his licensees, and inventors generally'.

of users or rights holders in countries differ, the interpretation of this objective will permit Member States to structure their own balance and implement the TRIPS Agreement in a manner most suited to their requirements. The public interest is a further objective that arises out of the object and purpose clauses in the TRIPS Agreement. The term 'public interest' refers to the 'general welfare of the public that warrants … protection'.[187] What is deemed to be worthy of protection for the welfare of the public at large evades close interpretation. It is a dynamic concept that evolves according to the demands of the public. Further, interests protected in one Member States need not be recognised as such in all Member States. The TRIPS Agreement does however refer to two examples of public interest: health and nutrition. Other examples public interest factors include the protection of the environment as well as culture, transport, education and knowledge. The extent these factors will influence the implementation of intellectual property rights, or *visa versa*, will depend on the specific circumstances.

2. The role of the object and purpose provisions in flexibilities found in other TRIPS provision

The intention of the negotiating parties, as set out in the object and purpose provisions of the TRIPS Agreement, and the flexibility in which it can be applied assumes a firm purpose when interpreting the meaning and flexibilities of the operative provisions of the TRIPS Agreement. The presence of flexible provisions within the TRIPS Agreement is extensive. Thus, as Member States debate the scope of provisions and where the ordinary meaning thereof is not clear, the interpretation and application of the flexibilities becomes of vital importance. The WTO Appellate Body has ruled that the interpretation of treaties should follow the customary rules for the interpretation of public international law. Where the interpreter must proceed beyond the ordinary meaning of the text he is, in accordance with the WTO *US – Shrimps* case, required first to determine the meaning in terms of the immediate context of the provision.[188] This requires to the extent applicable determining the meaning of the relevant *chapeau*. Where the meaning and the object and purpose are not apparent from the *chapeau*, the interpreter must turn to the object and purpose of the treaty as a whole. Articles 7 and 8, together with the preamble, are deemed to encapsulate the intention of the TRIPS Member States. In the *Canada –Patent* case the Panel stated:

> 'Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when [examining the scope of the Agreement] … as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes.'[189]

187 *Garner (ed)*, Black's Law Dictionary (8th edn Thomson West St. Paul 2004) p. 1266.
188 Contrast *Ortino*, 9 JIEL 1 (2006) p. 130-132.
189 WTO Canada – Pharmaceuticals p. 154.

The role of the preamble and Articles 7 and 8 is thus not only to help determine the scope of the TRIPS Agreement as a whole, but also to assist in the interpretation of the flexibilities found in the operative provisions themselves. This is achieved when Member States and other interpreters of the TRIPS Agreement use the contents of the preamble and Articles 7 and 8 to direct their interpretation and implementation of the 'wiggle-room' present in most of the operative provisions in the TRIPS Agreement. This entitlement of a Member State is not insignificant. It enables Member States the opportunity to tailor their implementation of the TRIPS Agreement. Many gaps and ambiguities can be found in the TRIPS Agreement and are, in the majority of instances, deliberate. They are characterised by either their refusal to regulate an issue, e.g. exhaustion (Article 6 TRIPS Agreement) or the limited intention to comprehensively regulate an issue.

3. The relevance given to the role of flexibility in the object and purpose provisions by the Member States

The relationship between the flexibilities present in other TRIPS Agreement provisions and the preamble and Articles 7 and 8 is therefore of significant importance as the implementation of the operational provisions will be guided by these provisions. The importance of these provisions is however dependent on the importance a Member State will confirm to it. The importance of the object and purpose provisions to Member States, especially developing Member States, became apparent in the wake of the HIV/AIDS epidemic and the ensuing debate within the WTO forum.

With the obligation to implement the TRIPS Agreement becoming increasingly relevant to the Member States, the developing Member States realised the extent of their commitments and sought confirmation that the flexibilities were still available to them.[190] The inability developing Member States had in effectively exercising the flexibilities was compounded by the lack of legal expertise and knowledge in these countries. The affected Member States were unsure of the scope and meaning of the flexibilities, which they saw as key to the implementation of the TRIPS Agreement, and sought 'guarantees and confirmation that the flexibilities under [the TRIPS Agreement] were available for the Members without challenge'.[191] The importance of the object and purpose provisions and their flexibilities was formally discussed in the TRIPS Council special session 'Special Discussion on Intellectual Property and Access to Medicines'.

190 The Indian representative is quoted as saying this 'issue is too important to be left either to chance or to future panels. This is why all of us here should collectively recognize and confirm the considerable degree of flexibility offered by the TRIPS Agreement in this regard'. Cf. India in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 22.

191 Zimbabwe in the TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 64.

The developing Member States sought, *inter alia*, to create a generally recognised obligation to apply customary rules of public international law when interpreting and applying the object and purpose provisions within the TRIPS Agreement.[192] The confirmation that customary rules of interpretation should guide the interpretation of treaties was strictly speaking unnecessary.[193] GATT panel rulings and WTO DSB decisions have confirmed the role of customary rules in their decisions.[194] Notwithstanding this, the developing Member States felt that the DSB had afforded insufficient weight to the customary rules and interpreted the object and purposes of the TRIPS Agreement in a restrictive manner. Within the context of the HIV/AIDS epidemic developing Member States focussed more attention on the meaning of the object and purpose provisions of the TRIPS Agreement, especially the references to social welfare and public health. They concluded that the role of the object and purpose provisions of the TRIPS Agreement meant that the protection of intellectual property rights was subordinated to public policy objectives.[195] Only by making this conclusion could the TRIPS Agreement implemented in a humane manner solidifying the primacy of human life and public wellbeing.[196] As confirmation of this standing, the developing Member States sought consensus that 'nothing within the TRIPS system should prevent Member States from adopting measures to protect public health', [197] thus seeking to reacquire the full use of the flexibilities found in the preamble and Articles 7 and 8. This was especially evident in their view that the provisos found in Article 8 requiring the compliance with the remaining TRIPS provisions does not 'neutralise' the flexibilities of the provisions.[198]

Developed Member States on the other hand took a more sceptical view of the role of the objectives and principles of the TRIPS Agreement. Whilst they confirmed that health protection measures could still be implemented without conflicting with the TRIPS Agreement they felt that the balance struck between the interests of the public and that of the rights holder had already been made and should not be renego-

192 WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 p. 5.

193 Art 3.2 of the DSU states 'The Members recognize that [the dispute settlement system] serves to preserve the rights and obligations of Members under the covered agreements, and to *clarify* the existing provisions of those agreements in accordance with *customary rules of interpretation of public international law*. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements' (emphasis added).

194 WTO United States – Gasoline Report of the Appellate Body p. 17, WTO Japan – Alcoholic Beverages II p. 11, WTO India – Patent Protection I p. 14.

195 Kenya in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 22-23.

196 Tanzania in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 29.

197 WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 p. 6.

198 Egypt in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 41.

tiated.[199] The application of the object and purpose provisions were seen as being of 'essential importance' for the interpretation of the TRIPS Agreement but did not permit a Member State to downgrade the intellectual property protection required by the TRIPS Agreement.[200]

VII. The role of health in the object and purpose of the TRIPS Agreement

Health, nutrition and other public interest factors were factors used to influence and exercise national intellectual property regimes prior to the TRIPS Agreement. The role of public interest in the patent system was also internationally recognised[201] and even an element recommended by the WIPO.[202] With the adoption of the TRIPS Agreement, public interest evolved into a more tangible factor in the evaluation and implementation of intellectual property rights. Of the various public interest issues referred to in the TRIPS Agreement, health and the protection thereof assumes a particularly prominent role. Article 8 expressly states that 'Members may … adopt measures necessary to protect public health'. This statement does not however permit Member States to use health issues as a ground for breaching the remaining provisions within the TRIPS Agreement. In terms of the proviso in Article 8, any measures taken to protect the public health must also be consistent with the TRIPS Agreement. The consequence is that health measures cannot override the obligations that Member States bound themselves to in the TRIPS Agreement. This consequence gives the impression that intellectual property protection is more important than health measures; that patent rights are more important than the protection of the public's wellbeing. This impression is no more than that, an impression. Legally, the Member States bound themselves to abide by the rules set out in the TRIPS Agreement. The *pacta sunt servanda* notion obliges Member States to abide by the rules

199 Switzerland in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 44-45. In the same document Pakistan referred to the so-called carefully negotiated balance as 'rhetoric, especially when the existing flexibilities in the relevant provision hardly do much to provide space to manoeuvre due to the fact that either the relevant provisions have been drafted in a manner which takes away the possible flexibility or these countries lack at the moment in technical expertise and also entrepreneurial skills to undertake production of generic drugs'. See in this regard Pakistan at p. 74. See also Communication by Canada in the Minutes of the TRIPS Council (02.11.2001) IP/C/M/33 p. 40 and the EU position in WTO *Canada – Pharmaceuticals* p. 154.

200 EC in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 7-8, EC and US in the TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 35, 37 respectively.

201 GATT Note from WIPO 'Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms or the Protection of Intellectual Property' (15.06.1988) MTN.GNG/NG11/W/24/Rev.1 9.

202 GATT Note from WIPO 'Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms or the Protection of Intellectual Property' (15.06.1988) MTN.GNG/NG11/W/24/Rev.1 9.

they accepted. Unlike the GATT and GATS Agreements, there is no general exception in the TRIPS Agreement whereby Member States may avoid compliance with an obligation on the grounds of health concerns. This may additionally give the impression that health issues must yield to intellectual property rights. Unlike the GATT and GATS Agreements, the TRIPS Agreement approaches the role of health in an indirect manner. The operative provisions of the TRIPS Agreement permit, as stated already, significant flexible interpretations. The interpretation and implementation of these provisions can and should be done in a manner 'conducive to social … welfare'.[203] This is supported by the contents of Article 8 that expressly permit the implementation of public health measures in a manner that may influence and 'bend' the TRIPS obligations, provided they do not breach the obligations. Article 8 expressly confirms that each Member State is entitled to legislate and administer measures that protect its citizens' interests. Although the discretion is limited to the exceptions, exemptions and flexibilities contained in the TRIPS Agreement, no constraints are made on the kinds and the subject matter of the measures that may be taken. As the flexibilities permit wide-ranging interpretations, health measures can be widely used to influence the scope and extent of an obligation. Thus, health measures, as referred to in the object and principle provisions of the TRIPS Agreement, can influence and redirect specific intellectual property provisions.

The role of health in the interpretation of the TRIPS Agreement is further strengthened by the very nature of the WTO Agreements. The principle of deference, a system whereby international rules defer to a Member States' policies – which is a common thread through the WTO Agreements – confers a unique role upon the protection of health within the scope of the implementation of WTO obligations.[204] The principle, a product of the scope and purpose of the WTO Agreements and its political influences, establishes the protection of health as an interpretive principle that allows Member States leeway to vary their structuring of resources, risk, and the balance between health issues and other policy issues in a manner that best suits the national circumstances.[205] In other words, the protection of health encourages and justifies more extensive use of the flexibilities found within the TRIPS obligations. Although the health prerogative has been applied nationally to shape the domestic legal arena, its role within international fora has been uncertain. It has been convincingly submitted that the protection of health can play a similar role in the international fora when interpreting the extent of the legal obligations Member States are bound to and the degree to which they can be interpreted.[206]

A Member State is thus entitled to interpret a flexibility found in a TRIPS obligation in a manner that favours the public health. As the interpretation of a TRIPS obligation requires a balancing of interests, the protection of health, especially in times of wide-spread ill health, will often be seen as a more important interest than the

203 TRIPS Agreement Art 7.
204 *Gregg Bloche*, 5 JIEL 4 (2002) p. 843.
205 *Gregg Bloche*, 5 JIEL 4 (2002) p. 846.
206 *Gregg Bloche*, 5 JIEL 4 (2002) p. 847.

protection of the patent holder's rights. The role that health plays in the objective and principles of the TRIPS Agreement is mirrored in the sovereign and inalienable duty a state has to ensure the well-being of its citizens and take the necessary steps to achieve better welfare. In doing so a state is entitled, as it has always been, to subordinate private rights to compelling public interests. Article 8 merely confirms this obligation and right and channels the methods of doing so into a formal process under the auspices of the WTO.

Despite an attempt to define the term 'public health', the TRIPS Agreement is silent on the scope or meaning of the term.[207] As such, no reason exists for Member States to interpret the term restrictively. The DSU has accepted that the protection of society's wellbeing can be a valid exception to the requirements of the WTO Agreements; examples include the Appellate Body's acceptance of psychological health and the protection against ill-health as valid exception grounds.[208] However the interpretations given must nevertheless comply with the good faith interpretation of the TRIPS Agreement. As the health measures remain a national prerogative they will only fall foul of the DSU if they defeat the objectives and principles of the TRIPS Agreement.[209] Moreover, once a Member State has found a health measure to be *prima facie* necessary it should be presumed to be consistent with the TRIPS Agreement.[210] Any Member States challenging this would thus be required to prove its inconsistency.

The use of health issues to influence the interpretation of the TRIPS Agreement is thus a valid and potentially invaluable to Member States seeking to balance what negative effects the intellectual property system or the use thereof may bring to certain countries. The DSU has accepted that once adopted, they will only be determined to be false or inappropriate where they are proved to be neither necessary nor reasonable in light of other alternative measures.[211]

207 During the TRIPS negotiations Japan sought to define 'public health' as being 'critical peril to life of the general public or body thereof'. GATT Note from Secretariat 'Meeting of Negotiating Group' (22.06.1990) MN.GNG/NG11/21 p. 24.

208 The DSU has not had the opportunity to rule on the scope of public health measures within the TRIPS Agreement. Notwithstanding this there appears to be no reason why such should not, in the right circumstances, apply to measures taken under the TRIPS Agreement. A similar treatment of the concept of public health within the scope of the TRIPS Agreement would indeed be consistent with the Article 31(1) of the Vienna Convention where it requires that, *inter alia*, in interpreting a treaty due weight must be attached to the context of the treaty; as the WTO Agreements form one undertaking, the DSU would only be required to apply public health concerns similarly, provided the provisions themselves do not require otherwise.

209 WTO *United States – Section* 211 (panel ruling) p. 85.

210 UNCTAD/ICTSD, Resource Book on TRIPS and Development (CUP New York 2005) p. 127. Compare WTO US – Gambling (Appellate Body ruling) p. 103.

211 Compare WTO *US – Gambling* (Appellate Body ruling) p. 102-103, WTO *EC – Asbestos* p. 63.

VIII. Other influences on the object and purpose of the TRIPS Agreement

The WTO Agreement preamble gave the WTO negotiating parties the opportunity to update the GATT preamble. The parties no longer desired the 'full' use of the world's resources but rather an 'optimal' use that did not ignore the importance of sustainable development, the environment and the differential needs and concerns of the Member States. The importance of these factors was confirmed in the WTO *US – Shrimps* dispute where the Appellate Body held that the intentions of the negotiating parties, encapsulated in the WTO Agreement preamble, 'must add colour, texture and shading to [the] interpretation of the agreements annexed to the WTO Agreement', of which the TRIPS Agreement is one.[212] One of the objectives identified as having a trickle-down effect on the other WTO Agreements was that of sustainable development.[213] The emphasis put on this objective is likely to further enhance and secure measures taken by developing Member States that have the aim of securing the advancement of their societies and economies.

The influence of agreements or treaties made subsequent to the adoption of the WTO Agreements is subject to debate. One view holds that the intention of the parties at the time of the agreement is conclusive for interpreting that agreement. Any change in the intention of the parties will need to be formally recorded in the form of an authoritative interpretation or an amendment in order for it to have any effect. A second point of view states that certain terms in an agreement are, by virtue of their nature, 'evolutionary'. An evolutionary term will reflect important legal, political and social developments. Whereas this may not be applicable to all terms, certain terms such as public interest, social and economic welfare, *ordre public*, morality, national emergency and extreme urgency lend themselves to an interpretation that reflects evolving circumstances. The latter approach has been adopted by the DSU.[214] In the WTO *Japan – Alcoholic Beverages II* case the Appellate Body announced that:

> 'WTO rules are not so rigid or so inflexible as not to leave room for reasoned judgements in confronting the endless and ever-changing ebb and flow of real facts in real cases in the real world'[215]

To determine the evolving meanings interpreters must concentrate on 'modern international conventions and declarations'.[216] Although the Appellate Body in the WTO *US – Shrimps* case referred principally to UN conventions and decisions to assist the objectives and principles of the treaty, it would be faithful to the decision's principle to include other multilateral decisions into the basket of worthy agree-

212 WTO United States –Shrimps p. 58.
213 WTO United States –Shrimps p. 58.
214 WTO *Canada – Pharmaceuticals* p. 150, WTO *Japan – Alcoholic Beverages II* p. 34, WTO *United States –Shrimps* p. 48, *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 700-701.
215 WTO Japan – Alcoholic Beverages II p. 34.
216 WTO United States –Shrimps p. 48-49.

ments. The rational behind the reference to multilateral agreements is that if all WTO Member States agreed to a certain text in another forum, it would be fitting to import that text or meaning into the WTO arena, should the circumstances apply. The acceptance of the evolutionary interpretation by the DSB decisions will assist developing Member States in structuring their intellectual property regime in a manner that favours development and health. The UN Millennium Declaration is an example of the UN's focus on development and health.[217] In respect of measures taken to protect health, the WHO resolutions will provide guidance as to their necessity, nexus and the legal weight afforded to them, especially in weighing up the interests of the rights holders and the public.[218]

It goes without saying that the WTO internal decisions and declarations will have a more immediate effect on the interpretation of the WTO Agreements. Of all the agreements reached on intellectual property rights by the Member States, the Public Health Declaration and the subsequent decisions are likely to have the most significant influence on the understanding and implementation of the TRIPS Agreement. The consequences of these agreements are discussed Chapters 6, 7 and 8 below.

C. The material provisions of the TRIPS Agreement

I. The subject matter of patents

An invention that is new, involves an inventive step and has industrial application must be capable of being patented in all Member States.[219] The obligation imposed on Member States is clear: any invention, regardless in what field of technology it exists and whether it is a product or process invention, must be eligible for patent protection in each and every Member State.[220] Despite the obligations imposed by Article 27.1 having 'universal' application, they are not absolute. Member States are empowered to safeguard their interests by enabling them to exclude certain inventions, 'the prevention within their territory of commercial exploitation of which is necessary to protect *ordre public* or morality'.[221] The terminology used in Article 27 and their role in balancing the interests of the parties concerned have left ample room for Member States to structure their implementation according to their own

217 UNGA Res S-62/2 'Declaration of Commitment on HIV/AIDS' (02.08.2001) UN Doc A/RES/S-26/2, UNCHR 'Economic, Social and Cultural Rights Report of the Special Rapporteur P Hunt' (01.03.2004) UN Doc E/CN.4/2004/49/Add.1 p. 5.

218 WHO World Health Assembly Resolution 'Global Health-sector Strategy for HIV/AIDS' (28.05.2003) WHA56.30.

219 TRIPS Agreement Art 27.1. Part VI of the TRIPS Agreement includes transitional measures that postpone the implementation this obligation.

220 Subject to the requirements of novelty, inventiveness and usefulness and the exceptions set out in Art 27.2 and 27.3 of the TRIPS Agreement. Developing Member States could further limit the patentability in terms of Art 65.4 and 70.8 of the TRIPS Agreement.

221 TRIPS Agreement Art 27.2.

understanding of the TRIPS Agreement. The flexibilities present in Article 27 and the possibilities they present for Member States are discussed below.

1. Article 27.1 of the TRIPS Agreement

> 'Patentable Subject Matter
>
> Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[222] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.'

The obligations deriving from Article 27 require a Member State to create a system whereby inventors meeting the requirements of novelty, non-obviousness and usefulness acquire an exclusive right granted by the state for a certain period of time in return for the disclosure of the invention in a patent specification. These obligations agreed to in the TRIPS Agreement extend far beyond those agreed to in the TRIPS Agreement's predecessor: the Paris Convention. Under the Paris Convention signatory states had free reign in defining their national requirements (and exclusions) for patentability.[223] The result of the TRIPS Agreement was that, for the very first time in international law common practices – such as separate patentability requirements for pharmaceutical and nutrition inventions, patentability exclusions for lack of local exploitation of the patent in the country of application and process inventions and other discriminatory practices – became unlawful for Member States to maintain. The extensive patentability scope was the object of controversy amongst the negotiating states, especially the mandatory extension of the patent subject matter to pharmaceuticals which, at the beginning of the Uruguay Round, was not patentable in more than half of the GATT Member States.[224]

The concepts of novelty, usefulness and non-obviousness are not defined in the TRIPS Agreement nor is there an international standard setting out the meaning of these terms.[225] The UK Commission on Intellectual Property Rights notes:

222 Original Footnote no. 5: 'For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.'

223 Cf. *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 171.

224 There were 91 GATT Member States as of 01.09.1986, of which around 50 did not grant protection to pharmaceutical products. Cf. GATT Note Prepared by the International Bureau of WIPO (15.09.1988) MTN.GNG/NG11/W/24/Rev.1 p. 79-82.

225 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 145, *Straus*, Patentschutz durch TRIPS-Abkommen – Ausnahmeregelungen und –praktiken und ihre Be-

> 'It does not however define the term "invention", nor does it prescribe how the three criteria for patentability are to be defined. Indeed we would note that it is not uncommon for different courts in Europe, even when applying identical law, to come to different conclusions on whether a patent is or is not obvious. There is therefore ample scope for developing countries to determine for themselves how strictly the common standards under TRIPS should be applied and how the evidential burden should be allocated.'[226]

This enables Member States the freedom to define their own standards for novelty, inventiveness and usefulness. The flexibility also extends to the subject matter of the patent. Member States are only required to permit inventions patentability.[227] Whether or not this extends to business processes, algorithms, computer programmes, discoveries, scientific theories, mathematical methods, games and presented information is not dealt with in the TRIPS Agreement.[228] The consequences of this national prerogative can be significant. Member States which implement these concepts restrictively will, as a result, award fewer patents and ensure more inventions fall into the public domain, free of exclusionary patent rights. The reverse side of a strict system is that fewer inventors will apply for patents and less innovative products will arrive on the market. The implementation of these concepts is a difficult task for many developing countries.

2. Article 27.2 of the TRIPS Agreement

> 'Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.'

The general rule that all novel, inventive and useful inventions are patentable does however permit a Member States to enact limitations to the scope of the subject

deutung, insbesondere hinsichtlich pharmazeutische Produkte in Bitburger Gespräche Jahrbuch 2003 (CH Beck Munich 2003) p. 122, *UNCTAD Secretariat*, The TRIPS Agreement and Developing Countries (UNCTAD Geneva 1996) p. 32-33.

226 *CIPR*, (2002) p. 114. Compare *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 195-196.

227 Creations of the human intellect as a whole were excluded from the TRIPS Agreement. See *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 197.

228 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 148-52. The author discusses computer software, business methods and second uses. See also *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 189.

matter. Article 27 permits Member States to limit the scope of eligible inventions in three ways:

- in order to protect the general public interest
- to exclude diagnostic, therapeutic and surgical treatment methods for man and animal and
- to exclude patents on plant and animals.

Of the three exceptions, only the first – found in Article 27.2 of the TRIPS Agreement – permits the Member State to enact patentability restrictions that are of general application and able to limit the patentability in any field of technology. As Article 27.2 effectively gives Member States the power to negate Article 27.1, the scope of the Article 27.2 exclusion is subject to extensive qualifications and/or restrictions. The qualified use of Article 27.2 centres on four issues: the exploitation of the invention, the necessity of the Article 27.2 exclusion, non-discriminatory use of the exclusion and the proviso against the mere statutory implementation of the exclusion. They are discussed hereunder.

a) Commercial exploitation

Article 27.2 of the TRIPS Agreement permits Member States to exclude an invention from patentability when the prevention of the commercial exploitation thereof is necessary to protect the public interest. This means that where the commercial use of an invention threatens the general wellbeing of the public, Article 27.2 permits a Member State to deny such an invention exclusive patent rights.[229] The rationale behind this is that if the invention itself that poses the threat, the exercise of the exclusive patent rights, which by their very nature are a 'commercial activity',[230] will be a threat too.

As a result of the direct correlation between the threat posed by the invention and the patentability exclusion is the question: if excluding the invention's patentability is required, does the TRIPS Agreement require the Member State to completely ban the exploitation of the invention? Whereas some authors have answered this question in the affirmative[231] and whereas such a result may be desired in many cases, the TRIPS Agreement does not set this as a requirement. It clearly states that only the 'commercial exploitation' of the invention needs to be considered.[232] No men-

229 *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen (Nomos Baden Baden 2002) p. 236.

230 WTO Canada – Pharmaceuticals p. 161.

231 *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 182, *Correa*, 16 EIPR. 8 (1994) p. 328.

232 *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen (Nomos Baden Baden 2002) p. 221, *Straus*, Patentschutz durch TRIPS-Abkommen – Ausnahmeregelungen und –praktiken und ihre Bedeutung, insbesondere hinsichtlich pharmazeutische Produkte in Bitburger Gespräche Jahrbuch 2003 (CH Beck Munich 2003) p. 122.

tion is made of non-commercial exploitation. Hence, it would be at least theoretically possible to ban the commercial exploitation of the invention but allow the non-commercial exploitation thereof.[233] Seen within the context of the TRIPS provisions on patents, this would mean that the 'public non-commercial use' would be permissible.[234]

A further of uncertainty within the context of Article 27.2 is whether or not the ban on the commercial exploitation of the invention must precede the exclusion from patentability.[235] The TRIPS Agreement does not however require a pre-existing ban on its commercialisation as a precondition for the exclusion from being patented.[236] *Leskien* and *Flitner* phrased it as follows:

> '… Article 27 (2) TRIPS does not require an actual ban of the commercialization as a condition for exclusions; only the necessity of such a ban is required. In order to justify an exclusion under Article 27 (2) TRIPS, a member state would therefore have to demonstrate that it is necessary to prevent – by whatever means – the commercial exploitation of the invention. Yet, the member state would not have to prove that under its national laws the commercialization of the invention was or is actually prohibited.
>
> In fact, approval or disapproval of the exploitation by national laws or regulations does not constitute per se a sufficient criterion for examining whether an invention may be excluded from patentability on the grounds of Article 27 (2) TRIPS. This means that a legal ban of the exploitation of an invention is neither a condition for excluding it, nor is it necessarily sufficient for justifying such exclusion. This is underlined by the qualification contained in Article 27 (2) TRIPS, "that such exclusion is not made merely because the exploitation is prohibited by their laws". This qualification makes clear that the assessment of whether or not the commercialization of a particular invention is necessary in order to protect ordre public or morality does not depend on any national laws. Conversely and by the same token, a particular invention may be excluded from patentability although its commercialization is (still) permitted under a member state's national laws.' [237]

The prior existence of a ban on the exploitation may in most circumstances already exist. However it is imaginable that an invention may be of such novelty that

233 *de Carvalho* mentions that not all means of exploitation need be excluded. Situations may arise where the patentability is excluded but, for example, the scientific research thereon is permitted. Cf. *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 173

234 TRIPS Agreement Art 31(c). Whereas Art 31(c) is generally limited to government or crown use, the use in Art 27.2 will extend to all instances where the invention is exploited in a non-commercial or not-for-profit basis. Cf. *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen (Nomos Baden Baden 2002) p. 222.

235 *Straus*, for example, states that a commercial ban should precede the patentability exclusion. *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 182.

236 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 378.

237 *Leskien and Flitner*, Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System in: Engels (ed) Issues in Genetic Resources No. 6 (IPGRI Rome 1997) p. 15-16 (original footnote deleted).

no existing general legal provisions are able to prevent its exploitation at the time upon which it was invented. Take the example of a patent for a process for the cloning of humans. It is most likely that many developing states have not taken the time to ban what is at present a theoretical situation. However should such a situation arise and surprise a countries legal system, this absence of an existing general legal prohibition should not hinder the exclusion of the inventions patentability on *public ordre* grounds.

Within the context of the exclusion of patentability on public interest grounds a Member State will only be required to determine if the use of the invention in a commercial manner has the potential to harm the public interest.[238][239] Member States will however be required to demonstrate a correlation between the denial of patentability and ban on the commercial use of the invention. Notwithstanding this, the commercial ban is not a prerequisite for the denial of patentability.

Rogge puts this debate into a practical perspective when he states that (almost) each and every reasonable means of commercial exploitation must be contrary to the *ordre public* before the invention's patentability can be excluded. This is in many ways merely common sense – why should a good invention be excluded from being patented when only one means of commercial exploitation would present harm to society?[240] It would not be justifiable to deny an inventor his rewards when the 'misuse' of the patent could present a threat to society.[241] Hence the debate as to the existence of a prior ban is largely unnecessary and in day-to-day situations theoretical.[242]

238 As the threats that potentially arise from patented inventions seldom become known before they are patented, this situation is under normal circumstances unlikely to arise. It is foreseeable that such a situation would arise where a country requires the patent authorities, in addition to the standard patent requirements, to assess the inventions potential for public harm. Here there would be prior knowledge of the potential danger the invention would pose.

239 *Rogge* correctly notes that the harm, or potential harm, must arise from each and every means of exploitation of the invention. The author also notes that as far back as 1960 that this position was a generally held position within the European patent regimes. Cf. *Rogge*, 100 GRUR 3-4 (1998) p. 306.

240 Even if all but one means of commercial exploitation would be a threat to society, the inventor should still be permitted to exploit its exclusive rights in respect to that permissible means of exploitation.

241 *Rogge* rightly mentions that even a hammer or a kitchen knife poses a potential danger in the wrong hands. Cf. *Rogge*, 100 GRUR 3-4 (1998) p. 306.

242 It is also practically unfeasible to impose restrictions as to the exploitation of the invention within the patent as it is almost certain that the threatening means of exploitation are already subject to general restrictions on use. *Rogge* however gives a theoretical example: the patenting of a process for cloning humans would be contrary to the *ordre public* and would not be patentable. However any mention in a claim that, amongst many others, the 'cloning of humans may be possible' would have to be removed from the claim on *ordre public* grounds. Cf. *Rogge*, 100 GRUR 3-4 (1998) p. 306-307.

b) Necessity

Before a Member States can exclude an invention's patentability it must determine if the denial of patentability is indeed *necessary* to protect the public interest.[243] The 'necessity' requirement is fundamental to Article 27.2 and essential to ensure the exclusion is exercised in good faith as it seeks to prevent the arbitrary and/or unjustifiable exclusions of patentability. The necessity of a measure has been extensively dealt by WTO jurisprudence.[244] As a result, the Appellate Body identified three points that should be considered when determining the necessity of an exception:

> '(a) the importance of the interests or values that these Acts are intended to protect;
>
> (b) the extent to which these Acts contribute to the realization of the ends respectively pursued by these Acts; and
>
> (c) the respective trade impact of these Acts.' [245]

It is therefore essential that a Member State wanting to exclude the patentability of an invention will have to evaluate how these factors, also referred to as the necessity test, apply to the relevant case at hand. The first factor, determining the importance of the protectable interests, requires an evaluation of the specific interests and circumstances of each case. Article 27.2 identifies two categories of interests, those of the public and those of the inventor.

Ordre public is a public interest concept that is found in a multitude of treaties, international court cases and national legal systems.[246] Essentially, the concept is a

243 This evaluation method is similar to that of Art XX (a and b) of the GATT Agreement. In WTO *United States – Gasoline* Report of the Appellate Body p. 29, the Panel stated: 'a measure is not 'necessary' if an alternative measure which a state could reasonably be expected to employ and which is not inconsistent with other GATT provisions is available'. WTO *Brazil – Retreaded Tyres* p. 199-201. It is also foreseeable that Art 2 of the WTO Agreement on Technical Barriers to Trade (TBT Agreement) will be of relevance, especially where Art 27.2 would be used as a tool to form barriers to trade. See *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 171-173.

244 The DSB has considered the meaning of 'necessary' in numerous circumstances (GATT Agreement Art XX(d) and GATS Agreement Art XIV(a) – see in particular WTO *US – Gambling* (Appellate Body ruling) p. 239 *et seq*. WTO *Korea – Beef* case (p. 49) the Appellate Body stated the following: '[T]he reach of the word "necessary" is not limited to that which is "indispensable" or "of absolute necessity" or "inevitable". Measures which are indispensable or of absolute necessity or inevitable to secure compliance certainly fulfil the requirements of Article XX(d) [GATT]. But other measures, too, may fall within the ambit of this exception. As used in Article XX(d), the term "necessary" refers, in our view, to a range of degrees of necessity. At one end of this continuum lies "necessary" understood as "indispensable"; at the other end, is "necessary" taken to mean as "making a contribution to". We consider that a "necessary" measure is, in this continuum, located significantly closer to the pole of "indispensable" than to the opposite pole of simply "making a contribution to".'

245 WTO *US – Gambling* (Appellate Body ruling) p. 242. Although the panel in the WTO *US – Gambling* case considered the scope of an exception, there is no reason why this would not apply *mutatis mutandis* to the Article 27.2 exclusion.

legal tool that has as its aim the protection of the public from attacks on its general good, integrity and security.[247] Threats to the *ordre public* tend to take a tangible form and are objectively identifiable. The TRIPS Agreement however permits exclusions beyond tangible threats and enables Member States to exclude an inventions patentability based on subjective threats found to be irreconcilable with the current acceptable standards of society or culture (*contra bonos mores*).[248] The DSB

246 Within the realm of the TRIPS negotiations, the '*ordre public*' concept was first formally referred to in a proposal made by the EC, cf. GATT Proposal from the EC (07.07.1988) MTN.GNG/NG11/W/26 and is a reference to the Art 53(a) of the European Patent Convention, *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 170. Reference to *ordre public* can also be found in Art 12(3) of the ICCPR, Art 10(2) of the Convention on the Rights of the Child, Art 16 of the EC Convention on the Law Applicable to Contractual Obligations (Rome 1980) and §6 of the German EGBGB. The concept is also common in tax treaties and statutes dealing with private international law. Note: whereas *ordre public* may assume the translated corollary 'public order' or even 'public policy' in certain cases, it is more generally used to apply to the term public interest, to which public order and public policy concerns belong. Accordingly public interest is the more favourable and apt translation for the purposes of this dissertation. Cf. WTO *US – Gambling* (panel ruling) p. 236, *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 222.

247 Despite the general application of *ordre public*, its scope and meaning are not identical throughout in all legal jurisdictions. Cf. *Correa*, Integrating Public Health Concerns into Patent Legislation (South Centre Geneva 2000) p. 12, *Beier,* 30 IIC 3 (1999) p. 261. The EPO refers to this test as the 'public abhorrence or unacceptability test'. In the US the courts apply a similar test where inventions are considered as 'frivolous or injurious to the well-being, good policy, or sound morals of a society'. See in this regard *Lowell v. Lewis*, 15 F. Cas. 1018 (CCD Mass. 1817), quoted in *Chisum,* Chisum on Patents (Lexis Nexis Santa Clara 2005) § 4.02[1] 4-4. It is to be noted that 'immoral creations' are considered under the requirement of utility in current US jurisprudence. In *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 170-171, the author comes to the conclusion after reference to the Art 53(a) of the EPC that *ordre public* in TRIPS refers to 'protection against physical damage, and not a general and abstract idea of general or collective interest'. This conclusion is extended to the protection of the environment. Cf. *Lançon*, 28 IIC 6 (1997) p. 891. The DSB has held that *ordre public* and public morals/order may encompass to both physical and psychological illnesses. See WTO *US – Gambling* (panel ruling) p. 242. In the *Compulsory License*, case the German Federal Supreme Court held that the public interest cannot be universally defined and that it is subject to change. *Compulsory License*, BGH 28 IIC 1997 p. 245 and *Beier*, 30 IIC 3 (1999) p. 261.

248 Compare *Beyleveld and Brownsword,* Patenting Human Genes: Legality, Morality, and Human Rights, in Harris (ed) Property Problems: From Genes to Pension Funds (Kluwer London 1997) p. 13 where the authors contend that morality should be interpreted and determined in light of human rights: 'Article 53(a) must be read as a charter for human rights in the specific field of patent law'. *Rogge*; also addressing the EPC, states that the *ordre public* threat must be against an essential ('*wesentlichen'*) or fundamental ('*tragenden'*) principle of the legal order. Rogge also notes that the principal differences regarding the scope of the *ordre public* between the EPC member .lay in their understanding of what was essential or fundamental. *Rogge*, 100 GRUR 3-4 (1998) p. 304. Art XX(a) GATT Agreement acknowledges that Member States are entitled to exclude certain GATT provisions in favour of public morals.

has, for its part, taken the view that a public interest exception should only 'be invoked only where a genuine and sufficiently serious threat is posed to one of the fundamental interests of society'.[249]

The importance of the interest at stake, depending whether it is an *ordre public* interest or moral value, is determined according to the threat the interest poses to that particular Member State. The Appellate Body speaks of a 'relative importance'.[250] Inventions found likely to seriously prejudice the protection of the 'public security and the physical integrity of individuals' can be excluded from being patented.[251] It seems however clear for the DSB jurisprudence that measures taken to secure 'the preservation of human life and health through the elimination, or reduction, of the well-known, and life-threatening, health risks' will be 'vital and important in the highest degree'.[252]

In determining the degree of the threat it is useful to consider Article 53(a) of the EPC. It essentially reflects the contents the Article 27.2 of the TRIPS Agreement.[253] The approach set out in the Guidelines for Examination of the EPO state a 'fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.'[254] The EPO approach to *ordre public* and morality defeats its purpose. By asking what the public considers to be abhorrent or inconceivable as a test for both *ordre public* and morality, the EPO is effectively nullifying the *ordre public* element. The scope of *ordre public* extends beyond public perception (which is adequately encompassed by the morality element) and includes objectively ascertainable threats to the wellbeing of a community. The narrow approach taken by the

249 WTO *US – Gambling* (panel ruling) p. 237.

250 WTO *US – Gambling* (Appellate Body ruling) p. 102, WTO *EC – Asbestos* p. 63, WTO *Korea – Beef* p. 49.

251 NAFTA Art 1709(3), OAPI Art 5 and Decision 344 Art 6. Common Provisions on Industrial Property (of the Andean Pact) specifically notes that 'diagnostic, therapeutic and surgical methods of treatment' may be excluded.

252 WTO *EC – Asbestos* p. 63. The Appellate Body stated: '"[t]he more vital or important [the] common interests or values" pursued, the easier it would be to accept as "necessary" measures designed to achieve those ends. In this case, the objective pursued by the measure is the preservation of human life and health through the elimination, or reduction, of the well-known, and life-threatening, health risks posed by asbestos fibres. The value pursued is both vital and important in the highest degree.' The WTO *Brazil – Retreaded Tyres* case goes further and states that measures taken to 'avoid the generation of further risk' will also be justified under the public interest scope. See WTO *Brazil – Retreaded Tyres* p. 167.

253 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 171. The author does however note that Art. 27.1 does extend beyond the scope of Art 53(a). For a discussion of the differences see *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 181-182.

254 *EPO* Guidelines: Part C Chapter IV', Art 53(a), para. 3.1.

EPO regarding the public interest is not, *per se*, to be assumed in the realm of the WTO Agreements.[255]

On a purely economic level, it would be grossly unfair to expect that developing WTO Member States to be required to implement the EPO approach. The reason for this is that the EPO is an organisation of principally developed nations, rich in financial and industrial resources.[256] Their financial wealth means that certain public problems may be less of a threat as the country has the resources to counter the problem. The WTO community however contains significantly more developing and least-developed countries in its fold. Requiring a WTO/TRIPS standard that equals the EPO would be to impose a standard beyond the capacities of a majority of the Member States. Aside from the 'fairness' of relating to the EPO standard within the TRIPS Agreement, there are legal arguments that would point to a separate consideration of Article 53(a) of the EPC and Article 27.2 of the TRIPS Agreement. Firstly, the origin of the 'abhorrence' element as a benchmark for the use of the *ordre public* concept is in itself unclear. The definition given by the EPO Board of Appeal is quoted as saying:

> 'The board defined the concept of ordre public as covering the protection of public security and the physical integrity of individuals as part of society'[257]

Only in respect to the environment did the board inject any qualification as to the degree of the prejudice; it stated that the prejudice be serious.

Secondly, the statement made in the EPO Guidelines established a link between the abhorrence the general public would feel and the *ordre public*. Placing the subjective feeling of the public within the scope of the *ordre public* concept runs contrary to the general opinion of the concept, i.e. that it generally refers to actual/objective threats.[258] This link is better served within the morality concept, a distinctive element both within the EPC and the TRIPS Agreement.

Finally, the *ordre public* standard itself is viewed less restrictively within the context of the WTO. The footnote to Article XIV(a) of the GATS Agreement states that the protection of the public order be 'invoked only where a genuine and sufficiently serious threat is posed to one of the fundamental interests of society'. The 'sufficiently' requirement is to be interpreted as a lower standard than 'abhorrence'. Fur-

255 It also appears that the EPO Board of Appeal does not consider the abhorrence concept to be essential. In the EPO *PPG Industries Ohio, Inc.* G 1/03 OJ EPO [2004] (08.04.2004) case the board considered Art 53(a) but did not refer to the abhorrence standard. It must also be noted that the board incorrectly applied the *ordre public* concept to subjective public perceptions. The board applied *ordre public* and morality in one breath, not making any distinctions between their scope of application. Cf. EPO *PPG Industries Ohio, Inc.* G 1/03 OJ EPO [2004] (08.04.2004) p. 10-11.

256 Compare *Straus*, Ethical Issues in Patent Law Biotechnology and Research Ethics: A European Perspective (presentation presented at CASRIP High Technology Protection Summit 2002).

257 Quoted in *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 171.

258 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 171.

ther, the sufficiency standard is not applied to threats to the physical and mental integrity of humans, animals and plants.[259] If the TRIPS Agreement is to be interpreted in the context of the treaty as a whole, the distinctions made in the GATS Agreement would need to be considered; both are annexes to the WTO Agreement and thus are to be interpreted as one. The GATS meaning is further important as the TRIPS Agreement does not provide a definition for *ordre public*.[260] Although the GATS Agreement and DSB jurisprudence[261] may provide for a standard, the grounds for the evoking the public interest, in whichever forum, is left to the Member States to independently identify and determine their own levels of public value protection.[262] In the WTO *US – Gambling* case, the panel stated:

> 'In the Panel's view, the content of these concepts for Members can vary in time and space, depending upon a range of factors, including prevailing social, cultural, ethical and religious values. Further, the Appellate Body has stated on several occasions that Members, in applying similar societal concepts, have the right to determine the level of protection that they consider appropriate. Although these Appellate Body statements were made in the context of Article XX of the GATT 1994, it is our view that such statements are also valid with respect to the protection of public morals and public order under Article XVI of the GATS. More particularly, Members should be given some scope to define and apply for themselves the concepts of "public morals" and "public order" in their respective territories, according to their own systems and scales of values.'[263]

The high regard that WTO jurisprudence has given to the protection of societal interests should dispel doubts that the DSB lays more importance in intellectual

259 GATS Agreement Art XIV(b). The distinction in the GATS Agreement between public morals and health (Arts XIV(a and b) respectively) is contrary to the US approach, which considers the protection of health as being a public moral. See WTO *US – Gambling* (Appellate Body ruling) p. 28.

260 Art 27.2 of the TRIPS Agreement states that the protection of human, animal or plant life or health or to avoid serious prejudice to the environment falls within the scope of the protection of *ordre public* and morality. These examples provided by the TRIPS Agreement give a good indication of the scope of the concept *ordre public*. However good these examples are they are no more than examples of what the *ordre public* could cover. As such their use within Art 27.2 could not constitute a definition of *ordre public*. Compare *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 181, *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 223.

261 WTO *US – Gambling* (panel ruling) p. 237.

262 The Appellate Body stated in the WTO *EC – Asbestos* case that 'it is undisputed that WTO Members have the right to determine the level of protection of health that they consider appropriate in a given situation.' WTO *EC – Asbestos* p. 61. Also WTO *US – Gambling* (Appellate Body ruling) p. 244, WTO *Brazil – Retreaded Tyres* p. 170. Compare *Correa*, Integrating Public Health Concerns into Patent Legislation (South Centre Geneva 2000) p. 12.

263 WTO *US – Gambling* (panel ruling) p. 237. Original footnote deleted.

property rights than on valid and justifiable public interests.[264] To the DSB the pursuit of human life and health is 'both vital and important in the highest degree'.[265]

The existence of a protectable public interest is alone not sufficient. The exploitation of the invention must pose a threat to this interest, i.e. there must be a nexus between the invention and the threat to the public interest. The EPO Board of Appeals has stated that where the exploitation is either to be misused or used in a destructive manner such exploitation would be considered sufficient grounds for the exclusion of the invention.[266] The negative exploitation need not be an intended result of the inventor; the unintentional harm or threatened harm will suffice. Further, the likelihood for negative exploitation must be greater than its potentially positive exploitation.

It is unlikely that Member States will be able to justify developmental interests within the scope of the necessity test. Although developmental interests may be regarded as being of critical importance to many developing Member States, Article 27.2 speaks of the protection of these interests. Hence, the invention would have to threaten the development interests of that Member States. Inventions however have the opposite effect; they encourage development. Likewise, excluding a pharmaceutical invention from patentability would in most cases fall foul of the necessity requirement.

In determining the second leg of the necessity test, the proportionality of the measure, the DSB case law has further laid a low standard for determining to what extent the measures must contribute to the attainment of the intended goals. In the WTO *US – Gambling* case the panel stated that the measures 'must contribute, at least to some extent, to addressing these concerns'.[267]

The necessity test requires that a Member State implementing measures that restrict WTO obligations to first consider other measures that might have the same result without impinging WTO laws.[268] To what extent this will apply to Article 27.2 is uncertain. Unlike most instances where the necessity test is applied, Article 27.2 is a permissible basis for an exclusion; not an exception.[269] Article 27.2 does not limit the patent rights as none are granted. The application of the 'lesser infringement'

264 *Matsushita et al*, The World Trade Organization: Law, Practice, and Policy (2nd edn OUP Oxford 2006) p. 920-921.

265 WTO *EC – Asbestos* p. 63. In the WTO *US-Gambling* case, the panel confirmed this by stating that the measures sought to limit gambling and, *inter alia*, protect compulsive gamblers (i.e. non-physical non-terminal threats) 'serve very important societal interests that can be characterized as "vital and important in the highest degree" in a similar way to the characterization of the protection of human life and health against a life-threatening health risk by the Appellate Body in *EC – Asbestos*'. See WTO *US – Gambling* (panel ruling) p. 243, WTO *Brazil – Retreaded Tyres* p. 169-170.

266 EPO *Plant Genetics Systems* T 356/93 OJEPO 1995 545 (21.02.1995) p. 23.

267 WTO *US – Gambling* (panel ruling) p. 244, WTO *Brazil – Retreaded Tyres* p. 171-173.

268 WTO *US – Gambling* (panel ruling) p. 252. The panel confirmed the *US – Tuna* case which required a Member States exercising an exception to exhaust all other options reasonably available.

269 Although similar in nature, to exclude means to shut out; to except means to take out.

principle to the patentability exclusion it would effectively require the Member State to grant patent and, should the threat persist, revoke the patent. This would therefore do away with the need for Article 27.2. As it presumed that the TRIPS negotiators intended this provision to play a role in the regulation of patent rights,[270] it must be assumed that Article 27.2 is independent and not part of the hierarchical limitations permitted under Articles 30 and 31 of the TRIPS Agreement. However, the severity of this measure is lessoned by the fact that it will only apply within the context of a ban of the commercial exploitation of the patent. Having regard to the low standard of proportionality required by the panel in the WTO *US – Gambling* case, it seems that Member States seeking to exclude the patentability of an invention will not be required to pay too much attention to alternative measures.[271]

The remaining factor, the impact of the exclusion on trade, will unlikely present Member States exercising Article 27.2 with much of a hindrance where the exclusion is done on a case-by-case basis and not done in a manner that would run contrary to the non-discrimination rules.[272] If however there is a concerted effort to use Article 27.2 to shroud an illegal trade barrier in the cloak of a public interest such actions will not (and cannot) be deemed necessary.

c) Discrimination and differentiation

The exclusion of an invention's patentability may not discriminate as to the place of the invention and/or field of technology.[273] Within the context of the WTO the DSB has viewed discrimination as a:

> 'normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment'[274]

'Discrimination' thus infers a differentiation on the grounds of certain characteristics or tokens[275] that have an unfair and/or unjustifiable adverse effect on affected

270 The EPO Board of Appeals, in considering Art 53(a) of the EPC, stated that although it might be difficult to apply *ordre public* and morality, it could not be disregarded. Cf. EPO *Plant Genetics Systems* T 356/93 OJEPO 1995 545 (21.02.1995) p. 23.

271 An alternative to all exclusions would allowing the patent but denying the commercial exploitation. This would present a good alternative as it would not infringe the patentee's rights under Art 28 of the TRIPS Agreement; Art 28 only grants exclusive rights against third parties, not a right to sell or market the patent (see Chapter 5(C)(II) hereunder). This alternative is not a TRIPS alternative as a ban on the marketing of the products is beyond the scope of the TRIPS Agreement.

272 See Chapter 5(C)(I)((2)(c) immediately hereunder.

273 Art 27.1 also prohibits discrimination according to the place of production of the invention/patent.

274 WTO *Canada – Pharmaceuticals* p. 171. The panel made this statement whilst interpreting the scope and meaning of discrimination as to the field of technology terminology used in Art. 27 of the TRIPS Agreement.

275 Webster's Third New International Dictionary.

individual.[276] Phrased differently, the DSB distinguishes between justified differential treatment (differentiation) and unjustified differential treatment (discrimination). This distinction is of vital importance to the operation of the Article 27.2 exclusion as it acknowledges that not all differential treatment is unlawful under the WTO Agreements.

Discrimination may take two forms: *de jure* discrimination and *de facto* discrimination. *De jure* discrimination refers to express measures that make an unlawful differentiation between the place of the invention, the field of technology or the place of production of the invention. *De facto* discrimination refers to 'ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects'.[277] *De jure* discrimination is easier to identify and prove as it is an express product of state actions or policies. Within the context of Article 27.2 *de facto* discrimination will only be able to be proven after multiple patentability exclusions. As patentability exclusions are arguably isolated in nature, proving a practice of *de facto* discrimination will require numerous unjustifiable examples of exclusions pertaining to a specific field of technology and to inventions invented or produced in a particular place.

Express or tacit differential treatments are not automatically prohibited. Only unjustified differential treatment is prohibited. When and where the differential treatment will be justified depends on the matter in question. The DSB has however noted that the 'standards by which the justification for differential treatment is measured are a subject of infinite complexity'.[278] Within the context of Article 27, the DSB went further and stated that:

> 'Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than a frustration of purpose.'[279]

The TRIPS Agreement thus leaves Member States the possibility to treat inventors differently without being discriminatory. Member States following an express policy to exclude the patentability of certain inventions may do so, provided that the policy motivating the exclusion is necessary to protect the public interest. Notwithstanding the ability to differentiate, an attempt to exclude a class of inventions would unlikely pass the necessity requirement. This is grounded on the reasoning that an open exclusion would not afford the future patents the opportunity to rebut their status. Further, as the 'necessity' in denying a patent grant needs to be balanced in each individual case, based on its relevant factors,[280] declaring an invention 'un-

276 *Abbott,* Quaker Paper 9 (2002) p. 49.
277 WTO Canada – Pharmaceuticals p. 171.
278 WTO Canada – Pharmaceuticals p. 171.
279 WTO Canada – Pharmaceuticals p. 170-171.
280 The WTO Appellate Body refers to this test as the 'weighing and balancing' test. This 'involves in every case a process of weighing and balancing a series of factors which prominent-

patentable' would frustrate the first requirement of the necessity test as the interests of the inventor would not have been considered. This inconsistency of a class-exclusion with Article 27.2 is further confirmed by the resident proviso which prohibits an exclusion on statutory grounds alone.[281] This is dealt with more specifically hereunder.

d) Implementation restrictions relating to the Article 27.2 exclusion

Patent grants are neutral in character.[282] On the one hand, they themselves do not permit (or for that matter deny) exploitation and, on the other hand, they have no control over whether or not the exploitation of the patent will be beneficial to society.[283] The duty to restrict the exploitation of inventions is a general duty on the state to ensure the safety and security of its citizens. Thus, a restriction on the manufacture and use of nuclear substances is a matter, *inter alia*, for state environmental bodies. Further, the exploitation of pharmaceuticals is prohibited without acquiring the authorisation from the relevant health regulatory bodies (e.g. the Food and Drug Authority (the 'FDA') in the US and the European Medicines Agency (the 'EMEA').[284] Article 27.2 states that these restrictions on the commercial exploitation of an invention should not form the grounds for denying the invention its patentability. This proviso is mere common sense. Why should a pharmaceutical invention be denied a patent when, usually many years later, the relevant health body denies market access to the pharmaceutical. Patents, and for that matter the patent offices, are not authorised to evaluate the safety and efficacy of an invention before granting the patent. Safety and efficacy are two separate tests that neither assist nor are relevant in determining whether an invention is suited to have patent rights granted to it. The denial of patentability on such grounds would prevent the inventor from having exclusive exploitation rights with regards to other acceptable means of realising the invention. The denial of patentability would clearly not meet the necessity requirements when the exclusive rights were denied merely because one means of exploitation was found to be socially (and ultimately statutorily) unacceptable. Such a step would deny the inventor the ability to realise his invention in other ways which would or could be advantageous to society. Further, it would be in the interests of society to ensure a clear separation of powers with respect to patented inventions and their use in and effect on society. Regulatory bodies looking after the pub-

ly include the contribution made by the compliance measure to the enforcement of the law or regulation at issue, the importance of the common interests or values protected by that law or regulation, and the accompanying impact of the law or regulation on imports or exports.' See WTO *US – Gambling* (Appellate Body ruling) p. 240.

281 Addressed in more detail in Chapter 5(C)(III)(2).

282 Cf. *Rogge*, 100 GRUR 3-4 (1998) p. 306.

283 *Rogge* uses the analogy of a knife; a knife as such bears no danger, only when it is used can it have a negative (or positive) effect on society. Cf. *Rogge*, 100 GRUR 3-4 (1998) p. 306.

284 Cf. *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 174 and *Rogge*, 100 GRUR 3-4 (1998) p. 306 for further examples of restricted markets.

lic health, the environment, the security etc. are better equipped and trained in identifying and addressing threats to society. The patent office is, in this respect, less able to ensure the general wellbeing of society, especially where the effects of the invention cannot be determined at the time of patenting. Hence, it is in the interests of an effectively regulated society to keep a clear separation between patent requirement and commercial exploitation should always be kept. Article 27.2 merely raises this common-sense approach to a clear legal obligation.[285]

3. Conclusion

The contents of Article 27 provide a good theoretical example of the flexibilities that are inherent in the TRIPS Agreement. It is also a good example of how public interest, whether as *ordre public* or morality, could play a role in preventing adverse consequences in the patent system.[286] Article 27.2 reconfirms the position that the TRIPS Agreement does not prevent a Member State from taking steps to protect the well-being of its citizens and provides a good example of how the WTO jurisprudence has acknowledged this.

Notwithstanding the theoretical implications of Article 27.2, the practical implication is that it is unlikely to be frequently applied to limit the subject matter of a patent. The instances where exclusion of the patent is found acceptable generally tend to be listed in Article 27.3 or require the complete ban of the invention, both from commercial and non-commercial exploitation. As a result, Article 27.2 would be an inappropriate and/or ineffective tool to encourage a Member State's development, to counter competition abuses by inventors or to increase access to health products. Other tools for reigning in abusive patents and patent holders, such as general exceptions under Article 30 of the TRIPS Agreement, compulsory licenses and revocations, are easier to apply and are a more viable public interest tool. Further, a Member State is able to reduce the threat of abusive patents by ensuring that the interpretation and implementation of the concepts of novelty, inventiveness and usefulness are done so in a manner suited to address domestic public interest needs.

285 *de Carvalho* makes a fitting (and amusing) analogy: preventing inventions from being patented because of a market restriction is like parents giving their teenager son a sports car but remove the car's speedometer because they are concerned he might speed. Cf. *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 169.

286 Art 27.2 and 27.3 are exceptions limited to the patentability of an invention. They do not permit public interest interventions in any other provisions contained in the TRIPS Agreement. In light of Art 30 of the Vienna Convention, the Art 27 exceptions are nevertheless likely to play an important role in the interpretation of other pubic interest provisions in the TRIPS Agreement.

II. Rights conferred to the patent holder

It is a general misconception that Article 28 of the TRIPS Agreement grants the patent holder the right to use, offer for sale, sell or import the invention. Instead, the patent holder acquires a 'right to exclude' others from making, using, offering for sale, selling or importing the patented product or process without his consent. The patent holder is thus the bearer of a negative right.[287] As such, the patent holder has no right to prescribe an action but merely a right to proscribe an action. In other words, the patent holder has a freedom from interference. The right is not universal; instead the exercise of the right is physically limited to the territory in which it was granted.

The implementation of Article 28 and the rights conferred are relatively unproblematic. The scope of the right is unambiguous and flexibilities are absent in Article 28. As such, developing Member States implementing Article 28 have little interpretational discretion. Notwithstanding this, once the requirements have been fulfilled and the patent right is granted, the Member State's obligations are passive. It will only be required to act, when the patent holder asks the courts to ascertain whether an infringement has actually occurred or when the patent's validity is actually challenged.

Being the holder of a negative right, a patent holder may be subject to general laws that restrict the manner in which he exercises the patent right. For example, the sale, transport and use of a patented poisonous chemical can, and often is, regulated by domestic laws. This regulation is not a restriction of the patent holder's rights; the patent holder has no right to sell the item – only to exclude others from doing so. Accordingly, Member States would not infringe the TRIPS Agreement were they to restrict or even prohibit the patent holder's use of the patented products. It therefore follows that national pharmaceutical pricing systems and registration procedures are not a limitation on the rights conferred in Article 28 of the TRIPS Agreement. Other TRIPS-conform measures that could limit the realisation of the products of patent rights include anti-trust laws, product safety restriction, prior third party rights and patent maintenance fees.

Absent from the list of entitlements the patent holder acquires is the right to exclude the product being exported.[288] It would therefore seem that the TRIPS Agreement entitles third parties to lawfully acquire the product and to export it without the patent holder being lawfully entitled to object to the export. This conclusion is not certain as it must be asked if 'exportation' could also be deemed to be 'use' in terms of Article 28. This does not seem to be the case.[289] 'Use' infers the employment/enjoyment of the product in the manner for which it was intended to be used. In other words the patent's field of use is dictated by the characteristics it displays.

287 *Garner (ed)*, Black's Law Dictionary (8th edn Thomson West St. Paul 2004) p. 1348.

288 WTO Communication by Brazil and others to the TRIPS Council 'Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health' (24.06.2002) IP/C/W/355.

289 *Abbott*, Quaker Paper 7 (2001) p. 14 and fn. 27.

Exportation would not be a characteristic displayed by a patented product or process.[290] It is also unforeseeable that the TRIPS Agreement would have entitled Member States to grant rights to patent holders that have the result of extending rights beyond their borders of the respective territory. Further, the general interpretation rule *unius inclusio est alterius exclusio* states that the inclusion of one is the exclusion of another.[291] Thus, the inclusion of importation into the scope of the patent holder's rights and not its corollary implies that the negotiating parties to the TRIPS Agreement intended to exclude the 'right to export'. The view corresponds to the context of the TRIPS Agreement, in particular Article 6. Article 6 accepts that the principle of exhaustion does not fall within the scope of the WTO. This legal principle is common to many, if not all, Member States. Exhaustion or the 'doctrine of first sale' refers to the limitation on the rights of intellectual property holders, i.e. that they do not extend beyond the first sale. Whereas these principles are the subject of abundant jurisprudence, the concept as a whole is consistent with an interpretation of Article 28 excluding the right to export. *de Carvalho* convincingly states that all patent rights conferred, with the exception of the exclusive right to 'make', become exhausted after the first sale.[292] Thus, even if the export were found to be a conferred right, the first sale of the patented goods by the patent holder or with his consent would exhaust its conferred rights and, as a result, no further restriction would stand in the way of a person who bought the goods from exporting the goods.

In addition to the abovementioned limitations, Member States are also able to impose direct restrictions on the rights conferred in Article 28. The exceptions to the rights are expressly referred to in Article 30 of the TRIPS Agreement. An analysis of the exceptions is dealt with Chapter 5(C)(III)(2) Seite 90 below.

III. The withdrawal and limitation of rights conferred

Patents and their exercise can lead to consequences that society, or elements thereof, find unacceptable. Where the patent or the exploitation thereof faces opposition, two measures exist that enable a rectification: the revocation of the patent rights and the limitation of the rights conferred. The revocation, the original means of redress, provided for the cancellation of the patent. A less drastic means to bring about social acceptance was the limitation of the patent holder's rights. The latter remedy has evolved into two distinguishable rectification remedies: limited exceptions and compulsory licenses. The role these rectification measures play in ensuring a balanced intellectual property system is discussed below.

290 The ECJ stated the 'substance of a patent right lies essentially in according the inventor an exclusive right to put the product on the market for the first time'. See *Merck v. Primecrown*, C267/95 [1996] ECR I-6285 para 3.

291 Unless the text indicates the contrary. Cf. *Botha*, Statutory Interpretation (Juta Cape Town 1994) p. 63.

292 Cf. *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 215.

1. Revocation

Some authors have referred to the revocation of a patent as effectively being the death sentence for the patent.[293] This statement is a melodramatic way of saying: the revocation of a patent extinguishes the patent holder's exclusive rights to the invention. Article 32 of the TRIPS Agreement acknowledges its presence in the patent system; the only restriction being the judicial review of the revocation order.

The effect of a revocation, also referred to as 'forfeiture' or 'annulment', is that the exclusive rights granted under a patent terminate *ab initio*/*ex tunc*.[294] As such, its consequences for the patent system are absolute and far exceed other actions under the patent system.

The terminal effect of a revocation makes it a powerful tool or weapon in the effective enforcement of patent rights. The grounds for invoking a revocation order are however absent from the TRIPS Agreement. During the negotiation process various proposals were forwarded describing how or when the revocation of a patent may be an appropriate remedy. The Brazilian proposal sought to authorise the revocation of a patent as the first remedy for patent abuse. On the other side of the spectrum the US proposed limiting the revocation grounds to those founding the patentability, i.e. the absence of novelty, non-obviousness and usefulness.[295] The EC also sought to limit the revocation grounds by excluding revocation for non-working.[296] None of these proposals made it into the final agreement. A reason for this was the presence of provisions in the Paris Convention regulating the forfeiture of patents. In terms of Article 5A of the Paris Convention no patent shall be revoked on the grounds of it not being worked.[297] Further, the Paris Convention requires, where they will prevent a patent abuse, a Member State to grant a compulsory licenses prior of the revocation of the patent.[298]

The absence of a clear formulation of the revocation clause in the TRIPS Agreement meant that the Member States continued to assert their pre-TRIPS Agreement

293 *Brinkhof*, 27 IIC 2 (1996) p. 225.

294 Despite the *ab initio*/*ex tunc* effect of a revocation, a voluntary license holder is generally unable to reclaim the license fees paid prior to the revocation. Cf. *Rebel*, Gewerbliche Schutzrechte (4th edn Carl Heymanns Berlin 2003) p. 245. Compare Chinese Patent Law Art 44.

295 Watal J *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer The Hague 2001) 329. Switzerland took a similar view. It stated 'there shall be no revocation of the patent, except for invalidity. Cf. GATT Secretariat 'Synoptic Tables Setting Out Existing International Standards and Proposed Standards and Principles' (29.09.1989) MTN.GNG/NG11/W/32/Rev.1 p. 31.

296 GATT Communication from the EC (29.03.1990) MTN.GNG/NG11/W/68, Art 24(3).

297 Art 5A (4) of the Paris Convention states that the revocation on non-working or insufficient working grounds shall not be permitted before 4 years have expired from date of the patent application or 3 years from patent grant – which ever period expires last.

298 This requirement may however be circumvented where relevant compulsory license granting authority is satisfied that a compulsory license would not halt the abuse. In such a case it could skip the grant of license and revoke the patent instead. The application and scope of compulsory licenses is dealt with in Chapter 5(C)(III)(3) below.

understandings within the TRIPS arena. The US stated the 'effect … is clear, the only basis upon which a WTO Member can revoke a patent are these grounds that the Member would have been justified in relying upon to deny the original grant of the patent on the application'.[299] The US's view is based not on Article 32 itself but on the inherent ability of a Member States to correct deceitful acts, errors or oversights made at the grant of the patent and detected thereafter. The US viewed Article 32 as a mere confirmation of a patent holder's right to *challenge* the revocation. India took a different view.[300] It saw Article 32 as directly dealing with the *subject* of revocation. The position taken by India meant that the scope of the revocation grounds was untouched by the TRIPS Agreement.[301] The Indian position finds more support within the context of the TRIPS Agreement. Like Article 31, Article 32 does not make an express reference to the grounds for which either a compulsory license or the revocation of a patent can be granted.[302] Both Articles contain specific references to the judicial review of a decision.[303] The express mention of the judicial review is present despite the existence of Article 41.4, requiring the judicial review of a decision. The affinity of the structure and content of the provisions leads to the conclusion that the absence of the grounds in both Articles would have the same result, i.e. that they remain the prerogative of the individual Member State, as is widely accepted in the case of Article 31.[304] The Indian position is supported by the fact that both clauses proposing the limitation of the revocation grounds in the Anell Draft are absent in the final TRIPS Agreement.[305] The lack of a TRIPS provision regulating the grounds for a revocation is, like that in Article 31, an indication that the TRIPS Agreement has left the grounds to the Member States themselves to decide. Which position will ultimately prevail is uncertain. *Watal* notes that a state seeking to use revocation for grounds not stemming from Article 27 will most likely have their action contested before the DSB.[306]

299 WTO Communication from the US 'Remarks on Revocation of Patents and the TRIPS Agreement' (06.08.1996) IP/C/W/32.

300 WTO Minutes of the TRIPS Council Meeting (30.10.1996) IP/C/M/9 p. 9.

301 GATT Secretariat 'Synoptic Tables Setting Out Existing International Standards and Proposed Standards and Principles' (29.09.1989) MTN.GNG/NG11/W/32/Rev.1 p. 31.

302 Neither does Art 27.1 for that matter. Art 27.1 refers to the characteristics an invention must display for patentability.

303 TRIPS Agreement Art 31(i and j).

304 Cf. Public Health Declaration para 5(b).

305 The Anell Draft contained both references to the patent grant criteria, non-working (Art 6A.1) and public interest (Art 6B) as being potential grounds for the regulation of the revocation of a patent. These limitations were not able to find the necessary consensus for the final act. Cf. GATT Chairman's Report to the GNG Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods (23.07.1990) MTN.GNG/NG11/W/76 ('Anell Draft') p. 21. Compare *Watal*, Intellectual Property Rights in the WTO and Developing Countries (Kluwer The Hague 2001) p. 329-330.

306 *Watal*, Intellectual Property Rights in the WTO and Developing Countries (Kluwer The Hague 2001) p. 330.

The lack of consent as to the scope of Article 32 has not led India to alter section 66 of the Indian Patent Act. In terms of section 66:

> 'Where the Central Government is of opinion that a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the Official Gazette and thereupon the patent shall be deemed to be revoked.'

The silence in the TRIPS Agreement on when and where a patent can be revoked has not prevented Member States and affiliated multinational organisations from listing their grounds for the patent revocation. Germany and the UK, for example, have provisions limiting the grounds for a revocation.[307] A similar exhaustive list has been adopted by the EPC.[308] These lists limit the grounds for the revocation to instances where a patent has failed to meet the criteria for the grant of the patent. *Brinkhof* formulates the EPC position as 'the positive requirements for granting a patent must, looked at from a negative angle, be the reasons for the patent being revoked'.[309] Despite the EPC's restrictions, the final word on whether a patent will be revoked remains with the national signatories of the EPC.[310] It is therefore clear under the TRIPS Agreement and the EPC that the revocation of a patent is a matter of major national importance, one that is to be ultimately determined by the national courts.

The formulation of the judicial review obligation under Article 32 is somewhat unfortunate. A strict interpretation of Article 32, like that of Articles 31(i and j), would lead to an eternal right to challenge the revocation (or compulsory license and remuneration as the case might be), thus preventing a decision from becoming final. The reason for this is that Article 32 requires 'any' revocation decision to be allowed the possibility of a review. Literally read this would mean that even a decision of a country's highest court should be reviewable. As it is clear that the negotiating parties would not have intended such a result, Article 32 must be implemented as the parties had intended, i.e. to allow the review of a revocation decision in a judicial process.[311] A further point of uncertainty that arises from the formulation of Article 31 is the reference to judicial authority alone (unlike Articles 31(i and j). To what extent will Member States with an administrative system for the revocation of a pat-

307 German Patent Act secs 21, 22, UK Patent Act Sec 72.

308 EPC Art 138. Rule 55 of the Chinese Implementation Regulation of the Patent Law notes that novelty, non-obviousness and usefulness shall 'compromise' the grounds for revocation.

309 *Brinkhof*, 27 IIC 2 (1996) p. 225.

310 A national judge examining the patent grant is not required to come to the same conclusion as the EPO, the EPO's Enlarged Board of Appeal included. Cf. *Brinkhof and Schutjens*, 27 IIC 1 (1996) p. 6.

311 Compare the US's and EC's submissions in GATT Secretariat 'Synoptic Table Setting out Proposals on Enforcement and Corresponding Provisions of Existing International Treaties' (07.06.1989) MTN.GNG/NG11/W/33 p. 14. *Watal*, Intellectual Property Rights in the WTO and Developing Countries (Kluwer The Hague 2001) p. 330.

ent have to alter its patent system? *Gervais* states that in such cases the administrative body will be required to follow certain formal legal procedures.[312]

The practical consequences of Article 32 for WTO Member States will be, perhaps because of the severity of the action, less than spectacular. A patent found, albeit *ex post facto*, to be deficient in one or more of the grant criteria required in Article 27.1 has simply failed to satisfy the grant. As such, the revocation is terminating something that was not validly sired. The legitimacy of this action is not disputed in any jurisdiction.[313] Differences arise as to whether the revocation can serve as a remedy for actions beyond the scope of Articles 27.1 and 29. On the assumption that the revocation extends beyond the patent grant criteria there will be few, if any, circumstances that would justify the revocation of a patent as the first remedy. Other measures within the patent system are better placed to counter abusive acts or threats to the public interest as a first remedy. Where the other measures have proven unsuccessful (or are likely to be unsuccessful) then, as confirmed in the Paris Convention, the route to revocation becomes a justified path.

2. Limited exceptions

The rights conferred by Article 28 of the TRIPS Agreement are comprehensive and contain few, if any, flexible interpretations common to other TRIPS provisions. The absence of flexibilities does not however render the conferred rights sacrosanct. As important as the conferred rights are, so too are the exceptions thereto. The TRIPS Agreement expressly acknowledges a Member State's right to limit the exercise of a patent holder's rights and so safeguard against situations where the rights conferred outweigh their benefit to society. Articles 30 and 31 of the TRIPS Agreement set out when and to what extent a Member State may allow such exceptions. Article 30 provides the general exception and Article 31 the specific exception – patent specific compulsory licenses (dealt with in Chapter 5(C)(III)(3) Seite 101 below).

Article 30 sets out the conditions for the establishment of general limitations to these rights. They are neither limited in scope, duration nor limited to a specific patent. Article 30 neither denies nor excludes the granting of the patent. Instead Article 30 permits a Member State to 'provide for limited exceptions to the exclusive rights conferred by a patent'.[314] In comparison to Article 31, the exceptions permitted under Article 30 can be taken advantage of automatically, that is without the

312 *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 254. Contrast EPO *B&H Manufacturing* T 557/94 [1996] (12.12.1996), *EPO*, Rechtsprechung der Beschwerdekammern des Europäischen Patentamts (EPA Munich 2002) p. 452.

313 Revocation proceedings arise principally in patent infringement claims where the defendant uses the invalidity of the patent as a defence and/or counter claim. Cf. *Brinkhof*, 27 IIC 2 (1996) p. 225-235.

314 TRIPS Art 30. See *WHO/WTO*, WTO Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat (WTO Secretariat Geneva 2002) p. 45.

need for specific judicial or administrative authorisation or for consent from the patent holder.[315] Although such exceptions may arise automatically, they are not without limitations. Article 30 of the TRIPS Agreement establishes three cumulative conditions for the admissibility of a limited exception: It must be limited, must not unreasonably conflict with the normal exploitation of the patent and must not unreasonably prejudice the legitimate interest of the patent holder, taking into account the 'legitimate interests of third parties'.[316] Subject to these limitations, a Member State is free to determine when and where it wishes to adopt limited exceptions.[317]

An example of an exception to the rights conferred is the principle of exhaustion of rights,[318] which assumes the form of an exception as it limits the patent holder's exclusive rights of importation. In the case of exhaustion the patent holder's exclusive rights are extinguished upon the first direct or consensual sale of the product to the purchaser, enabling the purchaser an unrestricted right of resale.[319] As patents are artificial monopolies protected by law, where the relevant national law accepts the doctrine of exhaustion the patent holder is subject to a restriction on his rights. To this extent Article 30 enables such exceptions to be granted and Article 6 expressly renders, with the exception of the principles of most-favoured-nation treatment and national treatment, exhaustion beyond the scope of the WTO review system.[320] Accordingly, all WTO Member Countries are free to implement whatever level of exhaustion they desire.[321]

315 As the exception under Art 30 of the TRIPS Agreement operated automatically, there is also no need nor requirement for the person making use of the exception to attempt to acquire the patent holders consent, as in the case of compulsory licenses, dealt with below.

316 TRIPS Agreement Art 30. Legitimate interests include 'relevant public policies [and] other social norms' and exceeds the meaning of legal interests. See WTO *Canada – Pharmaceuticals* p. 164, *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 225.

317 Unlike the German Patent Act and the Community Patent Agreement, the TRIPS Agreement does not contain a list of examples of limited exceptions. See also *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 202.

318 See also TRIPS Agreement Art 6.

319 *Letterman*, Basics of International Intellectual Property Law (Transnational Publishers New York 2001) p. 20 *et seq*.

320 Footnote 6 to Art 28 of the TRIPS Agreement notes that all rights granted under the Agreement are subject to Art 6. For a discussion of the test privilege in this regard see *Von Meibom and Pitz*, Patent World June/July (1997) p. 27-34, *Straus*, 23 AIPPI Journal 2 (1998) p. 211-246.

321 Subject to Arts 3 and 4 of the TRIPS Agreement. This was subsequently confirmed in para. 5(d) of the Declaration on the TRIPS Agreement and Public Health, 14.11.2001, WT/MIN(01)/DEC/2 ('Public Health Declaration'). Although disputes concerning exhaustion under the TRIPS Agreement are excluded from DSU proceedings a Member State is not immune from challenges to the system under the provisions if other WTO agreements, where such exceptions are not found, save for the Doha Declaration mentioned above. See *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 94-95.

The doctrine of exhaustion is not however universally accepted. Whereas the USA has expressly denied its application,[322] the EC has embraced exhaustion as a means of increasing regional integration.[323] The principle of exhaustion is to a certain degree an extension of the natural law justification of the patent system. Once a property right has been legally transferred the respective rights transfer too.[324] This serves the public interest by entitling the purchaser of a legally authorised patent product (or product of a patent process) to exercise his newly acquired property rights, deriving from the product, as he wishes. Accordingly the patent holder's rights of exclusive sale do not extend beyond a lawful and authorised first sale of the product.[325] Exhaustion therefore creates a boundary for the exercise of the patent holder's exclusive rights.[326]

The EC's application of the principle of regional exhaustion was used as an express tool to further the public interest by increasing market integration and the free movement of goods.[327] The lawful purveyance of parallel imports further underlines free market principles, encouraging both general and intra-brand competition within the EU common market.[328] Opponents of the principle of exhaustion of rights dismiss the short-term financial benefits and state that parallel imported products in fact hamper the public interest in that they introduce a product which free-rides on the local investment made by the patent holder and poses a risk to the public in that they may be defective and are traded beyond the realm where the patent holder can assure

322 This denial need be seen in relation to the accepted US principle of 'first sale'. This principle is however limited to copyright law and is codified in Sec 109 of the USA Copyright Act. See *Letterman*, Basics of International Intellectual Property Law (Transnational Publishers New York 2001) p. 20.

323 The EC accepts what is commonly know as 'regional exhaustion', permitting any patented product being legally brought onto the EU market in one Member State to be resold in any other EU Member State without having to acquire the patent holders consent to do so. It has however denied the application of international exhaustion. The Japanese Supreme Court on the other hand accepts the application of international exhaustion. See *BBS Kraftfahrzeugtechnik AG v. KK Lassimex* Japan, case no. Heisei 7(wo) 1988, 1.7.1997.

324 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 97.

325 See also *Merck v. Primecrown* C267/95 [1996] ECR I-6285.

326 The principle of exhaustion of rights accepts that there will be no consensual first sale where the products are brought onto the market by way of compulsory licenses. Cf. *Carboni*, A Review of International Exhaustion Development in Europe in: Hansen (ed) International Intellectual Property Law & Policy (Juris Huntington 2001) vol 6 p. 107-3.

327 EC Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted COM/2003/0839 final. See also *Centrafarm v. Sterling Drugs* 15/74 [1974] ECR 1147, *Merck v. Stephar* C187/80 [1981] ECR 2063, *Merck v. Primecrown* C267/95 [1996] ECR I-6285. See *Abbott,* JIEL 4 (1998) at 610-11, *Slotboom*, 6 JWIP 3(2003) p. 421-440.

328 *Carboni*, A Review of International Exhaustion Development in Europe in: Hansen (ed) International Intellectual Property Law & Policy (Juris Huntington 2001) vol 6 p. 107-18-107-20. The FTAA is considering adopting a regional from of exhaustion. See *Slotboom*, 6 JWIP 3(2003) p. 423, *Vivas-Eugui*, Quaker TRIPS Issues Papers (2003) p. 18.

product quality and safety.[329] The ECJ's answer was that the IP system should not be used to address core issues regulated by neighbouring legal systems.[330] *Abbott* notes that the public consumer interest is broader than just mere low prices, it extends to concerns of quality, availability and support.[331]

The example of exhaustion provides a good example of how the limitation of rights can be used to balance the patent system. Its beneficial impact is justified on two grounds: Firstly exhaustion, to what degree if at all, is a decision left to each individual Member State. Secondly, it meets the three cumulative criteria set out in Article 30 and the *Canada – Pharmaceuticals* case, i.e. the exception is limited, it does not unreasonably hinder the normal exploitation of the patent (as exhaustion is only valid upon the lawful and consensual brining onto market of the product by the patent holder) and despite the fact that exhaustion limits the patent holders exclusive rights the limitation is balanced by the interests of third parties.[332] Further examples of national exceptions to the rights conferred under the patent system include:[333]

- private non-commercial use[334]
- research and experimentation[335]

329 For pharmaceutical industry perspective see *Bale*, 1 JIEL 4 (1998) p. 637-653. Compare *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 103, 106. *Light* and *Lexchin* found no evidence that non-US 'free-riders' increased the price of pharmaceuticals in the US. *Light and Lexchin*, BMJ 331 (2005) p. 958.

330 *Centrafarm v. Sterling Drugs* 15/74 [1974] ECR 1147 para 27-29. The Court mentions, at para 29, that 'the specific considerations underlying the protection of industrial and commercial property are distinct from the considerations underlying the protection of the public and any responsibilities which that may imply'. This approach cannot be faulted to the extent that the IP system should be limited to the exercise and restriction of the rights and duties therein contained. Where the IP system conflicts with other rights and duties, the one need be weighed against the other on a case-by-case basis in order to determine which will prevail.

331 *Abbott*, 1 JIEL 4 (1998) p. 612.

332 WTO *Canada – Pharmaceuticals* p. 151. Contrast *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 202, who rejects the notion that international exhaustion can be justified by Art 30 as this would constitute an unreasonable prejudice for the patent holder. *Straus'* contention that Art 30 would however accept regional exhaustion only seems tenable where one takes the view that the region in question is integrated to such an extent that its common market can be seen to be a single market.

333 A list similar to this was circulated during the TRIPS negotiations. The panel makes reference to this in the WTO *Canada – Pharmaceuticals* p. 165. The panel also notes that the exclusion of the list of exception examples was abandoned for a more 'general authorisation'.

334 German Patent Act sec 11(1), *Correa*, 16 EIPR. 8 (1994) p. 330.

335 WTO *Canada – Pharmaceuticals* p. 82. Compare sec 11(2) German Patent Act, permitting the so-called '*Versuchsprivileg'*/test privilege. According to the German Federal Supreme Court in *Clinical Tests* BGH 26 IIC 1 1997 p. 110, all experimental acts are permissible to the extent that they serve the acquisition of knowledge. See also *Klinische Versuche* BVerfG GRUR, 2001, 43, *Klinische Versuche II* BGH NJW 1997, 3092. This exception ties in with the requirement of disclosure in that disclosure causes the patent claim to become public knowledge and experimental use permits, *inter alia*, the verification of the patent claim

- early working (the 'Bolar' exception)[336]
- stockpiling[337]
- individual medicine preparations[338]
- prior use[339]
- parallel importation[340]

though its testing. For a discussion on this point see *Von Meibom and Pitz*, Patent World June/July (1997) p. 27-34, *Straus*, 23 AIPPI Journal 2 (1998) p. 212-246, *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 202. Limitations for experimental use have also been accepted as permitting experimentation for certain commercial purposes, i.e. the testing on the patented invention, not with the patented invention. *Straus*, Optionen bei der Umsetzung der Richtlinie EG 98/44 über den rechtlichen Schutz biotechnologischer Erfindungen (IGE Bern 2004) p. 25-26, *Correa*, Integrating Public Health Concerns into Patent Legislation (South Centre Geneva 2000) p. 66-68, *Leskien and Flitner*, Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System in: Engels (ed) Issues in Genetic Resources No. 6 (IPGRI Rome 1997) p. 24.

336 The WTO *Canada – Pharmaceuticals* case confirmed the TRIPS-compatibility of an exception permitting a generic pharmaceutical producer to manufacture the invention prior to the expiry of the patent in order to obtain or meet regulatory approval for the sale of the invention after the expiry of the patent. See also the US 'Bolar' exception in 35 USC 271(e)(1) (introduced by the Hatch-Waxman Act in response to the Federal Circuit limited the common law research exception in the matter *Roche Products Inc. v. Bolar Pharmaceutical Co.* 733 F. 2d 858 (Fed Cir 1984). The US courts also recognise a common law early working right, although case law has significantly limited its use. In 2005 in the case *Merck KGaA v. Integra Lifesciences I Ltd* 331 F. 3d 860 (Fed Cir 2005) the US Supreme Court held that § 271(e)(1) 'leaves adequate space for experimentation and failure on the road to regulatory approval: At least where a drug maker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is "reasonably related" to the "development and submission of information under … Federal law." § 271(e)(1).' Also *Burgess and Lucas*, 87 JPTOS 1 (2005) p. 11-26. The Japanese Supreme Court case of *Ono Pharmaceuticals Co v. Kyoto Pharmaceutical Industries* Supreme Court 1998(ju)153, 01.04.1999 accepted the Bolar provision. The EC has also adopted a Bolar exception in Art 10(6) of the EC Directive Community code relating to medicinal products for human use EC 2001/83 (as amended by EC Directive 2004/27/EC L 136/34 (21.03.2004). See *Gassner*, 37 GRURInt 12 (2004) p. 989-990. On 23.12.2005 Italy amended its Intellectual Property Rights Code in order to permit the early working of medical patents prior to their expiry so as to fulfil market authorisation requirements.

337 Canada removed this exception from their patent laws (Sec. 55.2(2) of the Patent Act as amended) after it was found to be contrary to the TRIPS Agreement in WTO *Canada – Pharmaceuticals*.

338 WTO *Canada – Pharmaceuticals* p. 81, sec 11(3) German Patent Act. See *Correa*, 16 EIPR. 8 (1994) p. 330, *Correa*, Integrating Public Health Concerns into Patent Legislation (South Centre Geneva 2000) p. 80.

339 German Patent Act § 12, UK Patent Act sec 64. See also *Correa*, 16 EIPR. 8 (1994) p. 330.

340 For example the South African Medicines and Related Substance Control Amendment Bill (B30-97), which makes specific provision for the parallel importation of pharmaceutical in-

- regulated pricing structures for medicine[341]
- compulsory licenses[342] and
- governmental use.[343]

The inclusion of these exceptions in the form of a non-exhaustive list in the TRIPS negotiations was discussed.[344] In July 1990 Chairman Anell proposed the following examples of limited exceptions:

> '2.2 Exceptions to Rights Conferred
>
> 2.2 [Provided that legitimate interests of the proprietor of the patent and of third parties are taken into account,] limited exceptions to the exclusive rights conferred by a patent may be made for certain acts, such as:
>
> 2.2.1 Rights based on prior use.
>
> 2.2.2 Acts done privately and for non-commercial purposes.
>
> 2.2.3 Acts done for experimental purposes.
>
> 2.2.4 Preparation in a pharmacy in individual cases of a medicine in accordance with a prescription, or acts carried out with a medicine so prepared.
>
> 2.2.5A Acts done in reliance upon them not being prohibited by a valid claim present in a patent as initially granted, but subsequently becoming prohibited by a valid claim of that patent changed in accordance with procedures for effecting changes to patents after grant.
>
> 2.2.6B Acts done by government for purposes merely of its own use.' [345]

ventions patented in South Africa. Cf. *Correa*, 16 EIPR. 8 (1994) p. 330, *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 444.

341 For example the Canadian Patented Medicine Price Review Board as set out in Sec 79 *et seq* of the Canadian Patents Act.

342 By referring to the grounds of application, time restrictions and requirement for compensation, *Correa* makes a distinction between exceptions and compulsory licenses. Whereas compulsory licenses and exceptions do indeed differ, it cannot be denied that the compulsory license system is in fact an exception, albeit more specific, to the rights conferred on the patent holder. See *Correa*, Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries (South Centre Geneva 1999) p. 3-6. The TRIPS Agreement distinguishes between Art 30 exceptions and compulsory licenses (Art 31) in footnote 7 by stating that compulsory licenses exceptions can be applied to uses no falling within the scope of Art 30.

343 German Patent Act § 13, UK Patent Act sec 55 (referred to as 'crown use'). Although the system of compulsory licenses and governmental use are limited exceptions, their actual usage is distinguishable from Art 30 in that they do not apply automatically but are instead attach to a specific patent and require either judicial or administrative authorisation to implement.

344 GATT Chairman's Report to the GNG Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods (23.07.1990) MTN.GNG/NG11/W/76 ('Anell Draft') p. 18.

The examples provided in the Anell Draft were ultimately rejected. Instead the TRIPS Agreement adopted a general exception whereby individual Member States have the sovereign election to determine the grounds for a limited exception.[346] The rejection of the Anell Draft examples does not imply that these exceptions are no longer TRIPS-compliant. On the contrary, the inclusion of a list may have deterred Member States from adopting new exceptions. The absence of a list implies that any exception will be allowed, provided the requirements are satisfied.[347]

The DSB extensively addressed the requirements of Article 30 in the *Canada – Pharmaceutical* case and has laid the groundwork for the future implementation of the provision. The panel was asked to ascertain if the Canadian provisions permitting research use and stockpiling of generic pharmaceuticals was, *inter alia*, consistent with Article 30. In determining the TRIPS-compliance, the panel noted that the onus in proving the TRIPS-consistency of an Article 30 exception vested in Member States exercising the exception.[348] Further, the panel noted that the three requirements set out in Article 30 are cumulative and thus need to be satisfied separately and independently.[349] Also, in determining the compliance with each of the three Article 30 requirements the panel reaffirmed that the interpretation must retain the 'goals and limitations' set out in objects and principles of the Agreement.

The first requirement set out in Article 30 states that any exception to the rights conferred must be limited. This self-evident restriction was however interpreted to denote a 'narrow exception – one which makes only a small diminution of the rights in question'.[350] The panel required that any exception must be 'limited' in both time and quantity.[351] To determine an acceptable time restriction, the panel asked if the exception was for a 'commercially significant period of time'.[352] Thus, it would seem that the lesser the commercial impact the longer the period can be. The limitation in quantity or volume was interpreted in absolute terms. Finally, the test for the

345 GATT Chairman's Report to the GNG Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods (23.07.1990) MTN.GNG/NG11/W/76 ('Anell Draft') p. 18.

346 WTO Canada – Pharmaceuticals p. 165.

347 An exception allowing Member States to cater for compulsory licenses granted by countries without the capacity to exercise the license themselves has been proposed. A third country with manufacture capacity would be required to provide for a limited exception by entitling enterprises to fulfil foreign compulsory licenses by producing the relevant product solely for export. See *CIPR*, (2002) p. 47, *Baker,* Process and Issues for Improving Access to Medicines: Willingness and Ability to use TRIPS Flexibilities in Non-Procuring Countries (Fretwells London 2004) p. 28-29.

348 WTO Canada – Pharmaceuticals p. 151.

349 WTO Canada – Pharmaceuticals p. 152-153.

350 WTO Canada – Pharmaceuticals p. 155.

351 A further requirement for a limited exception is also the scope of the exception. This was not however expressly referred to in the *Canada – Pharmaceutical* case. Compare *Correa*, 16 EIPR. 8 (1994) p. 330, *Musungu et al*, Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks (South Centre Geneva 2004) p. 16-18.

352 WTO Canada – Pharmaceuticals p. 156.

limitation should, according to the panel, ask to what 'extent the affected legal rights themselves had been affected'.[353] The panel stated that the patent holder's ability to continue the use, sale and making of the patented product would not limit the exception.[354]

In discussing the limitation of an exception the panel required that the impact the exception has on the individual patent should be considered.[355] This requirement ignores the character of Article 30 which permits limited exceptions that are general in scope (i.e. not limited to a specific patent) and which apply automatically (i.e. when the conditions therefore have been met).[356] It would thus be illogical to require countries wanting to permit limited exceptions to consider the effect of the limitation on each and every affected patent as this would then defeat the purpose of the provision and it would effectively usurp the role of Article 31. The panel does however note that the extent to which the rights themselves have been impaired should form the basis for determining if the exception is limited.[357] This latter means of determining whether or not an exception is limited is to be favoured. The reason for this is that the extent of the limitation refers to all affected patents and the extent of their curtailment. The panel further resisted quantifying when an exception would be limited. It considered a 6 month period not to be limited but on the other hand considered the size of production to be irrelevant.[358] Instead it found that legislative requirements limiting the use of the exception to a specific purpose would comply with the limitation requirement set out in Article 30.[359]

The second requirement asks if the normal exploitation of the patent is unreasonably impaired by the exception. 'Exploitation' was defined by the panel in the *Canada – Pharmaceutical* case as 'the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent'.[360] In other words, does the exception diminish the financial returns a patent holder can

353 WTO Canada – Pharmaceuticals p. 158.

354 Although not discussed by the panel, the rationale behind this finding is to be based upon the right the patent holder has to exclude third party use, not the right to sell, use and make. Thus, the ability the patent holder has to continue using the patent whilst a limited exception is being exercised is of no relevance. Of relevance to Art 28 is the fact that third parties have use of the patent. This alone is the restriction on the patent holder's rights.

355 WTO Canada – Pharmaceuticals p. 156.

356 Taking the example of the limited exception for scientific experiments: no authorisation process is required to in order to lawfully conduct such experiments on the patented products, hence the right to conduct scientific experiments is automatic. Further, the right to do such experiments is not limited to one patent, rather they apply generally to all patents. Compare *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 241-242.

357 WTO Canada – Pharmaceuticals p. 158.

358 WTO Canada – Pharmaceuticals p. 156-158.

359 WTO Canada – Pharmaceuticals p. 158.

360 WTO Canada – Pharmaceuticals p. 161.

normally expect to flow from the patent?[361] If yes, is the loss unreasonable? The normal exploitation of a patent was regarded by the panel, for the period of the patent, as a 'key element' of the intellectual property system. As much as the period of exclusivity is critical to the patent system, the panel rejected considering measures that substantially extend the period of exclusivity to be 'normal'.[362] As the panel took a wide view on what was considered to be normal exploitation, it is foreseeable that most exceptions will be required to prove that the conflict is not unreasonable.[363] 'Reasonableness' is a dynamic and supple term; it invokes concepts of natural justice, logical thought and common sense.[364] Despite the concept resisting a clear definition, it can safely be surmised that firstly, not all conflicts with the normal exploitation of the patent are prohibited and secondly, those conflicts that do arise cannot be unfounded or not justified as they would then be automatically deemed unreasonable.

The final requirement asks if the prejudice inflicted by the exception on the patent holder's interests is unreasonable. In determining the reasonableness Article 30 requires the legitimate interests of third parties to be taken into account. Despite the close connection, legitimate interests cannot be equated to legal interests in the context of the third requirement of Article 30. In other words, the rights conferred in Article 28 would not automatically apply here. Any other reading of Article 30 would lead to the redundancy of the third requirement leaving only the test to determine the unreasonableness as having any purpose. As it can be assumed that the treaty authors intended this requirement not to be redundant. This has been confirmed by the DSB. 'Legitimate interest' was defined as 'a normative claim calling for protection of interests that are "justifiable" in the sense that they are supported by relevant public policies or other social norms'.[365] In determining when an interest becomes legitimate, the panel in the *Canada – Pharmaceutical* case considered how widely accepted the interest was amongst the Member States.[366] Without expressly stating when a patent holder's interest will become legitimate, the panel noted that exclusivity extensions based on delays caused by market approval requirements were not a generally accepted or implemented interest. In the facts presented to the panel, the panel did not find that a patent holder had suffered any prejudice to a legitimate in-

361 Normal was held to mean usual or typical (the literal meaning) and a 'normative standard common to that territory'. WTO *Canada – Pharmaceuticals* p. 161.

362 The panel found that the patent extensions inadvertently provided by the pharmaceutical approval process, which can result in *de facto* extensions of up to 6 years, could not be regarded as a legitimate interest within the meaning of Art 30. Short extensions were however be considered to be normal. WTO *Canada – Pharmaceuticals* p. 161. Contrast *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 224.

363 The panel found it unnecessary to consider what was meant by 'reasonable' and left the meaning open for future panels to consider.

364 *Garner (ed)*, Black's Law Dictionary (8th edn Thomson West St. Paul 2004) p. 1293-1294.

365 WTO Canada – Pharmaceuticals p. 164.

366 WTO Canada – Pharmaceuticals p. 168-169.

terest.[367] The panel further stated that a general exception to a patent does not grant the patent holder a legitimate expectation to be able to claim compensation.[368]

A requirement that the limitation be based upon the abusive behaviour of the patent holder is missing from Article 30. It has also been held by national courts that abusive use of a patent is a prerequisite for an Article 30 limitation is not an unwritten requirement.[369] Accordingly, the granting of a limitation within the scope of Article 30 can be made without their being any 'fault' in the use of the patent by the patent holder.

Article 30 requires that the legitimate interests of third parties must be taken into account when determining the unreasonableness of the third requirement. The panel in the *Canada – Pharmaceutical* case held that the term 'third party' extended beyond mere competitors of the patent holder – as proposed by the EC. Precisely what the concept 'third parties' includes was not however answered by the panel. The Canadian argument that the patent grant reflects a bargain between the patent holder and society meant that the extension or diminution of the interests would affect both parties and any alteration to the rights would require the balancing of the both the patent holder's interests as well as the interests of society.[370] As such, Canada's interpretation infers that the third parties referred to the interests of society in general. The Canadian argument is convincing and better reflects the objectives set out in Article 7 of the TRIPS Agreement.[371]

The legitimate interests of such third parties, in particular when considering the society at large, will accordingly equate with the concept of public interest.[372] More specifically and according to the approach adopted by the panel, the public's legitimate interests would include health, nutrition, education, environment and other public interests as these are widely accepted concepts and interests both in the domestic legal practice of the WTO Member States as well as in the international arena. They are addressed in constitutions, bills of rights, general statutes and administrative acts. Domestic courts have long acknowledged these policies and even regard them as state duties.[373] International treaties and organisations, to which a vast majority of the WTO Member States are a party to, have also stressed the im-

367 As there was no legitimate interest infringement suffered by the patent holder the panel did not weigh the legitimate interests of third parties against those of the patent holder. See WTO *Canada – Pharmaceuticals* p. 169.

368 *Abbott*, Quaker Paper 9 (2002) p. 47-48.

369 *Compulsory License*, 23 IIC 6 1997 p. 246.

370 WTO Canada – Pharmaceuticals p. 164.

371 The panel considered the position put forward by Canada as ultimately being more a more appropriate interpretation. WTO *Canada – Pharmaceuticals* p. 169.

372 The concept of legitimate interests goes beyond that of legal interests. Cf. *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 225, *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 243-244.

373 For example the US case of *Powell v. Pennsylvania,* 127 US 678 (1888). See also *Nidel*, 59 Food Drug L.J. 2 (2004) p. 357.

portance of such measures.[374] Thus, *bona fide* health, nutrition, education and environmental interests would qualify as legitimate interests.

Of all the restrictions that a Member State may impose on the patent holder's rights, it must be recalled that a restriction on patent rights, being negative rights, will not prevent a patent holder from continuing to commercially exploit the patent. The limitation on the patent holder's rights does not prescribe any mandatory behaviour. The patent holder remains able to license, sell, market and export the patent or its products. The quantification of the patent holder's loss is thus the extent to which his exclusivity is weakened. In most exceptions it is the pecuniary loss that is most painful for the holder of the patent rights – and yet in many circumstance unlikely to be significant. The panel in the *Canada – Pharmaceutical* case however rejected measuring the exception in financial terms and stated that it is not the size of the financial impact that is decisive but rather the extent to which the rights have been curtailed, in other words the *de jure* abrogation.[375] As the patent holder is no longer able to prevent third party use, manufacture or sale the *de jure* impact on the rights is not insignificant.

In conclusion, Article 30 allows WTO Member States to create an exception in law, limiting the exclusive rights of a patent holder subject. The exception, provided it is limited, permits automatic third party use of non-specified patented inventions without the patent holder's authorisation and without compensation. The general application of the exception is limited by notions of proportionality, reasonableness and equity. Both the commercial ex-ploitation and the public impact of the patent are considered. These exceptions permitted by Article 30 of the TRIPS Agreement ensure that Member States are able to create general ex-ceptions, free from procedural formalities or financial constraints, to ensure that both society and the inventor are able to acquire the most benefits from the system without inflicting any significant harm on the other.

374 For example the WHO and the ICESCR. In respect to health policies see Art 24(1) of the UN Convention on the Rights of the Child (adopted on 20.11.1989), Arts 3 and 11 of the European Social Charter (signed in 1961), Art 5(e)(iv) of the Convention on the Elimination of All Forms of Racial Discrimination (in force on 4.1.1969), Art II(I)(f) and Art 12 of the Convention on the Elimination of All Forms of Discrimination against Women (in force on 3.10.1981), Arts 16(1 & 2) of the African (Banjul) Charter on Human and Peoples' Rights (adopted in 27.06.1981), Art III(g) of the Annexure to the Constitution of the International Labour Organisation (adopted in 1919, as amended) and Arts 10 & 11 of the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (Protocol of San Salvador) (signed on 17.11.1988)

375 The panel held that even if the financial disadvantage will only be experienced after the expiry of the patent, there would be a limitation of rights. WTO *Canada – Pharmaceuticals* p. 156. The panel also rejected the Canadian view that in determining 'sale' that only the end sale to the consumer is critical (at 157).

3. Compulsory licenses

a) General

The second means in which the rights conferred to a patent holder can be limited is by way of the compulsory license.[376] Its use is regulated by Article 31 of the TRIPS Agreement.

Despite the long history of compulsory license systems, their use is not extensive. The lack of jurisprudence, especially under the rules contained in Article 31, has deterred its use and left many Member States unsure of how to effectively use such a system.[377] The failing familiarity with the compulsory license has, for all purposes, halted the use of the compulsory license system. However renewed interest in Article 31 has emerged as a potential tool to address health crises. Despite this, potential international disagreement on its use has further hampered its strategic use. The interpretation and implementation of Article 31 has thus become a vital issue in the TRIPS arena and the WTO as a whole.[378]

aa) The compulsory license system

Member States are not prevented from establishing a compulsory license system. The Paris Convention is clear in this regard.[379] Save for procedural limitations, Member States are free to implement and exercise the compulsory license system. This entails both an active and passive exploitation of the system.[380] The active exercise of the compulsory license system by the Member States themselves permits

376 Art 31 of the TRIPS Agreement deals with the non-authorised use of the patent where the use does not meet the requirements of Art 30. Cf. *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 251.

377 It must however not be ignored that the threat of a compulsory license application alone may bring about better voluntary license conditions. The extent of the role of the threat to use a compulsory licenses difficult to quantify; it is however fair to say the more often compulsory licenses are granted the more the threat to use a compulsory license will be taken seriously by the patent holder.

378 The *CIPR* summed the role of compulsory licenses as such: 'We do not regard compulsory licensing a panacea, but rather as an essential insurance policy to prevent abuses of the IP system'. Cf. *CIPR*, (2002) p. 42.

379 Each Paris Convention signatory 'shall have the right to take legislative measures providing for the grant of compulsory licenses'. Art 5(A)(2) Paris Convention. Compulsory licenses were first expressly acknowledged in the Paris Convention in 1925 and first expressly recognised the right to grant compulsory licenses in 1958. For a history of the evolution of Art 5A of the Paris Convention see *Bodenhausen*, Pariser Verbandsübereinkunft zum Schutz des gewerblichen Eigentums (Carl Heymanns Verlag Cologne 1971) p. 56-61, *Reichman and Hasenzahl*, Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA (ICTSD/UNCTAD Geneva 2003) Annex.

380 TRIPS Agreement Chapeau of Art 31.

government use. Passive exploitation of the com-pulsory license system by a Member State entails a compulsory license system whereby private individuals and organisations are able to seek governmental approval for use of the patent.

A compulsory license may only be granted by the state. As no further restrictions con-cerning the identity or role of the authorising body granting of a compulsory license exist, Member States are able to delegate the duty to whichever organ it feels most suited. Options open to Member States include a court-sanctioned authorisation process, a process governed by the patent granting body, a specially established organ, a governmental minister or its ministry. A combination of these systems is also possible.[381] The material requirements that need to be fulfilled by the license applicant are not specified in the TRIPS Agreement and, for that matter, the Paris Convention too.[382] Accordingly, Member States may establish a minimal standard of proof for the granting of a license.

The license issued by a granting authority permits third parties to use the patent, or any elements thereof, without unlawfully infringing the patent holder's rights. Where such use is within the bound of the license, it will not be deemed an unlawful infringement of the patent holder's rights. The TRIPS Agreement does not restrict the compulsory license to only certain types of infringements. Thus, where appropriate, a license may entitle the use of all the patent holder's rights or it may limit them to certain rights. The overlapping nature of the rights conferred may however potentially nullify the proper and/or intended use of a compulsory license. A compulsory license limited to the 'use' of a patent carries with it the potential to be interpreted in a way that would deny the selling or offering for sale of the licensed products.[383] Accordingly, and as compulsory licenses are not required to state which conferred rights will be limited, Member States may couple the license not to the rights it limits but rather to a particular purpose or function.[384]

bb) Grounds for compulsory licenses

The TRIPS Agreement is silent on the grounds for compulsory licenses. It regulates the scope and duration of a compulsory license but it does not specify when a compulsory license may be granted. Although the Paris Convention provides examples

381 The TRIPS Agreement (Art 31(f)) merely requires that the grant can be challenged, either by way of judicial review or an independent body superior to the granting body.

382 Art 5A(2 & 4) of the Paris Convention also includes provisions qualifying the use of compulsory licenses. These restrictions however are procedural in nature and limited to certain situations, i.e. non-working or insufficient working. Cf. *Bodenhausen*, Pariser Verbandsübereinkunft zum Schutz des gewerblichen Eigentums (Carl Heymanns Verlag Cologne 1971) p. 58-61

383 The interpretational rule *unius inclusio est alterius exclusio* may be read to mean that the inclusion of the use excludes the making, offering for sale, selling or importing of the product. Further, as Art 31 is a legal exception, the extent to which it impinges on the patent holder's rights is to be interpreted restrictively.

384 TRIPS Agreement Art 31(c).

of compulsory license grounds,[385] it too does not limit the grounds for compulsory licenses. The result hereof is that the grounds for a compulsory license are beyond the jurisdiction of the DSB and the WTO as a whole.[386] Accordingly, the grounds for a compulsory license are a Member State's prerogative. Examples of grounds for domestic compulsory licenses are:

- a patent holder's refusal to grant a license of use on reasonable terms [387]
- non-working of a patent [388]
- public non-commercial use [389]

385 *Bodenhausen*, Pariser Verbandsübereinkunft zum Schutz des gewerblichen Eigentums (Carl Heymanns Verlag Cologne 1971) p. 59.

386 In the TRIPS negotiations proposals were put forward in which 'necessity' and sector-specific limitations would restrict the grounds upon which compulsory licenses could be granted. Art 34(k) of the Brussels Draft stated: 'Laws, regulations and requirements relating to such use may [not] discriminate between fields of technology or activity [in areas of public health, nutrition or environmental protection or where necessary for the purpose of ensuring the availability of a product to the public at the lowest possible price consistent with giving due reward for the research leading to the invention]'. Square brackets as in the original. GATT Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations Draft Final Act Embodying (03.12.1990) MTN.TNC/W/35/Rev.1 ('Brussels Draft'). This formulation was however eliminated in the final TRIPS Agreement. For a historical analysis of compulsory licenses see *Reik*, 36 AER 5(1946) p. 813-832.

387 For national and regional examples see *Correa*, Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries (South Centre Geneva 1999) p. 10-11. Also see *Compulsory License* BPatG 22 IIC 3 1993 p. 404, *Clinical Tests* BGH 26 IIC 1 1997 p. 105 for an example with regards to the 'refusal to deal' for licenses for dependent patents.

388 Expressly foreseen in Art 2.1 of the TRIPS Agreement with reference to Art 5 A(2, 4) Paris Convention, subject to certain minimum periods. Cf. *Correa*, Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries (South Centre Geneva 1999) p. 8, 11-13. This view is not universally accepted. Opponents note that the TRIPS Agreement prohibits a discriminatory patent system, including discrimination on the basis of whether the products are locally produced or imported. *Straus* also takes the view that it is not the non-working *per sé* that should be addressed by compulsory licenses but rather the abusive consequences of the non-working; these consequences would then, in his opinion, satisfy the public interest requirement he contends is applicable in this respect. Cf. *Straus*, Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 204-205. Whereas almost all compulsory licenses would be used to serve the public interest in one way or the other (i.e. in preventing abusive patent holder practices or providing additional access to certain products) there is no express mention in either the TRIPS Agreement or the Paris Convention that makes public interest a requirement for the granting of a compulsory license. Public interest, in its widest sense, will only be applicable as a ground for waiving the prior negotiations requirement in Art 31(b) of the TRIPS Agreement. This waiver has a procedural effect and does not limit the grounds for the granting of a compulsory license.

389 Expressly foreseen in Art 31(b) of the TRIPS Agreement. Also referred to as 'government use' and 'crown use'. Compare *Correa*, Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries (South Centre Geneva 1999) p. 8, 11-18.

- for the importation of off-patent products [390]
- in cases of national emergencies where the patent's product or process will assist in alleviating or minimising the emergency [391]
- to guarantee the existence of basic commodities [392]
- for industrial policy objectives, including the socio-economic and technical development of critical sectors [393]
- to enable the exploitation of dependent patents and for the creation of industry standards[394]
- for circumstances of national security [395]
- to remedy anti-competitive practices [396] and
- public health issues.[397]

390 As in the case of South Africa.

391 Expressly foreseen in Art 31(b) of the TRIPS Agreement. *Abbott* cites the anthrax 'episode' as an example. Although no compulsory license was granted in procurement of Bayer's Cipro, the threat was used to obtain a more favourable price. Cf. *Abbott*, CIPR Study Paper 2a (2002) p. 14, -- 'US Negotiations with Cipro Renew AIDS Drug Debate' *Wall Street Journal Europe* (Brussels Belgium 26.10.2001).

392 The general application of this provision does not comply with the non-discriminatory requirements of Art 27.1 of the TRIPS Agreement. Individual national circumstances may however justify their granting in a case-by-case situation. Cf. *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen (Nomos Baden Baden 2002) p. 276.

393 For example the Tunisian *Système de la Corrélation* Circulaire N°13 du Ministère de la Santé Publique (18.02.2004), annulant et remplaçant les Circulaires CAB No.36 du 22.04.1991, No. 67 (29.06.1991) et 261 (22.04.1996) du Ministère de la Santé Publique. The US also grants non-voluntary licenses in connection with major development projects such as dams and electricity generation. Sec 59(1)(d) of the UK Patent Act provides for the 'promoting the productivity of industry commerce and agriculture'. Cf. *Reichman and Hasenzahl*, Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA (ICTSD/UNCTAD Geneva 2003) p. 15.

394 TRIPS Agreement Art 31(l). Compare *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen (Nomos Baden Baden 2002) p. 276, *Verbruggen and Lõrinz*, 33 IIC 2 (2002) p. 152, *Straus*, Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 207-208.

395 *Gold and Lam*, 6 JWIP 1 (2003) p. 17.

396 Art 31(b and k) TRIPS Agreement, including Art 31(c) TRIPS Agreement in reference to semi-conductor technology. See *Correa*, Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries (South Centre Geneva 1999) p. 8, 11-17.

397 TRIPS Agreement Art 31(b). See WTO Communication from the EC 'The Relationship between the Provisions of the TRIPS Agreement and Access to Medicines' (12.06.2001) IP/C/W/280 p. 2. Also for example Art 78.4 of the Tunisian Law on Patents No. 2000-84 (24.08.2000) which states that 'if required in the interests of public health, patents issued for medicines, for products necessary for obtaining those medicines or for processes for making such products may, in the event of the said medicines being made available to the public only in insufficient quantity or quality or at abnormally high prices, be made subject to *ex officio* licensing at the request of the Minister of Public Health, by order of the Minister of Industry'.

cc) Discrimination

Although the grounds for compulsory licenses are a national prerogative, the implementation of a compulsory license system is subject to certain restrictions. Firstly, and most importantly, compulsory licenses must not discriminate.[398] As mentioned above in Chapter 4(C)(I)(2)(c) Seite 81, there is a difference between discrimination and differentiation; the latter being lawful, justifiable differential treatment.[399] Within the context of compulsory licenses Member States will be required consider the following:

- general phrasing of the regulation
- sanctions and restrictions to apply to all affected patents and
- any explicit/*de jure* differential treatment should be justified on *bona fide* public interest grounds.

The findings in the *Canada – Pharmaceutical* case are influential to the application of compulsory licenses. Despite this the influence is not without limitation. Compulsory licenses are only granted on a case-by-case basis. It is therefore not easy to determine if a particular license granted is discriminatory. Only when there is an established practice differentiating one field of technology, place of invention or production from others in an unjustifiable manner will a Member State be able to allege that there has been *de facto* discrimination.[400] Practically, the challenge of a Member State's compulsory license system will derive from the enabling statute or regulation establishing the compulsory license system.

The non-discrimination rule in Article 27.1 of the TRIPS Agreement recognises only three grounds where the unlawful treatment will be TRIPS-incompliant: field of technology, place of production of the patent ('working') and place of invention. Other forms of discrimination are not deemed TRIPS-incompliant.

The field of technology is used to represent 'an area, category or division wherein a particular activity or pursuit is carried out'.[401] The *Canada – Pharmaceutical* case recognised the pharmaceutical industry as a sector.[402] Notwithstanding this, no offi-

398 The Brussels Draft included a specific non-discrimination clause in the compulsory license provision (Art 34). The final Agreement removed the non-discrimination provision from the compulsory license clause and inserted it into the Patentable Subject Matter clause (Art 27) thus resulting in a universal application of the non-discrimination clause to the exercise of patent rights. See WTO *Canada – Pharmaceuticals* p. 170, *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 370-371.

399 Contrast *Kiehl*, 10 J.Intell.Prop.L (2002) p. 166. *Kiehl* takes the view that 'legislation that attempts to utilise the TRIPS Article 31(b) … exception … could [have] an Article 27.1 discrimination problem'. This viewpoint ignores the distinction between discrimination and differentiation. Hence, only when the legislation or state action regarding a pharmaceutical compulsory license is unjustified will it be discriminatory.

400 See Chapter 5(C)(I)(2)(c) on page 64 above.

401 Webster's Third New International Dictionary.

402 WTO Canada – Pharmaceuticals p. 174.

cial list exists defining the fields of technology.[403] In determining a field of technology authors have analysed the term 'technology'.[404] Although general fields of technology can be identified, the evolution of trade and technology renders fixed classifications futile and of no lasting jurisprudential value.[405] Hence, field of technology is to be determined in each individual case.

The TRIPS Agreement also prohibits distinctions made in a compulsory license system as to the place of production of a patent (i.e. locally or imported) and the place of invention. A Member State is therefore prohibited from granting compulsory licenses on the grounds that the patent is not being worked locally. Thus, Member States cannot distinguish between patents produced locally and those imported.[406] Despite the non-working limitation in Article 27.1 of the TRIPS Agreement, the Paris Convention recognises the failure to work a patent or insufficient working thereof – irrespective of its origin – is an abuse and a valid ground for a compulsory license.[407] The interaction of the TRIPS Agreement and the Paris Convention results in compulsory licenses for non-working to be TRIPS-compliant provided that the time period has elapsed and that the license is not discriminatory.

dd) Causality approach

The freedom to establish the grounds for a compulsory license enables Member States to concentrate not on the patent, but on the consequences of use of the exclu-

403 An example of the lack of consensus is found when comparing the Panel's decision in the *Canada – Pharmaceuticals* case and the IntCl classifications. The Panel referred to pharmaceuticals as a field of technology. The IntCl does not recognise pharmaceuticals as a first level classification. See also Art 4 of the Strasbourg Agreement Concerning the International Patent Classification (adopted on 24.03.1971, last amended on 28.08.1979) 1160 UNTS 483. The Panel's decision to assume a more general meaning to 'field of technology' implies that the formal meaning, as applied in the patent classifications is not the meaning to be assumed. German jurisprudence has also acknowledged the developments in 'technology'. See *Jänisch*, 35 IIC 4 (2004) p. 382.

404 *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 187.

405 Generally acknowledged fields of technology include human necessities, performing operations/transport, chemistry and metallurgy, textiles and paper, fixed constructions, mechanical engineering, physics and electricity. These correlate with the eight International Patent Classification sections/first level classifications. See *WIPO*, International Patent Classification 2006 Vol. 5 (8th edn WIPO Geneva 2005) p. 10.

406 This applies *mutatis mutandis* to compulsory licenses granted on the place of where the invention was made.

407 Paris Convention Art 5(A)(2). Compulsory licenses for non-working are subject to certain time restrictions contained in Art 5(A)(4) of the Paris Convention. Art 2.2 of the TRIPS Agreement states that the TRIPS Agreement shall not derogate from the Paris Convention. Compare *Greif*, Law and State 23 (1981) p. 53.

sive rights.[408] By focusing the granting of compulsory licenses on the ill effects the patents may cause, Member States avoid being challenged on the anti-discrimination grounds. The causality approach reflects the origins of internationally recognised compulsory licenses. As early as 1925 there was consensus that patent *abuse* needed to be countered.[409] Although slightly amended, the current text of the Paris Convention still recognises that each country:

> 'shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.'[410]

As neither the Paris Convention nor the TRIPS Agreement provides for a definition as to what constitutes abuse, signatory states have been left to determine their own scope of an abuse.[411] Thus, this would permit a Member State to declare all acts performed by a patent holder that run contrary to the public interest to be deemed abusive.

ee) The relationship between Article 31 of the TRIPS Agreement and Article 5A(4) of the Paris Convention

The application of both Article 31 of the TRIPS Agreement and Article 5A of the Paris Convention to compulsory licenses has caused a degree of uncertainty as to which provisions will apply. Succinctly put, Article 31 is a *lex generalis* applying to compulsory licenses as an entirety. Article 5A of the Paris Convention is, on the other hand, a *lex specialis* referring only to patent abuses, for example the failure to work patents.[412] Thus, the TRIPS provisions will apply to all compulsory licenses

408 Accordingly, where the exercise of the exclusive rights infringes the competition policies, stymies development, unreasonably restricts domestic social goals (such as health, nutrition and education) and is contrary to environmental concerns, the affected Member State may permit third party use of the patent. The US is a prime example of a country using compulsory licenses (or synonymous systems) to remedy a patent abuse (or 'misuse'). The US's use is however relatively limited. See *Beier*, 30 IIC 3 (1999) p. 264-265, *Riziotis*, 26 GRURInt 5 (2004) p. 367-368, 370.

409 Second paragraph of Art 5 of the 1925 Act of the Paris Convention (adopted on 06.12.1925 and enacted on 01.06.1928). Also referred to as 'The Hague amendment'. It stated: 'Nevertheless, each contracting country shall have the right to take the necessary legislative measures to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent'. Compare *Bodenhausen*, Pariser Verbandsübereinkunft zum Schutz des gewerblichen Eigentums (Carl Heymanns Verlag Cologne 1971) p. 56-57.

410 Paris Convention Art 5A(2).

411 *Bodenhausen*, Pariser Verbandsübereinkunft zum Schutz des gewerblichen Eigentums (Carl Heymanns Verlag Cologne 1971) p. 59, *WIPO*, Introduction to Intellectual Property Theory and Practice (Kluwer London 1997) p. 146.

412 In the case of compulsory license applications for non-working or insufficient working alone, the Paris Convention (Art 5A(4)) enables patent holders the opportunity to defend the grant by providing evidence that the non-working was a result of legitimate reasons. This opportunity does not extend to other types of compulsory licenses. See also *Straus*, Implications of

and, consequently, the time restrictions contained in Article 5A(4) of the Paris Convention will only apply to compulsory licenses for the non-working or insufficient working of a patent.[413]

Although 'abuse' constitutes a pliable and expansive ground for compulsory licenses, Member States are not limited to this ground.[414] In the *Polyferon* case, the German Federal Supreme Court noted that other circumstances could also justify the granting of compulsory licenses. In this regard 'technical, economical, socio-political and medical' grounds were deemed to be viable grounds.[415]

ff) Commercial use of compulsory licenses

A further aspect absent from Article 31 is a rule preventing the exercise of the compulsory license for commercial purposes. Hence, Member States are not prevented from implementing a compulsory license system that seeks to develop and enrich the licensees.

What Article 31 does however regulate is the process and procedures that must be complied with when Member States grant compulsory licenses. Twelve sub-articles detail what protection and treatment patent holders can expect and what limitations compulsory license holders are required to abide by. They are dealt with individually below.

b) Article 31(a)

> 'authorisation of such use shall be considered on its individual merits'

The clause 'on its individual merits' suggests that each compulsory license must be applied for separately. This is not the case. A Member State would be TRIPS-

the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 205. Cf. *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen (Nomos Baden Baden 2002) p. 280.

413 Clause 34(n) of the Brussels Draft incorporated the material elements of Art 5A of the Paris Convention. This clause was excluded in the final TRIPS Agreement due to the inability of the negotiating parties to agree on a final wording. See *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 467, *WIPO*, Introduction to Intellectual Property Theory and Practice (Kluwer London 1997) p. 145. Contrast *Straus*, Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 205.

414 The German Federal Supreme Court concluded in the *Compulsory License* case (23 IIC 6 1997 p. 242) that neither agreements limit compulsory licenses to abusive practices. Cf. *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen (Nomos Baden Baden 2002) p. 280.

415 *Compulsory License*, 23 IIC 6 1997 p. 246.

compliant were it to consider the authorisation of a compulsory license for a group of patents. In order to remain TRIPS-compliant Member States would have to permit the rights holders and license applicants to submit individual information supporting their positions. As is the process in anti-dumping cases,[416] the granting authority would then have to review each individual patent. An example of a multi-patent compulsory license procedure could very well arise in the case of a large-scale national emergency whereby a number of proprietary medications are required for the management of an emergency.[417] Despite the ability to have multi-patent compulsory license applications, the TRIPS Agreement prohibits blanket licenses, so-called automatic licenses of right.[418]

The formulation of Article 31(a) further does not automatically grant patent holders the right to oppose a compulsory license authorisation nor does it grant the right to present evidence. The obligation set out in Article 31(a) merely requires that the granting authority evaluate the relevant specific factors and take into account all the substantive consideration when authorising a compulsory license for that specific patent. The lack of an opportunity to oppose a license grant is evident in the US legal system. The use of the US Government's eminent domain power entitles it to use a patented invention without notification to the patent holder and prohibits the patent holder form instituting an injunction against the government use.[419] The only avenue open to a patent holder to present evidence is by way of a claim for compensation in the Court of Federal Claims.[420] The US notes that compensation is the 'entire' and

416 GATT Agreement Art IV.1 Anti-Dumping Agreement Art 5.2.

417 A hypothetical example could be patented medication for the treatment of avian flu affecting both man and animal. It is highly likely that no one medication would be permitted for man and animal but instead different treatments for man and the different types of inflicted animals.

418 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 468. Cf. UK Patent Act of 1997 Sec 48. A partial exception to this is the so-called 'license of right' in the UK. Once the Comptroller has authorised a license of right all potential licensees may apply for a license on those terms. Although the grounds and the terms of the compulsory license are considered in the initial application, the license of right will nonetheless meet the Art 31(a) requirements as each subsequent licensee must make a separate ('individual') application. *Watal* also notes a similar situation in India, cf. *Watal*, Intellectual Property Rights in the WTO and Developing Countries (Kluwer The Hague 2001) p. 322.

419 In terms of the notion of 'eminent domain taking', as set out in 28 U.S.C. §1498, the US Government is acknowledges as being a 'compulsory, nonexclusive licensee'. See *Motorola Inc v. United States*, 729 F.2d 765 (Fed. Cir. 1984).

420 28 U.S.C. §1498 states '[w]henever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.' The government use without the patent holder's consent does not qualify as the tort of patent infringement. The government is thus excludes tort liability for its actions. This immunity is passed on to the contractors working the patent on the government's behalf and can indemnify the contractor from damages claims from the patent holder. Compare German Patent Act sec 13.

complete remedy for the patent holder.[421] Contrary to some suggestions that the US Governments use of its eminent domain may be viewed as a potential TRIPS infringement, this is not necessarily the case.[422] As the TRIPS Agreement does not require the Member States to grant the patent holder the opportunity to oppose the grant, § 1498 of title 28 of the USC does not infringe Article 31(a). An infringement would however occur if the granting authority did not take into account the substantive considerations before it. If the US Government were to permit the use of *a* patent without the patent holder's consent, the requirements set out in Article 31(a) would, *prima facie*, be met.

The contents of Article 31(a) do not prohibit a Member State from creating legal presumptions for or against the granting of a compulsory license. Active use of presumptions by Member States could require the patent holder to establish that his use of the patent rights is justifiable.[423] This could include requiring the patent holder to justify that there is a sufficient supply of the patented products on the market at an affordable price.[424]

c) Article 31(b), first sentence

> '(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.'

The requirement that negotiations take place between the compulsory license applicant and the patent holder prior to the granting of the license is a prerequisite for granting a compulsory license. In terms of the provisions within the first sentence of Article 31(b), the proposed user must:

- have made an effort to obtain an voluntary license (and failed)
- the negotiations on the conditions of the license must have been on reasonable commercial terms and
- the negotiations/efforts must have been conducted within a reasonable time period.

421 *Goldschneider*, 36 IDEA 1 (1996) p. 189.

422 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 468.

423 A recent US Supreme Court decision (*eBay Inc. v. MercExchange* 547 U.S. 388 (2006)) addressed the role of equity within the scope of permanent injunctions flowing from patent rights. Compare *Ntouvas*, 28 GRURInt 11 (2006) p. 889-890.

424 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 468. This would not infringe the non-discrimination rule in Art 27.1 as the presumption does not distinguish between locally or imported products. Instead the presumption seeks to ensure that there is sufficient market access; a notion consistent with the principles of the TRIPS Agreement set out in Art 8.

The first sentence in Article 31(b) clearly states that the licensed *use* of the patented invention must be delayed until the voluntary license negotiations can be declared unsuccessful. Thus, it would be TRIPS-compliant to *grant* the compulsory license prior to the expiry of the negotiations but suspend its *use* until either a time limit is exceeded or both parties declare the negotiations to be unsuccessful. As it is only the *use* that may not be exercised prior to the end of negotiations the TRIPS Agreement further permits Member States to allow other measures to be taken prior thereto. Thus, the fulfilment of administrative and logistical requirements specific to the manufacture, use and sale of the invention could be permitted.[425]

The ordinary interpretation of 'effort' implies that the potential licensee must attempt and/or endeavour to acquire a voluntary license. This implies a potential user is obliged to (i) seek out the patent holder, (ii) enter into negotiations in good faith, (iii) the conditions upon which the voluntary license is sought must be reasonable taking into account the commercial circumstances of the patent holder, the potential user and any relevant surrounding factors (determined by the granting authority) and (iv) the negotiations need provide both parties with a reasonable time frame to consider and evaluate the granting of the license. The requirements set out in the first sentence of Article 31(b) permit Member States to take diverging positions on what is deemed reasonable terms or a reasonable time frame. Not only does this flexibility permit a wide degree of TRIPS-compliant interpretations with respect to the reasonableness in general, it also permits Member States to impose varying standards of what is presumed to be reasonable. The reasonableness or degrees of flexibility may be made dependent on the particular type of patent[426], the circumstances necessitating the specific compulsory license application, the particular compensation demands of the patent holder, the intended duration of the license, the territorial scope of the license, the location of the patent holder, the time constraints affecting the negotiating parties and the practices of neighbouring countries.[427] The Member States would also be permitted to apply different standards depending upon the applicant

425 It is also foreseeable that a Member States could permit such use under the general exception provision in Art 30. As held in the *Canada – Pharmaceutical* case, limited use to satisfy administrative requirements and not commercial activities would not be deemed to unreasonably conflict with the patent holder's rights. The panel stated that the 'rights of the patent owner are generally viewed as a right to prevent competitive commercial activity by others, and manufacturing for commercial sale is a quintessential competitive commercial activity, whose character is not altered by a mere delay in the commercial reward.' See WTO *Canada – Pharmaceuticals* p. 161.

426 In terms of Art 27, a Member State would not be permitted to enact legislation providing for differing standards of reasonableness where they are not justified by the object and purpose of the TRIPS Agreement. Thus the application of Art 31, in connection with Art 8, would permit lower standards of commitment to obtain a voluntary license in cases where there is a need to protect the public interest.

427 Although the practice of neighbouring countries may be used, the global practices may also be used as a reference where the patented invention is also used on a global scale. See *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 165.

and its intended use of the patented invention. Accordingly, a Member State would be able to ease the burden of the Article 31(b) requirement for prior negotiations by creating predetermined norms for what it would deem to be reasonable. Such measures however cannot negate the object and purpose of the requirement.

Article 31(b) does not set out a strict substantive requirement. 'Reasonableness' is a pliable term that, if interpreted strictly, could provide significant legal barriers when granting compulsory licenses. The prior negotiation requirement is instead a procedural requirement that seeks to give the patent holder the opportunity to prevent a compulsory license by allowing him the occasion to negotiate a voluntary license. In the German *Compulsory License* case, the German Federal Supreme Court held that the reasonable efforts need not be strictly enforced. It also held that even when the offered compensation differs from the awarded compensation under the compulsory license this will not make the license applicant's offer unreasonable.[428]

d) Article 31(b), second sentence

> 'This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use' [429]

The TRIPS negotiators acknowledged that the prior negotiations requirement could delay Member States from implementing compulsory license measures when seeking to address circumstances of dire national importance. To ensure Member States are able to react swiftly and in a TRIPS-compliant manner they introduced the second sentence to Article 31(b). In terms of this a Member States could permit the use of a patented invention without requiring prior negotiations haven taken place. The waiver of the prior negotiations requirement is permitted in cases of 'national emergency or other circumstances of extreme urgency or in cases of public non-commercial use'.[430] In other words, where there is a 'state of national crisis or a situation requiring immediate or extraordinary national action,'[431] the TRIPS Agreement acknowledges that the interests of the public pre-empt private patent rights to prior consultation. The ability to use the expedited or 'fast-track' compulsory license authorisation process for extreme urgencies also extends to compulsory licenses for public non-commercial use. The two systems are dealt with hereunder.

428 *Compulsory License*, BGH 28 IIC 1997 p. 242, 243.

429 Art 1709 of the NAFTA provides for a strikingly similar expedited process for compulsory licenses. See also Sec. 6 of the US Executive Order 12889 of 28.12.1993, incorporating the NAFTA provisions.

430 Art 31(k) of the TRIPS Agreement further states that the prior negotiations requirement is not required when seeking to implement remedies for anti-competitive behaviour by the patent holder.

431 *Garner (ed)*, Black's Law Dictionary (8th edn Thomson West St. Paul 2004) p. 1051.

aa) Extreme urgencies and national emergencies

The absence of any guidance from the TRIPS Agreement concerning their meaning of an extreme urgency has left Member States a significant degree of flexibility when interpreting the terms. Added to this, the term 'extreme urgency' is a particularly difficult term to define. Uncertainty exists as to how 'extreme' is to be quantified. It is clear that the measurement of an extreme urgency cannot rest on a global predefined number of persons or animals that must have died or are expected to die. The absence of a clause in the TRIPS Agreement explaining extreme in the context of Article 31(b) enables the Member States themselves to interpret the term and can do so in a manner that best suites its own domestic resources and social and economic abilities.[432] This national prerogative, although not exempt from TRIPS review, permits Member States to set standards upon which certain circumstances will be automatically deemed to constitute an extreme urgency.[433] Such a system would ensure that the process for a compulsory license application would not be delayed by a potential dispute about the classification of a situation.

The TRIPS Agreement provides guidance as to when an urgency will be deemed sufficient to use a fast-track process. The Agreement cites a 'national emergency' as an example of an extreme urgency. This comparison provides a guide for the domestic interpretation of the extreme urgency.

The concept 'national emergency' is a well established concept and is found throughout the WTO Member State jurisdictions.[434] The national emergency system provides governments with the legal framework to counter matters requiring urgent state intervention and can involves the suspension of certain administrative functions or civil liberties. Although these systems are not designed for the limitation of intellectual property rights the reference thereto in the TRIPS Agreement indicates that even intellectual property rights may be required to yield to more important national needs. The national emergency prerogatives grant extraordinary powers to government agencies to enable them to counter a threat to the public welfare.[435] These threats may be natural (such as flooding or earthquakes) or man-made (pollution, civil unrest and warfare) and may extend not only to the physical consequences of the threats, but also to diseases, threats of diseases, nutrition, environmental consequences and other results that may arise directly or indirectly from the threat. Not-

432 Friedrich Nietzsche is quoted as saying '[n]ecessity is not an established fact, but rather an interpretation'.

433 The classification of circumstances of extreme urgency would not infringe the requirement of Art 31(a) as it does not regulate the authorisation of a compulsory license. Accordingly, each authorisation for a compulsory license would still be required to be considered on the individual merits of the license.

434 Contrast *Kiehl*, 10 J.Intell.Prop.L (2002) p. 163.

435 *Locke* answered the question as to when a national emergency will be justified by stating 'the tendency of the exercise of such prerogative to the good or hurt of the people, will easily decide that question'. Cf. *Locke*, Second Treatise on Civil Government (4th edn Awnsham Churchill London 1764) Chapter XIV, sec 161.

withstanding this, defining a national emergency is fraught with difficulties. It is an elastic concept that evades strict definition. The reason for this is that neither the dangers nor their consequences are foreseeable or equally regarded. Creating a fixed definition for a national emergency potentially restricts a state from reacting to new and unforeseen dangers that were not considered at the time of the codification. *Alexander Hamilton*, one of the US founding fathers wrote in 1787:

> '… IT IS IMPOSSIBLE TO FORESEE OR DEFINE THE EXTENT AND VARIETY OF NATIONAL EXIGENCIES, OR THE CORRESPONDENT EXTENT AND VARIETY OF THE MEANS WHICH MAY BE NECESSARY TO SATISFY THEM. The circumstances that endanger the safety of nations are infinite, and for this reason no constitutional shackles can wisely be imposed on the power to which the care of it is committed. This power ought to be coextensive with all the possible combinations of such circumstances; and ought to be under the direction of the same councils which are appointed to preside over the common defence.' [436]

A national emergency can however be dissected according to its characteristics: the existence of a danger or threat thereof, the threat must be national and, usually, is declared as such by a governmental authority.[437] A 'danger' can best be described as being an existing or threatened exposure to risk or peril. It is not restricted to a certain type of peril and can thus include perceived threats to animal and mankind as well as to possessions, territory, civil order and government.[438] Accordingly, no actual harm needs to have occurred in order for a national danger to exist; the threat thereof suffices.[439] Further, the cause of a danger is immaterial; in addition to it resulting from natural causes and 'acts of god' it may also result from intentional and negligent human acts and include instances where there is a mere political motive to declaring an occurrence to be a danger.[440] National emergency dangers are further not limited to physical or psychological threats. They may occur in economic, environmental, socio-political, educational and even developmental fields. It is therefore plainly evident that the danger that justifies a national emergency may derive from any source and affect any national interest.

The extent of the national emergency erroneously gives the impression that the danger must extend to the whole geographical area of the country concerned. This is

436 Original format. *Hamilton*, Federalist Papers (1787). *Gross* states that even if a working definition of an emergency could be given, it is doubtful that it would stand the test of actual emergencies. See *Gross*, 33 IYHR (2003) p. 21.

437 Webster's Third New International Dictionary defines a national emergency as a 'state of emergency resulting from a danger or threat of danger to a nation from foreign or domestic sources and usually declared to be in existence by governmental authority'.

438 Academics and politicians alike take the view that the crisis caused by the attacks on 11.10.2001 continue to exist. See *Cole*, 101 Mich.L.Rev 8 (2003) p. 2588.

439 The Belgium patent system recognises that the existence of a public health crisis need not exist for a compulsory license to be granted for public health reasons. See *Van Overwalle*, 37 IIC 8 (2006) p. 910.

440 The US has classified rail workers strikes and the possible consequences of the abandonment of the gold standard as a national emergency. See also *Gross*, 33 IYHR (2003) p. 29.

not the case. The extent of an emergency is not measured geographically but according to its national impact. Hence, either the nation as a whole must feel the direct and/or indirect effects of the danger or addressing the danger must be of a national importance.

Although not a formal requirement for the existence of a national emergency, the declaration of a national emergency sets in motion a state-orchestrated process that provides quick and effective response to persons affected by the crisis and suspends otherwise mandatory authorisation procedures.[441] The powers to declare a national emergency are usually found in the national constitution and vest either in the executive, the legislature or both.[442] In terms of a national emergency declaration the executive or other authorised body is able to exercise extraordinary powers, including law-making powers and the ability to amend or even suspend legislation, including the constitution.[443] The duration of a national emergency is firstly dependent on the existence of the danger or threat thereof and secondly the length of time the Member State determines is necessary to maintain measures to counter the danger and/or prevent the danger from occurring.

There is a rich history of national emergency use in the WTO Member States. The logical restraint of the TRIPS Agreement to select or limit the use of such emergency procedures reflects firstly that public crises will trump individual rights and secondly that past national practices represent accepted usage of the emergency system. Some Member States have made liberal and extensive use of the national emergency rules. In the US for example, national emergencies have declared to break un-

441 The national emergency concept derives in part from Locke. See *Locke*, Second Treatise on Civil Government (4th edn Awnsham Churchill London 1764) Chapter XIV.

442 Sec 37 of the South African Constitution is an example for the constitutional regulation of national emergencies and an example of a country whereby the national emergency is declared by the legislature. Although emergency provisions are generally found and regulated in national constitutions, this is not the rule. The US for example makes not specific mention of a general system for declaring national emergencies. A number of US states provide for local emergencies, including public health emergencies. The US Constitution further diverts from the common approach to national emergencies by permitting the US legislature, the Congress, to suspend certain rights on the occurrence of an emergency. Other countries that make a distinction between different types of emergencies also make a distinction between which government branch is authorised to address the emergency. See further *Gross*, 33 IYHR (2003) p. 19-20.

443 Art 28 of the Irish Constitution is an example of a constitution permitting its own limitation in emergency situations. See also sec 2 of the Irish Emergency Powers Act of 1939 whereby the government is empowered to take any and all actions 'necessary or expedient for securing the public safety or the preservation of the State, or for the maintenance of public order, or for the provision and control of supplies and services essential to the life of the community.' Constitutions such as the South African Constitution provide for a catalogue of rights that can and cannot be derogated. The binding nature of such a catalogue is uncertain as certain situations may justify the suspension of the constitution and thus any limitations therein. In this regard see *Gross*, 33 IYHR (2003) p. 37-40.

ion activity,[444] to fix milk prices,[445] to protect indebted farmers[446] and more recently as a result of the terrorist attacks on the US in 2001.[447] Further, the emergency measures often last longer than the emergency itself.[448] Some emergencies in the US have extended for periods exceeding 40 years.[449]

The absence of any TRIPS Agreement restrictions limiting the scope and application of national emergencies means that Member States can look to past national practice as examples of the availability of emergency provisions. In doing so Member States will however be required to recall that the use of compulsory licenses to address extreme urgencies is not boundless.[450] Member States are still required to apply the TRIPS Agreement in good faith, meaning that compulsory licenses for patent rights will be acceptable when their limitation serves to counter the national emergency.

The practical experiences in declaring national emergencies helps in understanding the scope of the Article 31(b) concept 'extreme urgencies'. Being the more general term, an 'extreme urgency' is, at *least*, a national threat, capable of being used in all areas where national interests exist, including but not limited to physical, physiological, environmental, social, educational, political and economical interests. Moreover, the threat need not directly or indirectly affect the country as a whole and may exist for extensive periods of time. The meaning of an extreme urgency, as interpreted in the context of Article 31(b), displaces the ordinary meaning given to it by the text alone. The meaning, as acquired in the context of the provision, reflects both the inalienable right a country has to defend its citizens wellbeing over the in-

444 *Wilson v. New* 243 US 332 (1917) 333. The Supreme Court justified its actions on the basis that interstate commerce would be ruined by the rail strike

445 *Nebbia v. New York* 291 US 502 (1934).

446 *Home Building and Loan Association v. Blaisdell* 290 US 398 (1934). The case concerned a statutory moratorium on mortgage foreclosures in Minnesota after a 'severe financial and economic depression'.

447 On 14.09.2001 the Declaration of National Emergency by Reason Of Certain Terrorist Attacks was proclaimed.

448 *Cole*, 101 Mich.L.Rev 8 (2003) p. 2566.

449 See US Senate Report No. 93-549 from 1973. The US sought to limit the scope of compulsory licenses to 'solely address … a declared national emergency or to remedy an adjudicated violation of anti-trust laws' in the TRIPS Agreement negotiations. The limited approach did not find wide agreement. Cf. GATT Secretariat 'Synoptic Tables Setting Out Existing International Standards and Proposed Standards and Principles' (29.09.1989) MTN.GNG/NG11/W/32/Rev.1 p. 30, GATT Note from Secretariat 'Meeting of Negotiating Group' (22.06.1990) MN.GNG/NG11/21 p. 9. The irony of the US's approach is that, notwithstanding their restrictive application of compulsory licenses, it has granted more compulsory licenses that most other countries. Israel has been in a state of emergency ever since it's War of Independence in 1948. See in this regard *Gross*, 33 IYHR (2003) p. 13. The UK has been at a state of emergency for the most part of the last 30 years. See *Cole*, 101 Mich.L.Rev 8 (2003) p. 2588.

450 WTO *United States – Section* 211 (panel ruling) p. 85.

dividual right of a patent holder and the right a Member State has to adopt measures to promote the public interest.[451]

The right to use the fact-track process is not limited to state interventions. Article 31(b) makes no distinction between state and individual actions to tackle extreme urgencies.[452] The availability of the fast-track private compulsory license is vital for public interest protection in developing countries, especially where the state itself is unable to act but where private individuals, organisations and/or non-governmental organisations possess the qualifications, know-how and competency to react.[453] This is especially true of international organisations such as the UNICEF and MSF which have significant resources and experience in attending to emergency situations.

bb) Public non-commercial use

In addition to circumstances of extreme urgencies, a Member State is also entitled to use the expedited procedure for granting a compulsory license 'in cases of public non-commercial use'. Included within the concept of public non-commercial use are government and crown use.[454] All three concepts refer to the power a government has to use the property, works and inventions of patents registered within its domain. Whereas the typical application of government use is found in the public health and national defence sectors, they are not limited to these fields.[455] It is foreseeable that some governments would be willing to extend the unauthorised use to inventions in the fields of nutrition, environmental protection and the promotion of social and economic development, as contemplated in Article 8.1 of the TRIPS Agreement.

Notwithstanding the guidance provided by the TRIPS Agreement, the concept 'public non-commercial use' is subject to significantly more flexibility than the con-

451 Contrast *Kiehl*, 10 J.Intell.Prop.L (2002) p. 162-165. *Kiehl* takes the view that developing countries 'are unlikely to find that [Art 31(b)] unequivocally support involuntary licenses in a public health emergency context' as public health legislation would not likely be 'necessary'. Whereas this may be true in the extreme, there is little doubt that the necessity test applied under based on Art 31(b) will cover *bona fide* measures to improve the public health. For a discussion of the level of necessity required see Chapter 5(C)(I)(2)(b).

452 The TRIPS Agreement does not require a formal waiver specifically exempting compulsory license applicants from the prior negotiation requirement. This requirement would be met by an administrative or judicial order, as is the case with anti-competitive acts (TRIPS Agreement Art 31(k)). It seems therefore that a general statute or order waiving the prior negotiation requirement in certain predetermined circumstances will suffice. Further, and to the extent that the emergency powers oblige, formal declarations of emergencies will also satisfy the waiver.

453 The US was the motivating factor for the inclusion of public non-commercial use as a fast-track ground in Art 31(b) of the TRIPS Agreement. Cf. *Watal and Mathai*, Global Forum in Industry (1995) p. 21-22.

454 Early drafts of the TRIPS Agreement referred to the use as being for 'public [non-commercial] purposes by the government or by any third party authorised by the government'. See *Gold and Lam*, 6 JWIP 1 (2003) p. 17.

455 UK Patent Act of 1977 sec 56.

cepts of extreme urgencies and national emergencies.[456] The absence of any qualifications on for 'public non-commercial use' permits a potential *carte blanche* for granting compulsory licenses.[457] There is no prerequisite for the existence of an urgency or emergency for the unauthorised use of a patented invention by the government and yet a government can still reach the same result as a declared national emergency by simply classifying the unauthorised use of the patent as being governmental use. In the US, there is widespread government use of patents.[458] This liberal application of government use has largely done away with their need to apply other compulsory licenses.[459] The unauthorised use of a patented invention by the government is however subject to two limitations: firstly, the compulsory license must principally be used in the carrying-out of a governmental obligation and secondly, not be used in a profit-driven manner.[460] As it is the duty of every government to look after the wellbeing of its citizens, it is theoretically possible that governmental use could extend to all patents which could further the public's interest.[461] As all governments are deemed to serve their citizens and their interests, there is a presumption that the government use is to the public's benefit. This theoretical abil-

456 *Gold* and *Lam* suggest that the eventual distinction between extreme urgencies and government use in the Brussels Draft indicates that the negotiators intended government usage to be treated more liberally. See *Gold and Lam*, 6 JWIP 1 (2003) p. 17-18.

457 This view has been confirmed on many instances. See for example the Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 8.

458 *Reichman and Hasenzahl*, Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA (ICTSD/UNCTAD Geneva 2003) p. 5.

459 *Reichman and Hasenzahl*, Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA (ICTSD/UNCTAD Geneva 2003) p. 14.

460 Art III(8)(a) of the GATT Agreement contains a similar provision. It states that the 'provisions of this [the National Treatment provisions in Art III] shall not apply to laws, regulations or requirements governing the procurement by governmental agencies of products purchased for governmental purposes and not with a view to commercial resale or with a view to use in the production of goods for commercial sale'. A similar provision is also found in Art XIII of the GATS Agreement. The similarity does not however imply that the commercial purpose prohibition will apply *mutatis mutandis* to Art 31. The principal difference is that these GATT and GATS Agreements clauses enable governments to favour domestic companies in the government procurement process without infringing the most-favoured nation and national treatment clauses. Government use in terms of Art 31(b) of the TRIPS Agreement however remains subject to the most-favoured nation and national treatment clauses. Art 31 also poses a lesser threat to international trade as it is granted on the individual merits of the patent and is subject to administrative or judicial review.

461 28 USC 1498 authorised US government departments and private individuals carrying out a state duty to use a patent, without the patent holder's authorisation, and cannot be barred by an injunction from continuing the use of the patent. This effectively excludes US government use from having to justify the use. The government use is defined as a 'non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States *any subject invention throughout the world*' (emphasis added).

ity to expropriate each and any patent is cemented by the reluctance of courts to override state policy decisions. Courts will generally refrain from overruling a policy decision unless there is evidence of *mala fides* in the state action. The governmental bodies and agencies authorised to exercise the 'government use' prerogative include both central and state/provincial branches of government and extend to private entities or 'contractors' authorised to exercise the license on behalf of such bodies.[462] The second limitation, 'non-commercial', prohibits the government from seeking to use the compulsory license for business or profit purposes. Non-commercial does not mean the government or its agents are prohibited from selling the licensed product.[463] Whereas the government is prohibited from making profits, an agent appointed by the government to exercise the license need not do so at a loss. Nothing within the TRIPS Agreement prevents the agent from making a reasonable return. Questions as to the good faith implementation of Article 31(b) could be raised where the agent makes profits that outweigh the purpose of the government use.[464] Accordingly, it would be acceptable for the appointed agent to charge prices that would cover its production costs and provide for reasonable profits.[465]

A further benefit of the government use compulsory license is that Member States can structure the procedural elements in order to ease its use. Article 44.2 of the TRIPS Agreement enables Member States to limit the remedies available to the patent holder. The only restriction is that Member States must allow the patent holder to seek remuneration for the licensed use of its patent. In the US for example, the patent holder's sole remedy is a remedy for compensation.[466] No legal review of the authorising decision is permitted.[467] In addition hereto the US permits the 'immunisation' of state actions against patent infringement claims.[468]

462 TRIPS Agreement Art 44.2. In a 1998 report, the US NIH stated that as 'a government agency, [it] may use and manufacture any patented invention, whether or not developed with federal funds, and authorize its use and manufacture by others for the United States, without a license … under 28 U.S.C. §1498'. See the *NIH*, (1998). This has been confirmed by the US courts in the matter of *Zoltek Corp. v. United States* 442 F.3d 1345 (Fed. Cir. 2006), see *Aichele and Godici,* 1 JIPLP 10 (2006) p. 633-635.

463 Sec 55(1) of the UK Patent Act permits 'any government department and any person authorised …[to] make, use, import or keep the product, or sell or offer to sell'.

464 Whilst the government contractor's use of a patent without a voluntary license to promote domestic industry development is not contrary to the TRIPS Agreement, a Member State wishing to undertake such steps would be well advised to ensure that the policy measures are justified in terms of Art 8.1.

465 TRIPS Agreement Art 31(g).

466 Art 44 of the TRIPS Agreement permits Member States to limit the remedies available to patent holders to remuneration alone where there has government use of a patent.

467 For example 28 USC § 1498(a).

468 In the US Supreme Court case *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank* 527 US 627, 148 F.3d 1343 (1999), the Court held that state governments were exempt from being sued for patent infringements. In this case the Court stated a state government agency possessed sovereign immunity and a federal statute seeking to abrogate this immunity was invalid.

A Member State making known use of a patent, without the patent holder's consent, is required to notify the patent holder of such unauthorised use 'promptly'. Whilst the notification obligation requires the government to act as soon as reasonably possible, the obligation only exists where there is knowledge that a patent will be infringed by the government's actions.[469]

The government use mechanism provides Member States the opportunity to use the exclusive rights granted to a patent holder as a policy measure for the development and protection of domestic industries – a goal set out in Article 8. The employment of government use as an industry development tool is not new to developed countries. The US has made active use to further *inter alia* research[470], the production or utilisation of special nuclear material or atomic energy,[471] major utility developments like river damming and electricity generation[472] and economic development as a whole.[473]

Despite the flexibilities contained in Article 31(b), Member States remain bound by the notion of 'good faith' when interpreting the provision.[474] In terms of Article 31 of the Vienna Convention Member States will need to ensure that measures taken to counter extreme urgencies and provide for government use that are not arbitrary or frivolous and do not prevent an 'effective and adequate protection for intellectual property rights'. Member States are not only obliged to implement the minimum standards required by the TRIPS Agreement but they are also required to ensure that they do not negate the patent system nor encourage discrimination.

The private rights protected by the TRIPS Agreement may be seen to restrict the ability a Member State has to conduct its duty of protecting and advancing its citizens. The use of compulsory licenses, in particular the extent to which they can and have been used, empowers those Member States negatively affected by intellectual property rights to react and ensure that patent rights vested in individuals do not limit the public interest. The *bona fide* use of compulsory licenses has no substantive restrictions. The only limitations are procedural in nature.

469 Art 31(b) of the TRIPS Agreement does not require the government to undertake a patent search to determine if its actions infringe a patent holder's rights. See *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 165.

470 35 USC § 200-212, introduced in the Bayh-Dole Act. The Act allows the government 'march-in' rights to license a third party without the consent of the patent holder. See also *NIH*, (1998).

471 *Watal and Mathai*, Global Forum in Industry (1995) p. 21-22.

472 *Reichman and Hasenzahl*, Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA (ICTSD/UNCTAD Geneva 2003) p. 15.

473 Letter from NIH Director H Varmus to CPTech Director Love J (1999) <http://www.cptech.org/ip/health/sa/varmusletteroct19.html> (04.01.2006).

474 WTO *United States – Section* 211 (panel ruling) p. 85.

e) Article 31(c)

> 'the scope and duration of such use shall be limited to the purpose for which it was authorized' [475]

The contents of Article 31(c) seek to ensure that a compulsory license does not abuse the rights conferred in the license. The aim of Article 31 is to ensure that those persons licensed to exploit the patented invention, only do so to the extent to which they were authorised. In other words, Article 31(c) requires that the licensee be bound by the license conditions granted by the authority. What the TRIPS Agreement does not regulate is the scope of the granting authority's licensing powers. Thus, a compulsory license with narrow conditions will limit the user's scope of exploitation and a compulsory license with expansive conditions will permit the user to exploit the license broadly. Both are permitted by the TRIPS Agreement. Article 31(c) therefore does not limit the scope and duration of a compulsory license but instead it limits the licensee to the scope and duration he has been authorised to. Thus, this ensures that the rights granted in the compulsory license are not abused. The effect of this formulation, i.e. that the compulsory licensee can exercise the license to the fullest extent to which he is authorised to do so, implies that the Member States and their authorities tasked with granting compulsory licenses can shape the purposes of the compulsory licenses in order to achieve a desired policy goal. It would therefore be plausible – and TRIPS-compliant – for Member States to promote a new domestic sector by granting compulsory license applicants licenses permitting extensive scope and duration. Where the granting authority declares its purpose to be the development of a new domestic sector and limits the conditions of the compulsory licenses accordingly, such Member States will not exceed the bounds of Article 31(c). Thus and in contrast to the exceptions permitted under Article 30, Member States are empowered to permit extensive scopes and durations for patented inventions in order to assist or promote the public interest.[476]

aa) Scope

The scope of the compulsory license must firstly be distinguished from that of the limited exceptions contained in Article 30. The footnote 7 to Article 31 specifically states that '"Other use" refers to use other than that allowed under Article 30'. This footnote implies that whereas compulsory licenses (i.e. Article 31) are also deemed to be exceptions to the rights conferred, they are not confined to 'limited exceptions'. Applying the principles raised in the *Canada – Pharmaceuticals* case an

475 Art 31(c) of the TRIPS Agreement provides for specific limitations for semi-conductor technologies. As this limitation is of limited application it is not discussed further.

476 Member States are cautioned when introducing such measures so as not to implement a system of discrimination against a field of technology or its place of production. Art 27.1 of the TRIPS Agreement, which prohibits certain discrimination, would be circumvented by Member States if they were to discriminate on the basis of grounds for a compulsory license.

unlimited exception would firstly be broad in nature; secondly it may permit extensive curtailment of the patent holder's rights and lastly may allow the derogation from any of the rights conferred in Article 28. As the footnote states, Article 31 refers to all exceptions other than those mentioned in Article 30. It is tempting to conclude that this implies that the absence of a reasonableness requirement would permit Member States to validly limit the exploitation of the patent holder's rights in an unreasonable manner and prejudice his legitimate interests.[477] This view is however countered by Article 7 of the TRIPS Agreement. It states that 'the protection and enforcement of intellectual property rights should contribute … to a balance of rights and obligations'. Article 7 is mirrored by the Member States' underlying obligation to implement the TRIPS Agreement in good faith and not in a manner that would circumvent the object and purpose of the agreement, i.e. the promotion of effective and adequate protection of intellectual property rights.[478] As such and although Member States are able to grant extensive compulsory license conditions, they are not permitted to grant the licensee the unencumbered use of the patent.[479] The balancing of the rights obliges the granting authority to ensure that the grounds for the compulsory license are proportional to the aims of the licence and patent holder's conduct.[480]

The scope of a compulsory license under Article 31 is limited to patents. The effect of this limitation is that it makes the granting of some compulsory licenses effectively obsolete. The reason for this is that modern day inventions can seldom be used by reading the disclosure in the patent application alone. The existence of undisclosed information such as know-how has become an essential part of the patent's use and its protection.[481] Hence, where a compulsory license is not able to extend to know-how, the effect would be that patent holders could thwart the balance created in the intellectual property system.[482] This is particularly a problem for developing countries where the patent product is only being imported as the required know-how is not present in that Member State.[483] The TRIPS Agreement does however state

477 *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen (Nomos Baden Baden 2002) p. 280.

478 WTO *United States – Section* 211 (panel ruling) p. 85.

479 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 472.

480 *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 251. *Beier*, 30 IIC 3 (1999) p. 261.

481 *WIPO*, Introduction to Intellectual Property Theory and Practice (Kluwer London 1997) p. 146.

482 Art 39 of the TRIPS Agreement requires Member States to protect, in which ever manner, undisclosed information from use by third parties in 'a manner contrary to honest commercial practices'. This is understood to mean either by way of breach of confidence or contract, or by way of gross negligence or dishonesty. Art 39 does not prohibit a government from authorising third party use. Such authorisations play an important role in rectifying anti-competitive acts.

483 The remedies for this predicament would be to require a detailed disclosure including the necessary know-how. These could be disclosed in a separate system which is confidential and

that undisclosed information need not be protected 'where it is necessary to protect the public'.[484] As the TRIPS Agreement merely confirms that the Member States do not have to protect undisclosed information where it is not in the public interest, the lack of a provision regarding the compulsory disclosure of trade secrets means that Member States are free to decide if they wish to compel its disclosure or not. The effect of such a compulsory disclosure together with the use thereof by third parties could be viewed as a quasi-compulsory license for undisclosed information.[485]

bb) Duration

In addition to the licensee's obligation not to exceed the scope of the compulsory license, the licensee is also limited to the period or duration that was set out by the licensing authority. Although the duration is dependent on a number of factors, the general rule is that the period should be limited to the shortest possible period of time necessary to fulfil the authorised purposes.[486] In determining the shortest period, both the interests of the patent owner and those of the licensee must be taken into account.[487] Each compulsory license will be subject to its own time restrictions and may be made conditional upon, *inter alia*:

- the occurrence of a fixed event (e.g. the expiry of a national emergency)[488]
- the actions of the patent holder (e.g. the exercise of the patent in a non-abusive manner)
- the actions of the licensee (e.g. to recoup the investment costs made)[489] or
- a combination of these events.[490]

The duration of the compulsory license is thus dependent upon the occurrence of one of these conditions or, at the very least, when the purpose for which it was granted ceases to exist and is unlikely to reoccur.[491]

prohibits third party use without the consent of the information 'owner' or the government. In the case of inventions requiring market approval, Member States could require the patent holder to disclose the relevant know-how as part of the access process.

484 TRIPS Agreement Art 39(3).

485 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 273-274.

486 Compulsory licenses that automatically extend to the end of the patent period infringe Art 31(c) of the TRIPS Agreement.

487 The interests of the patent holder are not the primary concern of the granting authority. Instead in the case of extreme urgency compulsory licenses or public interest licenses the interest of the public will prevail. The interests of the licensee will prevail in cases where there have either been abusive practices to the detriment of the licensee or where the licensee is required to make financial and structural outlays.

488 UK Patent Act of 1977 Sec 59.

489 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 473.

490 In *Microsoft* (Case COMP/C-3/37.792) EC Commission Decision C(2004) 900 final [2004] the EC Commission did not limit the duration of the compulsory license. Although the Decision primarily concerned copyrights, they also extended to patents.

To surmise, Article 31(c) does not limit the scope and duration of a compulsory license. According to the TRIPS provisions a patent owner has no innate right to challenge the scope and duration of the compulsory license. Although a patent owner is provided the opportunity to review the grant of a license, the TRIPS provisions provide no legal basis for a challenge of the scope and duration of the compulsory license where the purpose remains intact.

f) Article 31(d)

'such use shall be non-exclusive'

The compulsory license is a legal tool that, in terms of the TRIPS Agreement, permits the use of the patented invention without the consent of the patent holder. The entitlements permitted under the TRIPS Agreement do not extend to allowing the Member State to reserve its market for the sole benefit of the licensee.[492] With the exception of the compulsory license, the patent holder's exclusive rights remain in tact. Hence, the existence of a compulsory license will not prevent the patent holder from continuing to exercise his exclusive rights.[493] This includes the voluntary licensing of the patent to third parties; a fact expressly recognised by Article 31(d).

As a safeguard measure, Article 31(d) serves to ensure that patent holder rights are not restricted more than is necessary. By ensuring that the patent holder can continue to make use of his exclusive rights, the patent holder is given the opportunity to reap some rewards of its patent. The reverse side of this is that the compulsory licensee is subject to competition. In certain circumstances where the investment-return equation is limited, potential compulsory license applicants will be reluctant to invest significant resources in the compulsory use of the patent. The right to continue exercising its patent rights enables the patent holder the theoretical opportunity to scuttle the licensee's plans by either reducing the prices for the patented product or granting voluntary licenses to third parties at more favourable conditions that the licensee is entitled to. It is therefore possible for patent holders to effectively negate the compulsory license system by diminishing the financial prospects the potential licensee might have. Although the patent holder is able to compete in a free market, its actions are to be tempered with circumspection.[494] Patent holders are not ex-

491 In this regard see also Art 31(g) TRIPS Agreement, *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 251.

492 Contrast pre-TRIPS Agreement *Allen and Hanburys v. Generics (UK) Ltd* 434/85 [1988] ECR 1245. The ECJ did however overrule the UK practice of limiting compulsory licenses (here licenses of right) to locally manufactured licensed products.

493 *Reichman and Hasenzahl*, Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA (ICTSD/UNCTAD Geneva 2003) p. 23.

494 Compare *Reichman and Hasenzahl*, Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada

empted from competition law. The licensee is a lawful competitor and actions taken that amount to unfair business practices and repeat earlier abusive practices could result in the forfeiture of the patent.[495]

Although the prime aim of Article 31(d) is to ensure the continued business of the patent holder, Article 31(d) also prohibits Member States from restricting the number of compulsory license applicants, thus furthering the realisation of one of the basic WTO principles – the reduction of trade barriers. Added competition will further product improvements and/or lead to price reductions.[496] The non-exclusivity rule further means that Member States are prevented from using the compulsory license system to favour certain producers. In addition, multiple compulsory licenses would be more effective in countering intellectual property right abuses such as anti-competitive behaviour and non-working of the patent.

As mentioned above, non-exclusivity may also deter applicants for compulsory licenses and enable patent holders to continue perpetuating acts contrary to the public interest. As generic pharmaceutical producers, like all free-market businesses, only act where there is a financial incentive, the division of a limited market between multiple licensees would deter an application for a compulsory license with limited prospects of there being a recovery of the costs it will be required to invest.[497] Whereas there is often significant room for multiple generic producers in developed markets, this is not the case in small and poor markets. As the potential for multiple licensees in a restricted market would deter compulsory license applicants Member States in need of compulsory licensees would have to create incentives to encourage their participation. A potential solution would be to make the granting of a compulsory license conditional upon the potential profitability of the use of the license.[498] A further incentive would be for the government to enter into fixed supply/price arrangements, thus enabling the compulsory licensees to accurately weigh their potential investments. [499]

and the USA (ICTSD/UNCTAD Geneva 2003) p. 23. The authors note that a patent holder could also prevent competition by acquiring and taking over the licensee.

495 Paris Convention Art 5A(3). The forfeiture cannot be ordered within 2 years of granting the compulsory license.

496 Experience in the generic pharmaceutical sector indicates that with the entry of the first producer of generic medicine the average cost of the generic product is 70-80% of the original brand name pharmaceutical. Additional generic manufacturers lead to further cost reductions that are 50% or more less than the former patented product. See in this regard *Boast*, Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements Statement to the Committee on the Judiciary US Senate (24.05.2001).

497 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 473.

498 It would however be in bad faith and a circumvention of the TRIPS provisions where the granting authorities to prevent additional compulsory licensees on the basis that it would limit the profitability of the initial user. Such a limitation would be contrary to the TRIPS Agreement, which seeks to promote trade, not restrict it.

499 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 473.

A further ground for limiting the number of licensees is that of the public interest. Non-exclusivity does not force Member States to grant more than one compulsory license. In cases where the compulsory license is granted to serve the public interest, the granting authority would be within its powers to refuse subsequent compulsory licenses if there are convincing grounds that the subsequent license would be counter productive by preventing the original license(s) from accomplishing their authorised purpose.[500]

The TRIPS Agreement is clear with regards to the right of a patent holder to continue the patent's use during the period under which it is a subject of a compulsory license. This situation is less clear with regards to multiple licensees. Whereas the TRIPS Agreement requires that multiple licensees may be permissible, it does not require the granting authority to issue multiple licenses where it is not in the public's interest.

Generally speaking, the concept of non-exclusivity is a safeguard reconcilable with the varying interests in the compulsory license system. This does not however extend to government use. Although the patent holder is permitted to continue using the patent, the government is not obliged to delegate its eminent domain rights *ad infinitum*. Thus, where the government restricts the delegation of its government use powers to one agent, its actions would not infringe Article 31(d) *per se*. This concurs with government practices of delegating their powers by way of tender procedures, ensuring the best tender offer is accepted.

g) Article 31(e)

> 'such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use'

Article 31(e) seeks to prevent Member States from circumventing the spirit of the TRIPS Agreement by limiting the use of the individual compulsory license to the applicant. TRIPS negotiating parties had feared that allowing the assignment of the compulsory license would have two adverse consequences. Firstly, it could lead to the commercialisation of the compulsory license system by enabling the licensee to sell the right to use the patent to highest bidder. Secondly, the inability of the granting authorities to balance the rights of the patent holder and the actual user of the license could lead to a mockery of the compulsory license system. This would occur because the ultimate licensees could acquire a compulsory license on terms that they would not have been able to acquire had they themselves applied for the license.

The assignment of compulsory licenses can nonetheless occur by accompanying a transfer of the goodwill of the company, or part thereof, authorised to use the compulsory license. Accordingly, the TRIPS Agreement prohibits the compulsory li-

500 Such restrictions are unlikely to apply for compulsory licenses granted to rectify an abuse, especially where the subsequent license applicants have also been detrimentally affected by the abuse.

cense from forming the object of the assignment. Where the object of the transfer is the sale of a company or goodwill, the TRIPS Agreement will not prevent the transfer. Hence, Article 31(e) prohibits the direct assignment of a compulsory license but permits the indirect 'assignment' thereof. Although there is a degree of merit to the argument that the indirect assignment would effectively be a 'circumvention' of the non-assignment prohibition, this argument is countered by the clarity of the contents of Article 31(e). The consequences of the Article 31(e) exception are clear: where a compulsory license vests in a company or forms part of the goodwill, it can be transferred. The Article 31(e) exception injects a portion of realism into the use of compulsory licenses by businesses. The acquisition and sale of businesses is an economic reality in commerce today. This movement assists in ensuring businesses can survive and adapt without being forced to dispose of the license. The commercial wellbeing of the licensee will ensure that the license can continue to be exercised. Further, where the license forms part of a company that is transferred, all the rights and obligations that vested in the licensee are transferred too, ensuring that the transfer does not dilute the license. A final point countering the circumvention argument is that companies are juristic persons. With the sale of a company no rights are assigned. They remain vested in the company; it is the ownership of the company that is transferred, not the use of the license.

It must however be recalled that the TRIPS Agreement seeks to 'promote effective and adequate protection of intellectual property rights'.[501] A state endorsed system to disenfranchise patent holders of their rights would not be deemed a 'good faith' implementation of this goal.[502] It is foreseeable that the DSB would not take long to determine that a state-enforced policy to indirectly alienate patent rights would be a *de facto* infringement of the TRIPS Agreement.

h) Article 31(f)

> 'any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use'

The territorial nature of intellectual property rights and each country's independent national sovereignty preclude one Member State from granting a compulsory license on a patent awarded in another country.[503] The Member State is limited to solely restricting those rights granted in its own territory. Unlike the Member State's territorial restriction, the products of patents and compulsory licenses have, as tangible objects, the inherent ability to traverse national boundaries. This ability to transverse boundaries presents a problem where the product being exported is produced under a compulsory license. This is particularly the case where the importing country does not have a corresponding compulsory license for that product. The effect of

501 TRIPS Agreement preamble.
502 Vienna Convention Art 31.
503 The notion of independence is anchored in Art 4bis of the Paris Convention.

an exported compulsory licensed product would be to subject the patent holder in the importing country to the restrictions enforced by a country in which he or his patent is not subject to. As such, a widespread consensus has developed that compulsory licensed products should be limited to the territory in which the license was granted.[504] Although this rule is generally recognised, the TRIPS negotiating parties feared that the compulsory license system could nevertheless be abused for exportation purposes. In order to ensure that this did not occur the negotiating parties incorporated an express obligation into the compulsory license process requiring the Member States only to grant compulsory licenses that are 'predominantly' for the local market.

The analysis of Article 31(f) rests on the meaning of the word 'predominantly'. The ordinary meaning of 'predominantly' in Article 31(f) implies that the *main* use of the compulsory license should be performed within the Member State in which it was granted.[505] In other words, in terms of the TRIPS Agreement a compulsory license holder would be permitted to produce (or import) the licensed product for domestic use and, should it desire, export up to but not exceeding 49% of the licensed product to countries which have not issued a patent, alternatively have issued a compulsory license, for that product. Despite it being common practice, Article 31(f) does not oblige the granting authority to completely prohibit the export of the licensed products.

The TRIPS Agreement makes no reference to the predominance being determined in value or quantity. This lack of definition permits Member States a degree of flexibility, especially where higher export prices could be used to subsidise domestic prices. Although the theoretical possibility for the flexible interpretation of Article 31(f) exists, the practical value of the predominance concept is not significant. Any importation of the compulsory licensed product into a country with a valid patent on the product will likely be halted by a patent holder protecting his jurisdictional exclusivity.[506] It must also be noted that the fine line between a good faith and bad faith implementation of Article 31(f) becomes in such circumstances blurred. A compulsory license granted for domestic reasons but, as hypothesised above, used to

504 *Pharmon v. Hoechst* 19/84 [1985] ECR 2281. The effect of this ECJ decision was that, in addition to confirming the territoriality of compulsory licenses, the doctrine of exhaustion would not apply to products brought onto the market without the patent holder's consent. It was stated that '[w]here a compulsory licence is granted to a third party the patent proprietor is deprived of his right to determine freely the conditions under which he markets his product. The substance of a patent right lies essentially in according the inventor an exclusive right of first placing the product on the market so as to allow him to obtain the reward for his creative effort. It is therefore necessary to allow the patent proprietor to prevent the importation and marketing of products manufactured under a compulsory licence in order to protect the substance of his exclusive rights under his patent.' Cf. *Demaret*, 18 IIC 2 (1987) p. 173-174, 189, *Hestermeyer*, 37 GRURInt 3 (2004) p. 198.

505 Predominantly means 'numerical superiority, majority'. Cf. Webster's Third New International Dic-tionary.

506 This will not apply in jurisdictions where no valid patent exists or where a compulsory license exists for the importation of the patent product.

satisfy a foreign demand may not theoretically break the letter of the law but could very well break the spirit of the agreement, thus meaning the use and interpretation of Article 31(f) is no longer in good faith.

The limiting of compulsory licenses to the domestic market, although rational and justifiable on the whole, has a detrimental effect on small and poor Member States who are unable to exercise the compulsory license locally.[507] Being unable to exercise the license locally, Member States would be required to look to other countries to import the product. As the patent system is a territorial system, a domestic compulsory license would not be recognised in any other country.[508] The effect is that a Member State without the necessary production facility would only be able to use a compulsory license to permit international exhaustion of the intellectual property rights, alternatively permit the importation of the product produced in countries where there is no patent on the product or where it is also subject to a compulsory license.[509] Although these might appear to be reasonable alternatives, the restriction has significant effects. Firstly, restrictive use of compulsory licenses by all countries means that the chances of importing the licensed product from another country would indeed be slim. This would be accentuated by the unlikelihood that that country would have similar conditions under which the license was granted, either by time or scope, and it would be unclear whether the license holder would be in the legal or physical position to supply a second market. The second undesired effect why the limitation in Article 31(f) is significant is because the number of countries without patent protection has considerably decreased.[510] Those remaining countries without patent protection are, in the vast majority, countries that are themselves either poor or small. Patent holders are quick to note that where there are no or few local production facilities for their product, the likelihood that they would be subjected to a compulsory license is remote. Thus, a patent holder only needs to register patents for his products in those countries which have a production facility in order to have a control of the entire global market.

Prior to 2005 however, the likelihood of such market closure was reduced because a number of large Member States, including India and Brazil, were not re-

507 The inability to exercise a compulsory license stems from the lack of domestic production facilities (either complete absence or insufficient technical ability) and/or insufficient domestic facilities. The latter includes the physical inability on a supply/demand basis and the subjective inability where the owner of the production facility is unwilling to assist or where the production capacities are reserved for the production of other products.

508 There have been calls to unite or recognise the compulsory license system in the European Communities for almost 20 years. The EC Member State markets remain fragmented. Cf. *Demaret*, 18 IIC 2 (1987) p. 190-191.

509 In this case only the licensee in the importing country would be entitled to import the licensed product from the exporting country.

510 In 2005 the final transitional periods set out in Art 65 for the implementation of the TRIPS Agreement for WTO developing Member States expired. LDCs are subject to a separate transitional period. This period was extended to 2016 by the Decision of the WTO General Council 'Least-developed country Members – Obligations under Article 70.9 of the TRIPS Agreement with respect to pharmaceutical products' (08.07.2002) WT/L/478.

quired to grant patents to pharmaceutical products. Not bound by the patent rights, these countries were able to satisfy a large portion of the demand for affordable generic medicines. The ability to acquire generic pharmaceuticals from these countries provided the small and poor countries with an alternative and eased the negative effect of Article 31(f). The expiry of this exception at the end of 2004 has meant that those countries relying on the imports from India and Brazil will have to increasingly look for other alternatives, thus making the restrictions in Article 31(f) increasingly problematic.

The inability to satisfy a compulsory license nationally or internationally has meant that many Member States are hostages of Article 31(f) and at the mercy of the patent holders. This is particularly alarming in the health sector where pharmaceutical prices and widespread diseases have made access to affordable medicines difficult. In addition to not being able to use the compulsory license system for general public interest purposes, small and poor countries are further unable to use compulsory licenses to punish or counter abusive and anti-competitive patent practices.[511] The lack of a functioning check-and-balance process within the TRIPS Agreement for such Member States effectively means that the agreement is failing to achieve its stated objectives and principles in Articles 7 and 8.[512]

The contents of Article 31(f), in context with the WTO Agreements as a whole, do permit a degree of flexibility. Although the ordinary meaning of 'domestic' would tend to limit it to a single country, the WTO Agreements are prepared to regard customs unions and free trade areas as constituting a single market for certain purposes.[513] By applying the term 'domestic' as found in the Agreement on Safeguards to the Article 31 of the TRIPS Agreement, a compulsory licensed product produced in one country could be used to satisfy a demand from other countries in the union, provided that all the countries are subject to the same threat. Further, and

511 As anti-competitive practices are a barrier to trade and Art 31(f) prevents certain Member States from taking steps to rectify the abuse, the TRIPS provisions themselves become a barrier to legitimate trade – a goal the negotiating parties had set for the TRIPS Agreement. Notwithstanding this, Art 31(k) is an exception to the requirement for predominant local supply. It enables 50% or more of the produced items under a compulsory license to be exported where the license has been granted to remedy anti-competitive practices. An administrative or judicial decision acknowledging the anti-competitive acts of the patent holder must however be the basis for the non-application of Art 31(f). This will not however alter the predicament many LDCs suffer as the LDCs will only benefit where there have been simultaneous anti-competitive practices. In the case of pharmaceuticals, this will be rare as most prices are regulated by price controls and would thus not be deemed anti-competitive on price alone.

512 The preamble of the TRIPS Agreement grants LDCs an additional degree of flexibility in interpreting and implementing the TRIPS Agreement. This added manoeuvrability does not aid LDCs significantly. Firstly, LDCs are permitted to implement Art 31(f) in a flexible manner. It does not permit them to avoid its application. Secondly, the availability of the 'maximum flexibility' refers to the LDCs domestic laws and regulations and not to the laws from which the products would be sourced.

513 Agreement on Safeguards fn. 1 to Art 2, GATT Agreement Art XXIV and GATS Agreement Art V

provided the licensed product is patented in all the states in the union, all the states would be required to issue a compulsory license for its use. This would ensure that the patent holder receives the compensation it is due. A potential beneficiary of such an interpretation would be the Southern African Customs Union (SACU).[514] In terms hereof SACU would be able to produce medicines to satisfy the HIV/AIDS – a threat that is common to all of the SACU states. In the case of developing countries, a regional market would make more economic sense and would be more likely to establish the required markets of scale.

A further potential means to overcome the limitation in Article 31(f) has been suggested by *Abbott*.[515] He states that the definition of 'predominantly' as meaning 'as having supremacy over others' only requires that the domestic use outweigh the use in each other country importing the licensed product. This approach would, for example, permit the license holder to export 60% of its production to 3 countries (3 x 20% = 60%) and retain 40% for domestic production. Numerous quantity levels are permissible, provided they do not exceed the amounts produced for domestic use. Whereas this approach is hypothetically plausible, it is doubtful whether this could actually be realistically implemented or sustained.

The territorial nature of intellectual property rights and the strong desire of developed countries and other IPR advocates to solidify their rights globally have forced many LDCs and developing countries within the WTO to implement a system that denies them the ability to address deficiencies in their patent system. Article 31(f) thus forms an obstacle for small or poor Member States seeking to address patent abuses or threats. The flexibility of the provision provides little practical assistance to the lone Member State, thus creating a situation whereby the TRIPS Agreement becomes an impediment to the effective management of intellectual property rights.[516]

i) Article 31(g)

> 'authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led

514 The EC/South Africa FTA defines the South African domestic market as being SACU. Cf. EC-South Africa Trade, Development and Cooperation Agreement, [1999] OJ L 311/3. The EC would also meet the requirements here. Its position as a single market is amplified by the status it is given in the WTO Agreement where it is repeatedly given a similar treatment to independent contracting parties. Cf. WTO Agreement Arts IX, XI, XIV.

515 *Abbott,* Quaker Paper 9 (2002) p. 26.

516 The number of countries with no or limited pharmaceutical production facilities is extensive. 60 countries have no pharmaceutical industry and an additional 89 only have the ability to produce finished products. The total number of states not able to produce their own active ingredients amounts to 149. This amount would probably increase in respect to the complex manufacture processes necessary to produce pharmaceuticals for the treatment of HIV/AIDS. Cf. *Balance et al,* The World's Pharmaceutical Industry: An International Perspective on Innovation, Competition and Policy (Edward Elgar Aldershot 1992) p. 8-9.

to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances'

If a compulsory license is granted for a particular reason, it follows from natural justice that the patent holder is legitimately entitled to expect the compulsory license to terminate when the grounds that brought about the grant ceases to exist. Article 31(g) reflects this expectation, subject to two qualifications. Firstly, it recognises the interests of the license holder by requiring the 'adequate protection of [his] legitimate rights'. Secondly, the circumstances that led to the grant of the license must be 'unlikely to recur'.

The first licensee safeguard is the protection of its 'legitimate interests'. In the WTO *Canada –Pharmaceuticals* case the panel defined the term as being:

> 'a normative claim calling for protection of interests that are 'justifiable' in the sense that they are supported by relevant public policies or other social norms.' [517]

The conclusion reached by the Panel in the WTO *Canada –Pharmaceuticals* case acknowledges that the limitation and/or fortification of the licensee's interests can be based upon underlying public interest and social norms.[518] Further, where the authority tasked with reviewing the compulsory license has concluded that the original grounds for granting the compulsory license no longer exists (and are not likely to reoccur) the reviewing authority will nevertheless be able to deny the termination of the license where it is of the opinion that the licensee's interests will be unreasonably prejudiced.

The manner chosen to ensure the licensee acquires its due reward is a national prerogative and would permit Member States to postpone the termination of the compulsory license for, *inter alia*, the following reasons:

- the license holder has yet to recoup his investments and ancillary costs incurred for the production and distribution of the license and
- the license holder has not acquired a reasonable return for the use of the license.

The rationale behind the protection afforded to the rights of the license holder is two-fold. On the one hand, Member States need to ensure that the licensee is not prejudiced by the early termination of the compulsory license.[519] On the other hand, the poor or unreasonable treatment of a compulsory license holder will negatively reflect on future license applicants. By deterring future compulsory license applicants, a Member State will lessen the public interest purpose of compulsory licenses

517 WTO *Canada – Pharmaceuticals* p. 164. The interpretation of 'legitimate interests' in this case derived from its use in Art 30 of the TRIPS Agreement. Having regard for the Panel's method of the interpretation, i.e. determining its meaning in a general legal context, the *mutatis mutandis* application of this interpretation in the context of Art 31(g) is justified.

518 *de Carvalho* notes that the term 'legitimate interests' extends beyond 'legal interests. The scope of the term mirrors that of the scope the same term in Art 30. Cf. *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 245.

519 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 247-248.

and will encourage more restrictive practices by patent holders.[520] A Member State must therefore ensure that the treatment of the licensee is adequate enough to ensure the continued viability of the compulsory license system. This in turn means that an early termination of the compulsory license should not automatically prevent the licensee from being able to recoup the investment in resources and from making a reasonable financial return on the license.[521] In addition to the financial security, protection must also extend to preventing the licensee from unfair and undermining practices by the patent holder.

As the return on the use of the license is not prohibited by the TRIPS Agreement it can be used as an incentive by Member States to encourage individuals and businesses to apply for compulsory licenses. As Article 31(g) only requires the reviewing authority to consider whether or not the grounds have expired and if they are likely to recur, evidence that the license holder is deriving large profits, as long as they were not made a condition of the license grant, need not be considered in reviewing the continued existence of the compulsory license. The potential however for an abuse of the license is also real. In order to ensure the license holder does not make an inappropriate profit, Member States have a number of TRIPS-consistent measures that can be used to safeguard the sanctity of the compulsory license; they include permitting additional compulsory license holders, limiting the period of the license and permit its renewal only on certain grounds, requiring additional compensation to be paid by the license holder to the patent holder and finally, a Member State can simply terminate the license on the grounds of abuse. The controls placed on a license holder are of particular importance in instances where the license is being used to rectify price abuses and anti-competitive practices on behalf of the patent holder. By permitting the license holder to conduct itself in a similar abusive way would be contrary to the ideology behind compulsory licenses.

Absent from the review process is the influence of third party rights, i.e. consumer's interests or other public interests, on the termination of the compulsory license. The objectives and principles mentioned in Articles 7 and 8 will not be able to inject an additional public interest requirement into the qualification mentioned in Article 31(g).[522] Member States willing to ensure the continued presence of a public interest requirement would be advised to make the public interest a ground for the granting of the compulsory license. This would subject the applicant in the review of the license to having the onus to prove, in addition to all the other potential grounds, that the termination of the license is not contrary to the public interest and that the public interest's grounds have expired.

The second safeguard, the reoccurrence of the circumstances that led to the granting of the compulsory license, is a common sense provision: even if the grounds for

520 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 248.

521 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 474-479, *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 248.

522 This applies equally for the interests of the patent holder.

the compulsory license have disappeared, the compulsory license will not be terminated if there is a real threat that they will reoccur.[523] As the existence of a potential threat is sufficient to authorise the grant of a compulsory license it would be an unreasonable impairment of the licensee's rights to terminate the compulsory license where the threat remains.[524] To prove that the likelihood of the circumstances will not reoccur, the patent holder has the onus to provide sufficient evidence and/or guarantees that would satisfy the reviewing authority. This may include the declaration ending a national emergency, the objective findings that an extreme urgency has ceased and that the consequences thereof have been treated, the government use of the patent is no longer required, the dismantling of anti-competitive practices and the implementation of measures to prevent their reoccurrence[525] and the proof that the aided local industry is economically able to compete fairly and without the aid of a compulsory license and production no longer needs the compulsory license.

The closing sentence in Article 31(g) obliges the Member States to create a viable review mechanism to consider the validity of a termination application. A review process must, where the applicant is the patent holder, permit both the applicant and the license holder the ability to bring evidence to substantiate their positions.[526]

Article 31(g) phrases the review process as 'the authority to review … the continued existence of the circumstances'. The formulation of the Article 31(g) text thus appears to favour putting the onus in proving the termination of the compulsory license grounds on the party seeking to terminate the license – in most cases the patent holder. Further, as the request is to be motivated, the TRIPS Agreement does not provide for the automatic termination of the license prior to the period set out in the compulsory license. The degree of 'motivation' required by the reviewing authority is a matter for national regulation and may encompass proof that the early termination of the compulsory license will not unreasonably affect the legitimate interests of the licensee.

By incorporating the safeguards of non-reoccurrence and adequate protection for the legitimate interests of the license holder, Article 31(g) ensures that the termination of compulsory licenses will not occur at the expense of the license holder. The wisdom of the inclusion of these safeguards is clear: without the protection of the compulsory license holder, the compulsory license system as a whole would fail.

j) Article 31(h)

> 'the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization'

523 The TRIPS Agreement does not require the *ex post facto* reassessment of compulsory license grant where there is a change in the circumstances that led to the compulsory license. Also TRIPS Agreement Art 31(k).

524 Chapter 5(C)(III)(3)(d) above on page 95.

525 Such as granting licenses to third parties and guaranteeing reasonable pricing structures.

526 TRIPS Agreement Arts 31(g & i) and 42.

A patent holder subject to a compulsory license is entitled to remuneration. The TRIPS Agreement expressly confirms this in Article 31(h). Notwithstanding this, neither the type of remuneration nor the calculation thereof is set out in the TRIPS Agreement.

The correlation between license and remuneration implies that the responsibility for the remuneration lies with the license holder. Whereas this may prove to be the most common approach adopted by Member States, the TRIPS Agreement does not require this. The granting authority has the freedom to apportion the duty to remunerate to the party it feels most appropriate, be it the licensee, the state or a third party. Member States may create special legislative vehicles to provide for the remuneration in special instances, e.g. to attend to public interest needs.

The remuneration itself may take numerous forms. Where it is indeed granted, it may be awarded either as a once-off monetary payment, monthly instalments and/or a percentage of the sales or profit made by the licensee. It may even take a non-monetary form. It would thus be TRIPS-conform for a Member State to remunerate the patent holder with an extended patent exclusivity period. This would enable Member States lacking financial resources to grant the patent holder an additional period to work the patent – a reasonable remuneration where the license grant was not as a result of the patent holder's abusive or culpable conduct.

The only qualification on the remuneration requirement is that it be 'adequate'. This qualification serves rather as a proportionality requirement than a limitation. As such Member States possess substantial flexibility when interpreting and implementing the provision domestically.[527] Member States can take into account a wide spectrum of information that may affect the amount and form of the remuneration granted. Circumstances that affect the remuneration may arise from the actions of the patent holder, from the actions of the license applicant, whether the license is granted for the import of the product or not[528] and the current or future political, social, economic and legal circumstances in which the Member State finds itself.

The freedom to determine what is adequate is itself qualified. Article 31(h) requires that the 'economic value of the authorisation' be taken into account.[529] 'Authorisation', as seen within the context of Article 31, refers to the grant of the actual compulsory license. Thus, one should rightly ask: what economic value does the license have? The value of the license can be determined in two principal ways: the loss of value to the patent holder and the gain in value to the licensee. Remunerating the loss of the patent holder means that Article 31(g) would effectively 'compensate' the patent holder for the loss it suffers. The negotiating history of Article 31(h)

527 'Adequate' can mean both 'fully sufficient … or barely sufficient: no more than satisfactory'. Cf. Webster's Third New International Dictionary.

528 A compulsory license granted for the importation of a patented product put onto the market with the patent holder's consent will be a reason to reduce the amount of compensation to be paid as the patent holder has already received due compensation from the first sale of the product. Cf. *Abbott,* Quaker Paper 9 (2002) p. 49.

529 The requirement to take into account does not oblige the Member States to abide by it. Other factors may be more relevant in that individual case.

shows that no single approach to the calculation of the remuneration could be agreed upon. The Anell Draft contained the following suggestion:

> 'The payment of … remuneration to the right holder adequate to compensate the right holder fully for the licence … shall be required.'[530]

Although the remuneration need not automatically equate to the damages suffered, it appears that this correlation finds more use and acceptance. The US courts have taken the view that it is not the compulsory licensee's gains that serve to determine the remuneration paid but the losses suffered by the patent holder.[531] *de Carvalho* draws a correlation between the Arts 31(g) and 44.2 and takes the view that adequate remuneration should equate to the damages. Further he states that the calculation of the remuneration should be a pure financial equation and not one swayed by political considerations.[532]

Although damages may be used to calculate the remuneration, Article 31(h) does not expressly require this approach. Another approach that would reflect the terms of Article 31(h) would be to use the 'economic value of the authorisation' as a starting point and, once a value is found, ask it this is adequate in the circumstances of the case in question. This means that as the compulsory license vests in the licensee, i.e. the authorisation is for its benefit, the added value of the license brings represents the real value of the authorisation.[533] Taking this approach the economic value (E) may be determined as the income derived from the sales of the licensed product (I) less the capital (C) and resource (R) investments.

$$E = I - (C + R)$$

Such a calculation method is likely to acquire more social acceptance as it would ensure that non-profit orientated licensees, such as certain NGOs, would pay minimal amounts and for-profit orientated licensees a greater more socially justifiable amount.[534]

In addition to the economic value factor and the Member State methods of implementation thereof, the TRIPS Agreement permits a great deal more flexibility by permitting the Member States to elect which factors they consider relevant. These include, to whatever extent deemed necessary, the following factors:

530 GATT Chairman's Report to the GNG Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods (23.07.1990) MTN.GNG/NG11/W/76 ('Anell Draft') p. 2.

531 The US 28 USC 1498(a) for its part speaks of 'reasonable and entire compensation'. This was interpreted to mean "[b]ecause Recovery is based on eminent domain, the proper measure [of compensation] is 'what the owner has lost, not what the taker has gained'". Cf. *Leesona Corp. v. United States* 599 F.2d 958 (Ct. Cl. 1979) p. 969.

532 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 246-247.

533 This approach is also adopted by patent holders in voluntary licenses. The patent holder does not ask what loss it will suffer from the license but rather what share of the financial gains of the licensee will it be able to demand without scaring away potential licensees.

534 *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen (Nomos Baden Baden 2002) p. 288.

- government policies, including industrial development objectives and emergency treatment goals
- subsidies available and/or used by the patent holder in researching, developing and marketing the product prior to the compulsory license application[535]
- the pricing of the product[536]
- the 'reasonable commercial terms' proposed in the negotiation stage[537]
- patent holder practices in other countries including conducting technological transfers
- the economic status of the licensing country and the availability of national resources
- the amortisation of the patent[538]
- the potential users of the licensed product
- the cost of exercising the license
- the function of the compulsory licenses, i.e. to redress abusive practices[539] or attend to public interest issues[540] and
- the urgency of the production.[541]

The special attention afforded to medicines has also led to pharmaceutical-specific factors when considering the remuneration of a pharmaceutical patent holder.[542] They include, *inter alia*:

- the therapeutic value of the medicine (best in class), including the extent to which it represents a pharmacoeconomic advance over other available products[543]
- the ability of the public to pay for the medicine
- actual, documented expenditures on development of the medicine

535 Likewise the costs of the R&D and marketing approval may also be taken into account. Cf. *Sykes*, 3 Chi. J. Intl. L (2002) p. 68, *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 247.

536 Where the purpose of the compulsory license is to lower prices and encourage access, the remuneration award should assist and not aggravate the purpose. Cf. *Love*, WHO Health Economics and Drugs TCM Series No.18 (2005) p. 6.

537 TRIPS Agreement Art 31(b).

538 *Correa*, 16 EIPR. 8 (1994) p. 333.

539 *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 252.

540 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 476.

541 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 476.

542 The JPO royalty guidelines as applied in *Love*, WHO Health Economics and Drugs TCM Series No.18 (2005) p. 69-79.

543 For an evaluation of the use of the pharmacoeconomic assessment in the pricing of pharmaceuticals see *Dickson et al*, OECD (2003).

- the extent to which the invention benefited from publicly funded research subsidies available and/or used by the patent holder in researching, developing and marketing the product prior to the compulsory license application[544]
- the need to respond to public health emergencies
- the importance of the patented invention to the final product and
- the cumulative global revenues and profitability of the invention.

The status of developing countries is a particularly relevant factor in determining remuneration. The lack of state financial resources and the poverty of its citizens are factors that can weigh heavily on determining what is deemed 'adequate'. Some remuneration calculation methods advocate, for example, the apportionment of marginal and R&D costs according to the countries share in the world income and, as a result, reach remuneration figures that are very low – some at zero and some negative.[545]

In order to determine what this value may be, Member States have applied a number of methods. The 'market rate' uses the current market royalty rates and practices, i.e. patent holders pricing system for sales and/or the sector's licensing practices to determine the economic value.[546] The problem with the use of the current commercial practices is that they are potentially subjected to active or passive colluding practices and inter-sector pricing strategies that do not exist in the market as a whole.[547] Using the entire domestic market as a reference may also be inappropriate. This is especially the case in many markets characterised by large wealth differences amongst the population – a situation common to developing countries. In addition hereto, the use of the patent holder's pricing and/or licensing formulas would defeat the object if a compulsory license was granted on excessive pricing grounds. An attempt to find a similar 'like' product on which to base the pricing also presents problems as a patent, by nature, must be able to distinguish itself from other inventions. The problem with the market rate method is accentuated in small markets where market distortions have an amplified effect. Although using a regional market price could assist in some instances, the use of additional foreign factors may complicate and burden the process further.[548] Other systems for determining value propose requiring the patent holder to put forward a royalty suggestion and placing

544 Likewise the costs of the R&D may also be taken into account. Cf. *Sykes*, 3 Chi. J. Intl. L (2002) p. 68.

545 *Jack and Lanjouw*, 19 WBER 1 (2005) p. 64.

546 *Goldschneider*, 36 IDEA 1 (1996) p. 190. This method is also called the 'willing buyer-willing seller' method. To establish this price US courts have identified 15 factors that, under a hypothetical license negotiation, would assist in determining the compensation. Cf. *Georgia-Pacific Corp v. United Stated Plywood-Champion Papers* 318 F.Supp. 1116 6 USPQ 235 (SD NY 1970).

547 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 476.

548 Only where the regional market is (relatively) free from diverging state-controlled interventions in price formulations and the sufficiently similar (e.g. the EC) will the regional market be of assistance.

the onus on the patent holder to substantiate the amount by providing documentation and facts to support its suggestion. Such a system enables the granting authority to address all the concerns raised by the patent holder. A similar system would be to determine the actual costs the patent holder has incurred in bringing the product to the market. Other systems base the remuneration on the production sales of the license holder, using a royalty percentage of the wholesale price.[549] These methods primarily consider the patent holder's position and practices in the market.

Comparing specific national compulsory license practices with the TRIPS Agreement provides assistance in determining which domestic approaches suite which country. In the US the value of the compulsory license is central to determining the remuneration paid. In terms of 28 USC 1498 the US is required to compensate the patent holder for the government use of the patent on the basis of what 'is lost by the taking'[550] – not what the license holder has gained.[551] The so-called 'lost profits' test, if applied strictly, can lead to high levels of remuneration.[552] Despite the USC's requirements, the US courts have not limited themselves to remunerating the patent holder for its lost profits.[553] Instead US courts have applied other tests to calculate the remuneration, e.g. the 'reasonable royalty' standard and 'government savings'.[554] In practice, and notwithstanding 28 USC 1498(a) requiring 'reasonable and entire compensation',[555] some US compensation awards have ranged from royalties as high as 10% and as low as 1%,[556] and in some cases even 0%.[557] Notwithstanding the wide range of the royalty percentages, a general guideline in US proceedings has been established that where no evidence can be brought to the contrary, a 6% royalty will be applied.[558]

549 *Abbott*, Quaker Paper 9 (2002) p. 46.
550 *Goldschneider*, 36 IDEA 1 (1996) p. 189.
551 *Gargoyles Inc. and Pro-Tec, Inc. v. the United States* 113 F.3d 1572 (96-5089,-5094), *Hughes Aircraft v. United States* 86 F.3d 1566 (Fed. Cir. 1996).
552 *Scherer and Watal*, 5 JIEL 4 (2002) p. 913, 920-922.
553 *Goldschneider*, 36 IDEA 1 (1996) p. 188-190.
554 The US Patent Code, 35 USC 284, provides that in cases of patent infringement, the damages awarded shall be 'adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs'.
555 The reference to remuneration in Arts 1709(10)(h) and (j) and 1715 of NAFTA were implemented to reflect the 28 USC 1498(a) requirement of 'reasonable and entire compensation'. See in this regard the White House Executive Order 12889 of 28.12.1993
556 *Hughes Aircraft v. United States* 31 Fed. Cl. 481 35 U.S.P.Q.2d (BNA) 1243 (1994). The Court of Claims refused Hughes' claim for a 15% royalty on the use of it geostationary orbit technology. Royalties of 0.01% have also been paid for the government use of liquid-propelled rockets. Cf. *Scherer and Watal*, 5 JIEL 4 (2002) p. 913, 920-922.
557 *Scherer and Watal*, 5 JIEL 4 (2002) p. 917. The examples included referred to compulsory licenses granted as a result of anti-competitive behaviour on behalf of the patent holder. Cf. *Goldschneider*, 36 IDEA 1 (1996) p. 188-190.
558 *Scherer and Watal*, 5 JIEL 4 (2002) p. 922.

In Canada, and prior to the TRIPS Agreement, it was practice to award 4% of the generic price as reasonable remuneration for the rights holder.[559] The UK on the other hand has used a cost- and profit-based system whereby the patent holder's median research, development and testing costs were determined and a profit margin was calculated thereon to produce a royalty to compound weight rate.[560] The UK's pre-TRIPS royalty rates ranged between 18 and 22%.[561] The German Federal Patent Court found an 8% royalty to be an adequate remuneration.[562] See Annex IV below for a tabular summary of remunerations given in instances of compulsory licenses.

A further remuneration relevant factor is whether or not the compulsory license was granted for culpable and non-culpable acts of the patent holder. The actions of a patent holder will be of extreme relevance where it has been found guilty of using the patent in an anti-competitive manner.[563] The function of Article 31 of the TRIPS Agreement in redressing anti-competitive practices is to use the expropriation of the patent holder's rights to serve as an indirect punishment for the culpable behaviour.[564] Excessive pricing, dominance abuse, restrictive licensing practices and other inappropriate behaviour by the patent holder could also be qualified by Member States as being anti-competitive practices and thus also subject to remedial measures in the form of compulsory licenses with little or no remuneration. Remunerating the patent holder would potentially negate the punitive effects of the compulsory license.[565] This thought is mirrored in the 'clean-hands' doctrine[566] which states that

559 *Frank W Horner Ltd. v. Hoffmann-La Roche Ltd.* [1970] 61 Ex CR. 243. The Exchequer Court rejected the contention that compensation could also be claimed for research and development outlays. This practice was uniformly adopted thereafter for other similar compulsory license orders. Contrast *Sykes*, 3 Chi. J. Intl. L (2002) p. 68.

560 Sec 57 A of the UK Patent Act of 1977 makes allowance for the compensation of the patent holder for government use of the patent. Licenses of right must provide for a royalty on a 'willing licensor and a willing licensee' basis. Cf. *UK Patent Office*, Manual of Patent Practice (5th edn The Patent Office London 2003) p. 48.18.

561 *Scherer and Watal*, 5 JIEL 4 (2002) p. 923

562 *Compulsory License*, BGH 28 IIC 1997 p. 242. The compulsory license was however denied on appeal to the BGH. Cf. *Kraßer,* Patentrecht (5th edn CH Beck Munich 2004) p. 861. In sec 24(5)(5) of the German Patent Act states that the patent holder has a claim for adequate compensation, in accordance with the circumstances of that matter, taking into account the economic value of the license

563 TRIPS Agreement Art 31(k).

564 The ECJ has taken the position that even the threat of anti-competitive behaviour may also form the basis for a compulsory license. Cf. *Leupold and Pautke*, 16 EWS 3(2005) p. 113-114.

565 Most competition systems provide for pecuniary penalties to counter anti-competitive practices. It is also possible that such penalties are also accompanied by compulsory licenses. Cf. *Leupold and Pautke*, 16 EWS 3(2005) p. 109 and 115, *Microsoft* (Case COMP/C-3/37.792) EC Commission Decision C(2004) 900 final [2004] p. 299.

566 The 'clean-hands' doctrine (also 'unclean-hands') is defined as the 'principle that a party cannot seek equitable relief or assert an equitable defence if that party has violated an equitable principle'. Cf. Webster's Third New International Dictionary.

the court will not assist the party who has acted in an unethical or immoral way.[567] US courts for their part have confirmed royalty fees of 0% as being 'reasonable and entire compensation' as dictated under 28 USC 1498(a).[568] The computer company Dell consented to a royalty-free license after the FTC sued the company for patent abuse.[569]

Determining remuneration may, and in some cases does, justify separate proceedings to the main compulsory license proceedings.[570] One of the reasons for this is that the calculation of remuneration is often a complicated and lengthy task. In addition to ensuring the remuneration amount is dependent on the economic wealth of a country the UNDP's Human Development Report highlighted the importance of a 'predictable and easy to administer' remuneration system.[571]To achieve this some Member States have implemented remuneration guidelines.[572]

The legal weight the granting or awarding authority lends to the various factors is not dealt with in the TRIPS Agreement; the relevant authorities and/or the state may apportion their own weight thereto and may make for preferences and/or presumptions in favour of one or the other factor. The formulation used in Article 31(h) thus leads to the conclusion that remuneration need not merely consider the interests of the patent holder and the licensee but can and, in light of the scope and purpose of the TRIPS Agreement, should also consider the interests of the public at large.[573]

k) Article 31(i and j)

> '(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
>
> (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member'.

567 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 249. US courts have acknowledged that this doctrine also applies with regards to disclosures made to the US PTO. Cf. *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery* 324 US 806 (1945).

568 *Scherer and Watal*, 5 JIEL 4 (2002) p. 917.

569 *Verbruggen and Lõrinz*, 33 IIC 2 (2002) p. 139-140.

570 Art 31(j) of the TRIPS Agreement expressly requires Member States to provide for the judicial and/or administrative review of a remuneration order. The obligation mirrors the *separate* obligation to allow the review of the compulsory license award.

571 *UNDP*, Human Development Report 2001 (OUP New York 2001) p. 108.

572 For example Japan ('New Guidelines for Licensing Patents Owned by the Government' <http://www.okuyama.com/news.html> (26.01.2006)) and Ghana (*Cohen et al*, 1 Globalization and Health 17 (2005) p. 5).

573 *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen (Nomos Baden Baden 2002) p. 287.

The rule-of-law, renewed in the Uruguay Round, is evident throughout the WTO Agreements as any non-compliance is subject to judicial review.[574] The DSB, especially created to attend to the adjudication and enforcement of the WTO Agreements, highlights the goal of introducing a system whereby compliance could be determined and reviewed. The TRIPS Agreement, specifically empowered to regulate private rights, extends the rule of law by requiring Member States to allow private individuals the ability to challenge the authorisation, alteration, remuneration and termination of compulsory licenses.[575]

The obligations created by Articles 31(i and j) only require a system whereby the decision of the granting authority can be reviewed, and thus potentially amended or rejected by a body of higher standing than the authority that made the initial order. Article 41.4 of the TRIPS Agreement extends the review by permitting the parties to the proceedings the opportunity to have the review of 'all final administrative decisions' to be conducted by a judicial authority.

As Articles 31(i and j) independently address the actual compulsory license authorisation order and the remuneration order, either order should be able to be reviewed independently of the other. The separation of these two procedures is an indication firstly of the possibility that some Member States may provide for separate procedures and secondly of the importance of the remuneration to the patent holders.

In terms of Article 44.2 of the TRIPS Agreement permits Member States to limit the remedies available to patent holders to remuneration alone. Thus, a Member State would be entitled to deny a patent holder the review, either by way of an injunction or an appeal, of a compulsory license authorisation. This approach has been actively applied by the US[576] and, as a result of the ensuing procedural benefits for government agencies and their contractors, could present many Member States with an alternative compulsory license process that is both simplified and TRIPS-compliant. In a recent patent infringement the US Supreme Court refused to grant an injured patent holders a permanent injunction against the infringing party (thus permitting the infringement to continue) on equity grounds.[577]

The existence of the review mechanisms in Articles 31(i and j) are, as a result of Article 41.4, not strictly necessary. The Article 41.4 obligation to provide for judicial reviews of administrative decisions is a general obligation. Articles 31 (i and j)

574 TRIPS Agreement Preamble, GATS Art XXII and XXIII and Agreement establishing the WTO Art III.

575 Art 31(i) requires the opportunity for a review of 'any decision relating to the authorisation [of the] use' of the compulsory license. 'Use' is to be interpreted in the context of the chapeau and Art 31 (c). The 'authorisation' of 'any decision relating' to such use thus encompasses any decision relating to the authorisation, alteration and termination of a compulsory license. Art 31(j) extends this to remuneration.

576 28 USC 1498. See *Aichele and Godici,* 1 JIPLP 10 (2006) p. 633.

577 *eBay Inc. v. MercExchange* 547 U.S. 388 (2006). The court stated that the equity discretion is 'well suited to allow courts to adapt to the repaid technological and legal developments in the patent system'. Cf. *Bravin et al*, EBay wins latest round of US patent battle, Wall Street Journal Europe (Brussels Belgium 16.05.2006) p. 2.

make certain however that the exceptions to Article 41.4 do not apply to compulsory licenses.[578] The *lex specialis* nature of Articles 31 (i and j) ensures however that there is a clear and irrefutable obligation to provide for a review opportunity.[579] The express protection of compulsory licenses is an indication of the level of importance the non-voluntary use of the invention has in relation to the other rights afforded in the TRIPS Agreement.

The TRIPS Agreement does not indicate how a Member State is to fulfil the obligations set out in Articles 31 (i and j). The absence of a definitive obligation enables Member States to permit the continued use of a license, even whilst it is subject to a review process, i.e. preventing a suspensive effect.[580] The exclusion of a suspensive clause will enable Member States with limited legal resources and/or lengthy appeals processes to ensure the patent holder does not simply enter an appeal to delay the use of a compulsory license.[581]

The structure and procedures for the reviews required under Article 31(i and j) are not stipulated in the TRIPS Agreement. To cater to this Member States have created specific procedures to attend to the review process. The most prominent example is the US's Court of Federal Claims. § 1498 of USC Title 28 states that 'the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.'[582] In the light of the circumstances of extreme urgency noted in Article 31(b) and their corresponding fast-track provisions, it would be well within the scope of the TRIPS Agreement for a Member State to suspend the review until the emergency is under control. It would further be TRIPS-compliant to create a separate legal procedure for compulsory license reviews in emergency situations, where the normal rule of law is suspended.[583]

578 Doubt may have arisen when Art 41.2 is seen in the greater context of Art 41. Art 41.1 refers to protective measures to permit effective action against infringements. As a compulsory license is not an infringement Art 41.4 may have been interpreted as only applying to administrative decisions made in respect of infringement matters – thus excluding compulsory license decisions.

579 Subject to Art 44.2 TRIPS Agreement.

580 The suspensive effect of appeals in patent related decisions in not uncommon, see for example sec 75 of the German Patent Act, Art 106(1) of the EPC. Examples exist where the contrary is true, for example Art 49 of the Argentinean Patent and Utility Models Law and Art 73(8) of the Brazilian Law No. 9.279 to Regulate Rights and Obligations Relating to Industrial Property. For a discussion of the US's approach see *Taub*, 6 J. Marshall Rev. Intell. Prop. L 1(2006) p. 151-184.

581 The patent holder's rights are not unreasonably prejudiced as a decision dealing with the merits of the matter has already been considered and approved. The suspensive effect would pose more of a prejudice to the licensee as the lack of the suspension would to the patent holder.

582 Compare German Patent Act sec 13.

583 For example under martial law. Cf. *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 478.

l) Article 31(k)

> 'Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur'.

This Article has been referred to within the scope of Articles 31 (b and f) and as such these elements will not be dealt with here. However, as anti-competitive procedures are playing more of a role in intellectual property rights, a brief mention will be made as to a Member States ability to remedy patent rights abuses through anti-competitive practices.

As mentioned in Chapter 5(B)(IV) Seite 56 above, intellectual property rights are an exception to the general prohibition against trade restraints, as they further trade and mankind indirectly. As society has developed, the use of patent grants has become more sophisticated. This sophistication combined with the globalisation of patent rights and the desire of patent holders to protect their invention for as long as possible with a scope as wide as permissible, permits the patent holder a minimum level of global uniform protection.[584] The spread of the patent holder's rights will increasingly result in fewer off-patent products being available on the international market. Thus, such Member States will be obliged to pay the prices the patent holder demands for the patented product. With the likely increase in prices that will follow, it also seems likely that Member States will make more use of the anti-competitive provisions in the TRIPS Agreement to counter unaffordable prices. The freedom a Member State is permitted, to determine what is deemed anti-competitive, will make Article 31 a viable option for Member States unable to afford access to the patented product.

m) Conclusion

The implementation and use of Article 31 by Member States contains significant opportunities to exercise compulsory licenses in a manner that suits its individual domestic circumstances.[585] In adopting a system laden with flexibilities, the implementation of the TRIPS Agreement has led to diverging stances as to the extent to which the flexibilities can and must be applied.[586] This uncertainty, combined with

584 Diverging national laws, inconsistent domestic implementation and the occasional unwillingness to comply with these rules sometimes give the appearance that the protection is not uniform. It must also be recalled that some Member States (certain LDCs) are not required to implement certain intellectual property rights until 2016.

585 *Watal*, Intellectual Property Rights in the WTO and Developing Countries (Kluwer The Hague 2001) p. 327.

586 See for example *Kiehl* which, contrary to the discussion above, nevertheless comes to the conclusion that a public health compulsory license would unlikely be deemed to be TRIPS-

the 'might-is-right' stance some developed countries have taken in dealing with the global implementation of these flexibilities, has dissuaded certain Member States from taking advantage of these permissible interpretations and implementations of these provisions. The effect has been, and continues, to hamper the implementation of the TRIPS Agreement as it was foreseen on the 1st of January 1995. Those Member States critical of the continual growth of intellectual property rights are however gaining a greater understanding of the contents of the TRIPS Agreement and, in solidarity with other Member States in similar positions, are becoming more confident in taking advantage of the flexibilities contained therein – a 'right' expressly conferred on LDCs and indirectly on other Member States in the TRIPS preamble and the Decision on Measures in Favour of Least-Developed Countries. [587]

Whether or not the Member States make use of a simplified and more accessible compulsory license system should remain their prerogative. The choice, and ultimately the responsibility, is theirs.[588]

IV. Disclosure

Disclosure is the price an inventor pays to secure the exclusive rights conferred under Article 28 of the TRIPS Agreement. Disclosure is also the instrument that facilitates the spread of knowledge, technological development and commercial independence. Without disclosure there is no justification for the exclusive rights.[589] This symbiosis can only be legally, economically and socially validated where the disclosure is complete. If society is not able to reap the full rewards of the disclosure because it is incomplete then the inventor has not justified the exclusive rights it

compliant. Cf. *Kiehl*, 10 J.Intell.Prop.L (2002) p. 169. This point of view fails, amongst others, on *Kiehl's* view that any other alternative, ignoring the reasonableness or viability thereof, would make an Art 31 compulsory license TRIPS-inconsistent. The DSU has confirmed that alternative measures need be reasonable to be considered. See Chapter 5(C)(III)(2 and 3) above. Further, *Kiehl* infers that emergency concept in Art 31(b) will fail because other public health measures may be taken to minimise the emergency. The emergency concept is however only relevant to compulsory licenses that take place without prior negotiations with the rights holder. The existence of an emergency is not a requirement for a compulsory license.

587 Decision on Measures in Favour of Least-Developed Countries Art 2(iii).

588 The economic and social consequences of the use of compulsory license have not been considered here. They do, and will continue, to play a significant role in choosing which compulsory license policy is best suited for a Member State. *Reichmann* and *Hasenzahl* rightly refer to the decision as being a 'two-edged sword' and the active pursuit of a liberal or conservative compulsory license policy as both bringing advantages and disadvantages. Cf. *Reichman and Hasenzahl*, Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA (ICTSD/UNCTAD Geneva 2003) p. 23-25.

589 *Beier and Straus*, 8 IIC 5 (1977) p. 387-406, *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 239.

seeks.[590] Disclosure not only serves to ensure the new and valuable information reaches the public realm but it also serves to demonstrate the invent-tion's novelty, non-obviousness and usefulness.[591] Thus, the fulfilment of the disclosure requirement is fundamental to determining the ideological and utilitarian justification for the grant of exclusive rights. The TRIPS Agreement confirms the mandatory requirement to disclose the invention in Article 29.

Article 29.1 states that an inventor 'shall disclose the invention in a manner that is sufficiently clear and complete for the invention to be carried out by a person skilled in the art'. Hence, the disclosed information must, first and foremost, be 'sufficiently clear and complete'. This is the primary standard for evaluating if the invention justifies the exclusivity. Disclosed information that fails to describe each of the elements of novelty, usefulness and non-obviousness of the invention will not justify the exclusive rights. The descriptions must further be vacant of terminology or formulations that cause confusion or misunderstandings. Although the standard does not require absolute compliance, the sufficient compliance infers a standard that is more than 'necessary'.[592]

The sufficiency of the disclosed information is determined, not by general standards, but according to the standard of a 'person skilled in the art'. Such a person is however a legal fiction and is determined in each patent application anew.[593] Thus, when the body reviewing the disclosure confirms that a person skilled in the art is able to work the invention in the manner described in the patent application and achieve the result claimed will the disclosed information suffice the Article 29.1 TRIPS requirement.[594]

The ordinary meaning given to the Article 29.1 TRIPS terminology has not been uniformly interpreted by the Member States. The reason for this is both the flexibility of the terminology used and the independence countries have in examining patent

590 Disclosure is not a condition for the continued use of the exclusive patent rights; it is instead a condition for the grant of the exclusive rights.

591 The contents of the claim form the boundary for the patent: 'what is not sufficiently disclosed cannot be claimed' *Kraßer*, 23 IIC 4 (1992) p. 470-471. Compare German Patent Act sec 14, *Kirin Amgen Inc. and others v. Hoechst Marion Russel Ltd.* UKHL 46 [2004], (2005) 38 GRURInt 4 343-350 at 344. Lord Hoffman states '[w]hat is not claimed is disclaimed'.

592 The disclosure 'must not merely be necessary; it must be sufficient'. *Kirin Amgen Inc. and others v. Hoechst Marion Russel Ltd.* UKHL 46 [2004], (2005) 38 GRURInt 4 343-350 at 349. Cf. *Rebel*, Gewerbliche Schutzrechte (4th edn Carl Heymanns Berlin 2003) p. 185.

593 *Rebel*, Gewerbliche Schutzrechte (4th edn Carl Heymanns Berlin 2003) p. 185.

594 The usability of a patent, as set out in the disclosure, forms part of the disclosure requirements set out in Art 29 of the TRIPS Agreement. Cf. *Hüni*, 8 IIC 6 (1977) p. 501, *Kraßer*, 23 IIC 4 (1992) p. 470. Contrast the position taken by the UK Courts: *Kirin Amgen Inc. and others v. Hoechst Marion Russel Ltd.* UKHL 46 [2004], (2005) 38 GRURInt 4 343-350 p. 345. Lord Hoffman does however note in the *Kirin Amgen* case that the interpretation is a matter of national law.

applications.[595] These characteristics of Article 29 of the TRIPS Agreement permit Member States to structure the disclosure requirements in a number of ways.

The 'person skilled in the art' is, as stated above, a fictional legal standard. It is used by the examiner to determine, *inter alia*, whether the information disclosed is sufficient to enable its duplication. A standard that confers the skilled person substantial knowledge would mean that the information disclosed need not be particularly comprehensive to be 'sufficient'. It follows that countries wishing to increase the amount of information transferred will regard the skilled person as having lesser knowledge. Adjusting the skilled person's standard to reflect the technological development and knowledge of a country would reflect the objectives of the TRIPS Agreement, i.e. 'intellectual property rights should contribute to … the transfer and dissemination of technology … in a manner conducive to social and economic welfare'. By setting the standard lower for developing countries, the patent applicant will be obliged to disclose more information, thus putting additional information into the public arena and increasing the knowledge wealth of a country. A lower standard would also enable examiners in developing countries with lower technological understanding the ability to better understand the application and make more informed decisions. Adjusting the standards according to national skills levels would also ensure that domestic knowledge deficiencies, where present, are filled by the disclosure of information. The national adjustment of the disclosure levels by way of the skilled person standard will further ensure that, upon the expiry of the patent, the citizens of that country will have the choice of whether to use the knowledge disclosed or not. An inability in that country to understand or duplicate the invention upon the expiry of the patent would effectively extend the exclusivity period and the country would have been deceived out of the technical, economic and social development it bargained for.[596]

It would be erroneous to infer that the disclosure/domestic skills relationship would necessarily result in a relative novelty standard. A distinction needs to be drawn between the disclosure requirement and the novelty requirement. Although both requirements are interrelated – requiring the patent applicant to comply with both – it would be possible for a Member State to permit a national skilled person standard and an absolute novelty requirement.[597] Whereas the former refers to the disclosure standard the latter refers to the determination of novelty.

595 Art 4bis of the Paris Convention states: '1. Patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not. 2. The foregoing provision is to be understood in an unrestricted sense, in particular, in the sense that patents applied for during the period of priority are independent, both as regards the grounds for nullity and forfeiture, and as regards their normal duration.'

596 *Beier and Straus*, 8 IIC 5 (1977) p. 393, TRIPS Agreement Art 7.

597 Absolute novelty refers to the destruction of novelty by the description in print or made known in any other way in any country prior to the date of the patent application. Relative novelty refers to the destruction of novelty by a locally printed publication, local prior use and/or a combination of these with international publication. Cf. *Ladas*, Patents, Trademarks,

In addition to the skilled person standard being used to increase the scope of the information being disclosed, a Member State could also enforce a strict disclosure system that restrictively interprets 'sufficiently clear and complete'. As Article 29 of the TRIPS Agreement refers to disclosure as a whole, Member States could interpret the concept to include not only the core claims but also the those elements that accompany the specification.

Article 29.1 of the TRIPS Agreement provides a further possibility Member States have in requiring in the disclosure the 'best mode' to acquire the results mentioned in the application. The benefit of the 'best mode' requirement is that it simplifies the duplication of the invention. The 'best mode' requirement also has the effect of indirectly including know-how and even trade secrets in the patent application and, depending on the scope of the disclosure requirements, may require the disclosure of such restricted knowledge in points that are not directly related to the invention.[598] Failure to comply with this requirement would result in the denial of the patent grant. The US implementation of this system[599] is generally regarded as referring to the 'technically' best method of duplication to be disclosed. The TRIPS Agreement does not prohibit a Member State from interpreting best to mean commercially best. A third and more direct understanding was the Canadian approach where the patentee is required to 'put the public in possession of the invention in as full and ample a manner as he himself possesses it and give them the opportunity of deriving benefits therefrom equal to the benefits accruing to him'.[600] Despite the fact that the relevant Canadian provision is no longer in effect, the formulation would nonetheless meet the requirements of the TRIPS Agreement.

The above examples of interpreting Article 29 of the TRIPS Agreement in an expansive manner will likely have one of two possible results. The first foreseeable consequence is that some inventors would view the disclosure as being too onerous and requiring information they deem 'too valuable' to put into the public realm.[601] This will only be an effective tactic where the patent's disclosure in other countries does not include this additional information and where this information is unlikely to become public. The reverse side of the coin is that competitors would have free reign to develop equivalent products without fearing infringement claims. The second and most likely consequence is that inventor will comply with the disclosure requirements. Although onerous, the economic benefits would be viewed to outweigh the disclosure requirements.

and Related Rights Vol. 1 (Harvard University Press Cambridge 1975) p. 22, *Baxter et al,* World Patent Law and Practice Vol. 2 (Lexis Nexis New York 2005) p. 4-3-4-8.

598 *Adelman et al,* Cases and Materials on Patent Law (2nd edn Thomson/West St. Paul 2003) p. 497.

599 *Adelman et al,* Cases and Materials on Patent Law (2nd edn Thomson/West St. Paul 2003) p. 497-524.

600 *Goldsmith*, Patents of Inventions (Carswell Toronto 1981) p. 110.

601 *Watal*, Intellectual Property Rights in the WTO and Developing Countries (Kluwer The Hague 2001) p. 107.

It would thus seem to be in a developing country's interest to enforce a detailed and comprehensive disclosure system.[602] The additional information would assist knowledge hungry countries and would accelerate the development of that country. An information laden disclosure system does however have a significant drawback: as patent offices are currently struggling to process the information at present, it would be unclear how it would cope where the disclosure requirements would to be increased.[603] One possibility to overcome this overload and still maintain a wide dissemination of information would be to make increased use of digital applications. Another would be to make references to foreign fillings. A further possibility would be to ease the proceedings for oppositions to patent grants.[604] As failure to make a sufficient disclosure in the patent application can lead to the annulment of the patent,[605] an extended opposition period together with a simplified and inexpensive opposition process would also help ensure that the disclosure requirement serves its purpose of transferring knowledge.[606]

V. Exhaustion

The exhaustion of rights doctrine is the 'principle that once the owner of an intellectual property right has placed a product covered by that right into the marketplace, the right to control how the product is resold in the marketplace within that internal market is lost'.[607] The basic principle behind the doctrine of exhaustion is that the rights of an intellectual property rights holder do not extend *ad infinitum*[608] The

602 The transfer of technology and the development of poor countries is one of the core goals of the TRIPS Agreement. The disclosure requirement should be interpreted in this regard; failure to do so would ensure that patents become a barrier to trade and contrary to the TRIPS Agreement and WTO Agreements as a whole. To ensure this does not occur, developing Member States are legitimately empowered under the TRIPS Agreement to structure the disclosure requirement to further the 'developmental and technological objectives' and the 'transfer and dissemination of technology'.

603 *Watal*, Intellectual Property Rights in the WTO and Developing Countries (Kluwer The Hague 2001) p. 107.

604 *Watal*, Intellectual Property Rights in the WTO and Developing Countries (Kluwer The Hague 2001) p. 108.

605 EPC Art 138(1)(b), German Patent Act sec 21(1)(2).

606 TRIPS Agreement preamble, Art 7.

607 Webster's Third New International Dictionary.

608 For a brief introduction to the principle of exhaustion see *Hubmann*, Gewerblicher Rechtschutz (6th edn CH Beck Munich, 1998) p. 174-175. A further key aspect of the exhaustion doctrine is that the product or service which embodies the intellectual property right must be put onto a/the market with the intellectual property rights holders consent. Cf. *Burrell*, Burrell's South African Patent and Design Law (3rd edn Butterworths Durban 1999) p. 135, *Splittgerber and Schröder*, Lizenzen und Open Source rechtlich einwandfrei nutzen (Interest Kissing 2005) p.11. Contrast *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 106-107 where there is the suggestion that any legal or legitimate putting onto the market would suffice. This would thus extend to products produced under a

boundary of the rights is the point at which the rights are deemed to be exhausted, i.e. terminate. The boundary is, like the rights themselves, a creature of law, i.e. they are established and terminated by statute or court decisions. Determining when a rights holder's rights will expire is a matter for each country to determine. Article 6 of the TRIPS Agreement confirms this.[609] The effect of Article 6 is that exhaustion is *ultra vires* for the DSB.[610] In other words and with the exception of Articles 3 and 4, the DSB shall not make a ruling on a material TRIPS provision when it relates to exhaustion. This is confirmed in footnote 6 to Article 28 which states that the making, using, offering for sale, selling or importing of a patent shall likewise not apply to the exhaustion of intellectual property rights.

There are three generally accepted forms of the doctrine of exhaustion: domestic exhaustion, regional exhaustion[611] and international exhaustion.[612] A domestic / national exhaustion regime will only deem the rights holder's rights to be exhausted

compulsory license. This view would be reasonable where the compulsory license was granted to rectify an anti-competitive or abusive practice. Cf. *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen (Nomos Baden Baden 2002) p. 251. *Abbott* notes that rules regulating parallel trade may in fact constitute a non-tariff trade barrier in terms of Art XI of the GATT Agreement and may also fail to meet the safeguard requirements set out in Art XX(d). He also notes rules implementing domestic exhaustion may constitute a discriminatory practice in favour of domestic producers. Cf. *Abbott*, 1 JIEL 4 (1998) p. 632-633.

609 For a brief history of negotiations leading up to Art 6 of the TRIPS Agreement and a discussion of the economic impact of parallel imports see *Abbott*, 1 JIEL 4 (1998) at 609-624. *Straus* and *Katzenberger* note that Art 6 can be viewed in other ways, in particular, that Art 6 can be interpreted to exclude international exhaustion. Another view is that Art 6 in fact requires international exhaustion. Cf. *Straus and Katzenberger*, Parallelimporte: Rechtsgrundlagen zur Erschöpfung im Patentrecht (Schweizerische Eidgenossenschaft Munich 2002) p. 38-47.

610 Art 6 states that 'nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.' Under the TRIPS Agreement the 'freedom' to determine when the rights will be exhausted is subjected to the proviso that the exhaustion regime does not infringe the basic trade principles of MFN and national treatment. Compare *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen (Nomos Baden Baden 2002) p. 246 fn. 1340, *Stothers*, 1 JIPLP 9(2006) p. 589, *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 112-113, *Beier*, 26 GRURInt 1 (1996) p. 9. Contrast *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: *Beier and Schricker* (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 202, *Einhorn*, 35 CML Rev 5 (1998) p. 1083.

611 Some authors classify regional exhaustion as being a part of international exhaustion. A distinction should however be made between regions which display a degree of unity, as does the EC, SACU, the NAFTA states and other regions linked through treaties creating a common market. Compare *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 202, *Rao and Guru*, Understanding TRIPS: Managing Knowledge in Developing Countries (Response New Delhi 2003) p. 55.

612 *Abbott*, 1 JIEL 4 (1998) p. 611. Further, the freedom to elect an exhaustion regime is not subject to any restriction from the Paris Convention, including Art 5quater.

when that rights holder himself brought the product onto the domestic market.[613] Similarly the rights will be deemed to be exhausted under a regional exhaustion regime when the product was put onto any country within the regional market.[614] Under the international exhaustion regime the rights over the product will be deemed to be exhausted when they are brought onto any marketplace around the globe.[615] The three largest markets, the US, the EC and Japan provide examples of all the above. The US, by way of the doctrine of first sale and the patent ex-haustion doctrine, apply a system of IPR primacy and thus have, in general, restricted themselves to a domestic exhaustion regime.[616] The EC accepts that the putting into commerce of a product anywhere in the EC market will exhaust the rights holder's intellect-tual property rights over the product – enabling a common market primacy.[617] In Japan the courts have acknowledged that, in certain circumstances, the rights holder's rights can be exhausted when the product is put onto a foreign market by the patent holder.[618]

613 The corollary is that the protection rights will not be exhausted when they have been brought onto the market in a foreign country. Cf. *Straus and Katzenberger*, Parallelimporte: Rechtsgrundlagen zur Erschöpfung im Patentrecht (Schweizerische Eidgenossenschaft Munich 2002) p. 7.

614 Of principal importance for regional exhaustion is a common market or economic area that is sufficiently integrated. Cf. *Straus and Katzenberger*, Parallelimporte: Rechtsgrundlagen zur Erschöpfung im Patentrecht (Schweizerische Eidgenossenschaft Munich 2002) p. 8.

615 Cf. *Straus and Katzenberger*, Parallelimporte: Rechtsgrundlagen zur Erschöpfung im Patentrecht (Schweizerische Eidgenossenschaft Munich 2002) p. 8-9.

616 The US expressly denied the exhaustion doctrine. This denial is has been rationalised by the application of the doctrine of 'first sale' and 'common control'. The first sale doctrine is however limited to copyright law and is codified in sec 109 of the USA Copyright Act. Cf. *Letterman*, Basics of International Intellectual Property Law (Transnational Publishers New York 2001) p. 20. Despite this, the US regime does allow international exhaustion where the rights holder in the US and in the country where it was first put onto the market is one and the same. Cf. *Barrett*, 24 EIPR 12 (2002) p. 571-573, 575, *Straus and Katzenberger*, Parallelimporte: Rechtsgrundlagen zur Erschöpfung im Patentrecht (Schweizerische Eidgenossenschaft Munich 2002) p. 24-26. The doctrine of common control is restricted to trademarks. Cf. *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 95, *Chiapetta*, 21 Mich.J.Int'l.L 3 (2000) p. 347, 350-351.

617 *Centrafarm v. Sterling Drugs*, 15/74 [1974] ECR 1147, *Merck v. Stephar*, 187/80 [1981] ECR 2063, *Merck v. Primecrown,* C267/95 [1996] ECR I-6285. Compare *Stothers*, 1 JIPLP 9(2006) p. 579-586, *Abbott*, 1 JIEL 4 (1998) p. 610-11.

618 The Japanese Supreme Court has accepted the application of international exhaustion. Cf. *BBS Kraftfahrzeugtechnik AG v. KK Lassimex* Heisei 7(wo) 1988, 1.7.1997. *Straus* and *Katzenberger* state that the position taken by the Japanese High Court mirrors the UK implied license doctrine and thus permits patent holders to contract out of the international exhaustion regime. Cf. *Straus and Katzenberger*, Parallelimporte: Rechtsgrundlagen zur Erschöpfung im Patentrecht (Schweizerische Eidgenossenschaft Munich 2002) p. 29-30. Compare *Beier*, 26 GRURInt 1 (1996) p. 1, 8-9. Further examples arise in England and South Africa whereby international exhaustion will apply where the original seller did not sell the product subject to export limitations. Cf. *Heath*, 27 IIC 5 (1997) p. 624, *Burrell*, Burrell's South African Patent and Design Law (3rd edn Butterworths Durban 1999) p. 136.

A prominent example of an international exhaustion system within the scope of patents, health and the TRIPS Agreement is the South African Medicines and Related Substances Control Act which permits the importation of any medicine put onto a foreign market with the consent of the patentee into South Africa – thus allowing parallel importation.[619] Despite initial objections from the US[620] and a highly politicised court action between the South African government and the Pharmaceutical Manufacturers Association (PMA)[621] the opposing parties reached an agreement which, *inter alia*, stated:

> 'In reliance of this commitment, the referenced applicants recognize and reaffirm that the Republic of South Africa may enact national laws or regulations, including regulations implementing Act 90 of 1997 or adopt measures necessary to protect public health, and broaden access to medicines in accordance with the South African Constitution and TRIPS'.[622]

There is also strong academic support for an international exhaustion regime.[623] *Abbott*, *Cottier* and *Stucki* identify Articles III and XI of the GATT Agreement as being grounds for declaring a domestic or regional exhaustion regime as being GATT-inconsistent.[624] This view finds an echo in the TRIPS Agreement itself where Article 40 states that the creation of exclusive territories, *inter alia*, for the marketing of products may be regarded as being anti-competitive.[625] By their nature domes-

619 South African Medicines and Related Substances Control Act 101 of 1965 (as amended) sec 15 C(b). Cf. *Straus and Katzenberger*, Parallelimporte: Rechtsgrundlagen zur Erschöpfung im Patentrecht (Schweizerische Eidgenossenschaft Munich 2002) p. 32-33.

620 *USTR*, Special 301 Report (2000). The Report notes that the 'new law, at 15C(b) allows for the parallel importation, a violation of TRIPS Article 28 which while not actionable through WTO dispute settlement procedures, poses a serious threat to the viability of American pharmaceutical investment in South Africa'.

621 *Pharmaceutical Manufacturers Association et al v the President et al*, TPD, 4183/98 [not published]. It has been suggested that domestic challenges to the exhaustion system are not exempted by Art 6 of the TRIPS Agreement. Cf. *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 105.

622 Joint Statement of Understanding between the Republic of South Africa and the Applicants (19.04.2001). The US

623 Compare *Grubb*, Patents for Chemicals, Pharmaceuticals and Biotechnology (4th edn OUP Oxford 2004) p. 407-408.

624 *Abbott*, also citing *Cottier* and *Stucki*, notes that rules regulating parallel trade may in fact be a non-tariff trade barrier in terms of Art XI of the GATT Agreement and may also fail to meet the safeguard requirements set out in Art XX(d). He also notes rules implementing domestic exhaustion may constitute a discriminatory practice in favour of domestic producers. Cf. *Abbott*, 1 JIEL 4 (1998) p. 632-633, 635, *Hermann*, 13 EuZW 2 (2002) p. 41. *Hermann* notes that the exclusion of the concept of exhaustion from the scope of the TRIPS Agreement does not render immune to the remaining WTO rules. Being a *lex specialis* means that where there the TRIPS Agreement does not regulate a provision the regulation of that provision must then be corresponding *lex generalis*, in this case the GATT Agreement.

625 Compare the US where courts have rejected intellectual property protection to re-imported goods. Cf. *Rao and Guru*, Understanding TRIPS: Managing Knowledge in Developing Countries (Response New Delhi 2003) p. 56. The authors also note that a domestic exhaustion regime may effectively grant the patentee double protection.

tic exhaustion rules are an impediment to trade and contrary to the general terms, spirit and structure of the WTO.[626]

Other academics come to another conclusion in respect of Article 6. They state that Article 6 is merely procedural in nature and that the material rights granted to a patentee under the TRIPS Agreement and the prohibition of discriminatory treatment effectively ban inter-national exhaustion as an alternative for Member States.[627] *Straus*, the most noteworthy proponent of this view, states that as Article 6 is not a material provision that international exhaustion of patent rights be only be tolerated under the TRIPS Agreement in exceptional circumstances and in these circumstances the exceptions to the general rule will have to be justified under the material provisions in the TRIPS Agreement, i.e. Article 30 or Article 31.[628] *Straus* further substantiates his view by saying that although international exhaustion may at first appear to run contrary to free trade principles, the aim of the TRIPS Agreement was ensure Member States implemented adequate intellectual property protection in their *own* legal system, i.e. the focus was on the each country's domestic intellectual property regime and not the desire to create a global territory in which the rights would be exhausted after any sale around the world. As strange as it may seem, a globally implemented international exhaustion would in fact mean that poorer countries would have to pay more expensive prices than under a regional or domestic exhaustion regime. The reasoning is that under a domestic exhaustion regime rights holders tend to adjust their prices according to the 'wealth' of the country in which they intend to sell.[629] Further, the implementation of an international exhaustion regime by a developing country would defeat one of the purposes of the TRIPS Agreement, i.e. promoting the transfer of technology and the creation of a viable technology base.[630] *Straus* finds support for his opinion not only amongst academics[631] but also the WIPO Secretariat who, notwithstanding Article 6, view the territorial restrictions in the Berne Convention as being applicable.[632] Rightly or wrongly,

626 *Chiapetta*, 21 Mich.J.Int'l.L 3 (2000) p. 346.

627 Compare *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schricker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 202.

628 *Straus* states that regional exhaustion will only be justified under Art 30 of the TRIPS Agreement where the region in question is sufficiently integrated. Cf. *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: *Beier and Schricker* (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 202.

629 For a further of the social and political value of not implementing an international exhaustion regime see *Stothers*, 1 JIPLP 9(2006) p. 590-591, *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: *Beier and Schricker* (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 202 *et seq*.

630 *Einhorn*, 35 CML Rev 5 (1998) p. 1083.

631 *Einhorn*, 35 CML Rev 5 (1998) p. 1082-1083.

632 *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 113-114.

this view is a minority view amongst academics.[633] The diverging views, not only amongst academics but also amongst the WTO Member States themselves, created a large degree of uncertainty in how to implement a TRIPS-compliant exhaustion regime.[634]

Despite the differing opinions on what Article 6 permits, it is clear that the inability of the TRIPS negotiators to reach a common understanding on the matter means that the issue is, at least *prima facie*, up to the Member States to decide upon.[635] This 'agreement to disagree' in Article 6 of the TRIPS Agreement guarantees Member States the freedom to construct an exhaustion regime that would best suit the domestic circumstances.[636] The sheer magnitude of diverging exhaustion regimes, even amongst developed Member States, and the inconsistencies in their national application[637] would render any attempt to implement a common system futile and inappropriate. The ability to tailor each Member States exhaustion system permits Member States to optimise their intellectual property rights system to better reflect public interest policies.[638] The benefits of an international system of exhaustion grant Member States more flexibility to source products beyond its borders, thus providing a competition stimulus.[639] It would also enable a government the possibility to suspend the exhaustion regime when there is either a transfer of technology, improved access to the product or to encourage the local production of the product.

D. Conclusion

The TRIPS Agreement is a remarkable treaty. Never before have so many countries been able to reach an agreement that went to the core of intellectual property rights. The price for this global consensus is the treaty itself. Despite having the effect of reaching deep into the national legislative domain it lacks the clarity and precision a national statute would require. This lack of precision – both intentional and unintentional – has been the source of much disagreement in the WTO arena. Yet without the intentional ambiguity, termed 'flexibility, no agreement could have been

633 *Straus and Katzenberger*, Parallelimporte: Rechtsgrundlagen zur Erschöpfung im Patentrecht (Schweizerische Eidgenossenschaft Munich 2002) p. 41.

634 The dispute surrounding the South African compulsory license for the importation of certain medication is effectively a question relating to international exhaustion. See Chapter 4(B)(II) above.

635 *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 114.

636 *Chiapetta*, 21 Mich.J.Int'l.L 3 (2000) p. 339, 346.

637 *Straus and Katzenberger*, Parallelimporte: Rechtsgrundlagen zur Erschöpfung im Patentrecht (Schweizerische Eidgenossenschaft Munich 2002) p. 10-35, *Chiapetta*, 21 Mich.J.Int'l.L 3 (2000) p. 347-348.

638 For a discussion of the factors that are relevant in deciding which system is most appropriate *Chiapetta*, 21 Mich.J.Int'l.L 3 (2000) p. 333-392.

639 *Carboni*, A Review of International Exhaustion Development in Europe in: Hansen (ed) International Intellectual Property Law & Policy (Juris Huntington 2001) vol 6.

reached. The haggling over how much flexibility or wiggle room the TRIPS Agreement provisions afford is the price the Member States will pay for this accord. How it will be paid and how the TRIPS Agreement will evolve is a matter of practice, pressure and time. The basis for this however, is legal jurisprudence.

The most contentious of the wiggle areas was that of patent rights, in particular their impact on domestic health policies. The Public Health Declaration reflects the culmination of these disputes.

Chapter 6 The Public Health Declaration

The availability of the extensive flexibilities found in the TRIPS Agreement to Member States was seldom recognised – let alone exercised – in the early and uncertain years of their application. Despite the wording of the TRIPS Agreement, Member States were unable to agree on the existence, let alone the scope and extent, of the flexibilities. Although initially theoretical, the differences of opinions became 'real' when dealing with the effect of the TRIPS Agreement on the access to affordable medicines. The extent of public health problems like HIV/AIDS and the public attention to the discussions pressured the Member States to clarify, reaffirm or alter the TRIPS-provisions and their flexibilities in order to ensure that they would not hinder measures to protect the public health. The product of their efforts was the Public Health Declaration.[640] Although hailed at the time, it contains not novel law or solutions. It is little more than a reiteration of existing laws. Its role is however more subtle; it identified real problems and removed large portions of uncertainty in applying the TRIPS Agreement – at least psychologically.

The Public Health Declaration is important to the TRIPS Agreement for two reasons. Firstly, it mandates two problematic issues that require active attention. Secondly, it seeks to clarify a number of contentious issues in the TRIPS Agreement. These, together with the legal implications of the Public Health Declaration are analysed briefly in 'A' and 'B' respectively hereunder. The effects of the Public Health Declaration on the TRIPS Agreement are discussed in 'C' thereafter.

A. The scope of the Public Health Declaration

Essentially, the Public Health Declaration seeks to clarify the relationship between the intellectual property rights and public health. In addition to the clarification of this relationship, the Public Health Declaration also mandated the Member States with two modalities: to resolve an inadvertent 'technical' problem and to grant an extension to certain obligations for LDCs. These three points are briefly elucidated below.

640 Declaration on the TRIPS Agreement and Public Health, 14.11.2001, WT/MIN(01)/DEC/2 (Annex I hereto)

I. Clarification of the relationship between the TRIPS Agreement and public health

In an unusually clear formulation the Public Health Declaration confirms that:

> '… the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health'.[641]

This statement has helped resolve a dispute that lay at the bottom of a number of intellectual property disputes:[642] what role do public health policies play in interpreting the TRIPS-flexibilities? The answer given by the WTO Member States is that intellectual property obligations will not stand in the way of measures taken to protect the public health. To this effect the TRIPS-provisions and flexibilities should be interpreted in a 'manner supportive of WTO Members' right to protect public health'. This clarification does not imply that Member States implementing public health measures are entitled to ignore their intellectual property obligations under the TRIPS Agreement. The TRIPS-obligations remain; their implementation and interpretation however can be effected in a manner that supports the protection of health. This statement is of utmost importance when seen in relation to the numerous flexibilities vesting in the Member States' implementation of the TRIPS Agreement. Added to this, it was further agreed that the flexibilities in the TRIPS Agreement may be exercised to the fullest extent for the purpose of protecting the public health.

The Member States further took to clarifying the flexibilities by specifically addressing four specific issues. The Member States agreed that:

- the interpretation of the TRIPS Agreement must take into account the object and purpose of the agreement, as set out in the customary rules of interpretation of public international law
- they have a sovereign right to determine the grounds for compulsory licenses and to provide for their use[643]
- they have a sovereign right to determine what constitutes extreme urgencies[644] and

641 Public Health Declaration para 4.

642 *Abbott* notes that much of the implementation difficulties expressed by developing countries arise from the political and economic pressure applied on these countries to conclude the agreement and the lack of understanding of the obligations they consented. *Abbott*, Quaker Paper 7 (2001) p. 3. This is confirmed in WTO Proposal by the African Group *et al* to the TRIPS Council 'Ministerial Declaration on the TRIPS Agreement and Public Health' (04.10.2001) IP/C/W/312 p. 2. Compare *Abbott*, CIPR Study Paper 2a (2002), *Sykes*, 3 Chi. J. Intl. L (2002) p. 50-61, *Sun*, 15 EJIL 1 (2004) p. 123-131. *Straus* provides empirical evidence that the TRIPS Agreement can, and has, benefited certain countries. Cf. *Straus*, 6 J. Marshall Rev. Intell. Prop. L 1(2006) p. 4-9. Contrast *Gervais*, 1 JIPLP 4 (2006) p. 252-253.

643 WTO Communication from the EC 'The Relationship between the Provisions of the TRIPS Agreement and Access to Medicines' (12.06.2001) IP/C/W/280 p. 2-3, WTO Proposal by the African Group *et al* to the TRIPS Council 'Ministerial Declaration on the TRIPS Agreement and Public Health' (04.10.2001) IP/C/W/312 p. 3.

- they have the freedom to establish national regimes for the exhaustion of intellectual property rights.

The heading given to the Public Health Declaration is the 'Declaration on the TRIPS Agreement and Public Health'. This being the case, does the scope of the Public Health Declaration only permit the expansive implementations of the TRIPS flexibilities with respect to measures based on public health? The formulation of paragraph 4 and 5 of the Public Health Declaration seems to suggest that this is indeed the case:

> 'In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose'.

This statement clearly acknowledges that public health actions necessitate a permissive implementation of the flexible provisions contained in the TRIPS Agreement.[645] The question that naturally follows is: is the full use of the TRIPS flexibilities restricted to public health circumstances? General interpretational rules state that the inclusion of one means the exclusion of others. This rule however will only apply, to the extent that the negotiating parties desired it to apply. This does not seem to be the case here. The reason lies firstly in the negotiations leading up to the Declaration. India and the USA took turns in stating that the Public Health Declaration should not lead to a restriction of either the Member States rights or the rights holder's rights.[646] Secondly, the rule is unlikely to apply because of the terminology chosen by the Public Health Declaration negotiators. Paragraph 4 reaffirms the right to use the flexibilities to the maximum advantage. The terminology is not restrictive in nature nor does it limit the application of paragraph 5 to the listed points. Further, the Public Health Declaration does not create a new right; rather it acknowledges the existence of a right ('we reaffirm the right of WTO Members'). With the exception of LDCs, this right is not expressly mentioned in the TRIPS Agreement. Accordingly, it cannot be excluded that other rights to maximum usage of the flexibilities can, or do, exist.[647] A review of the TRIPS Agreement would seem to suggest that

644 WTO Proposal by the African Group *et al* to the TRIPS Council 'Ministerial Declaration on the TRIPS Agreement and Public Health' (04.10.2001) IP/C/W/312 p. 3.

645 This statement reflects an answer to one of the prime demands of the developing Member States. As early as April 2001 Zimbabwe stated that '[a]lthough the TRIPS Agreement allowed developing countries the flexibility to apply patents in ways that still enabled the protection of the health of their people, recent legal challenges by the pharmaceutical industry and some Members in national law and under the DSU had highlighted the lack of legal clarity on the interpretation and/or application of the relevant provisions of the TRIPS Agreement'. Cf. Zimbabwe on behalf of the African Group in the TRIPS Council Minutes (01.06.2001) IP/C/M/30 p. 68.

646 India and US in the TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 33, 37.

647 TRIPS Agreement preamble. Critics of this view may state that the scope of this statement is clearly made within the context of public health and as such should be interpreted in this context (as according to the Vienna Convention). The Vienna Convention does however require that the wording used should be of primary importance. In this context it is important to remember that the statement is merely a reaffirmation. As such this statement confirms that the

other situations may indeed permit the maximum usage of the existing flexibilities within the TRIPS Agreement. They would include nutrition, the promotion of the public interest and the prevention of intellectual property right abuse, as foreseen in Article 8 of the TRIPS Agreement. The right to use the 'wiggle room' in a treaty is universal – provided it actually exists and provided it is done in good faith. It therefore seems unlikely that, despite the clear restriction of the Public Health Declaration to public health, that the use of the flexibilities will not have a follow on effect on the other measures. Where Member States are faced with similar public interest situations the Public Health Declaration may indeed provide the affected Member States with a degree of guidance and security.

A further issue regarding the scope of the Public Health Declaration arose in submissions made after the Doha Ministerial Conference wherein it was stated that the Public Health Declaration consequences should only be limited to developing and least-developed countries.[648] The reason being that paragraph 1 of the Public Health Declaration refers to public health problems faced by such countries. As the Public Health Declaration seeks to remove the perceived obstacle in the TRIPS Agreement to resolve the problems it was contended that the Public Health Declaration is not to be applied where the Member States are developed countries. Whereas this may be true in regarding the extension of the transitional provisions in paragraph 6, this interpretation is not supported by the contents or the context of the Public Health Declaration. The central paragraph of the Public Health Declaration, paragraph 4, states that the TRIPS Agreement should not prevent Member States from taking measures to protect public health. It refers to all Member States – there is no restriction.[649] The contents of paragraph 4 are subsequently used to 'qualify' the scope and use of the flexibilities in paragraph 5.

II. Countries without domestic productions facilities

The inability that some Member States have in domestically producing pharmaceutical products has meant that granting compulsory licenses in these countries for the domestic production of these products is a fruitless venture; effectively rendering

right existed prior to the Public Health Declaration and, as the TRIPS Agreement was not subject to the public health context of the Public Health Declaration, one can conclude that this right is not restricted to the scope of public health. Accordingly, the scope and purpose reflected in Arts 7 and 8 will be guiding. Cf. *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 131.

648 The US stated that 'the Doha Declaration on the TRIPS Agreement and Public Health makes it clear that the public health problems addressed by the Declaration are those gravely afflicting many *developing and least-developed countries*' (emphasis added). Cf. WTO Communication by the US 'Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (09.07.2002) IP/C/W/358 p. 2.

649 Paragraph 6 also refers to all Member States, not just developed or LDC Member States.

compulsory licenses in these countries toothless and ineffective.[650] This problem is amplified by the fact that Article 31(f) of the TRIPS Agreement prevents these predominantly poor or small countries from having their compulsory license worked in a third country.[651] Although being aware of this technical quandary in the negotiations preceding the Doha Ministerial Conference,[652] the Member States were unable to reach an agreement on how the problem should be solved.[653] To rectify this, the Member States issued a formal instruction 'to find an expeditious solution' to the problem of local use of compulsory licenses within the context of pharmaceuticals.

III. The postponed implementation of certain TRIPS-obligations

Article 66.1 of the TRIPS Agreement acknowledged that LDCs would require additional transitional periods for the enforcement of all TRIPS obligations. Economic, financial and administrative constraints made the implementation of intellectual property rights problematic, especially where the lack of a viable technology base would render these countries more dependent on foreign products. Article 66.1 of the TRIPS Agreement permitted the 10 year transition period – expiring in 2006 – to be extended on making a 'duly motivated' request by individual countries. It was however clear in the negotiations preceding the Doha Ministerial Conference that the LDCs were not in the 'economic, financial and administrative' position to implement the remaining TRIPS obligation,[654] especially when faced with the constraints they would impose on the access to pharmaceutical products.[655] Despite initial opposition,[656] the developed Member States concurred that LDCs should be afforded more time to implement the TRIPS Agreement. To this effect the Member States at the Doha Ministerial Conference agreed that a further 10 year extension be

650 The option to grant a compulsory license for the importation of pharmaceutical product remains a theoretically valid option. With the global scope of patent protection, especially after the transitional periods expired in 2001 and 2005, the availability of off patent versions of the sought products will progressively wane.

651 Compare Chapter 5(C)(III)(3)(h) above. Cf. *Gregg Bloche*, 5 JIEL 4 (2002) p. 840.

652 The EC submission was first to formally note that Art 31(f) may pose a problem for supplying foreign market without adequate domestic pharmaceutical production facilities. This was followed shortly thereafter by a submission from the developing countries group. Cf. WTO Communication from the EC 'The Relationship between the Provisions of the TRIPS Agreement and Access to Medicines' (12.06.2001) IP/C/W/280 p. 3, WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 p. 8.

653 *Straus*, Patentschutz durch TRIPS-Abkommen – Ausnahmeregelungen und –praktiken und ihre Bedeutung, insbesondere hinsichtlich pharmazeutische Produkte in Bitburger Gespräche Jahrbuch 2003 (CH Beck Munich 2003) p. 128-129.

654 WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 p. 9.

655 Compare Zimbabwe in TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 46. Contrast *USTR*, Special 301 Report (2006) p. 11.

656 Compare Australia, EC in TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 56, 58.

given to LDCs with respect to pharmaceutical products. The Public Health Declaration instructed the TRIPS Council to give effect to this concession.

B. The legal status of the Public Health Declaration

The Public Health Declaration, like the Doha Ministerial Declaration,[657] was adopted by the WTO Member States at the Doha Ministerial Conference in November 2001.[658] Although separate documents, both Declarations were adopted by a consensus decision of the Ministerial Conference – the core decision making body at the WTO.[659]

The Public Health Declaration was hailed as a political success at the Doha Ministerial Conference. However, before the dust could settle, questions arose concerning the precise effect of the Public Health Declaration.[660] In the years that followed much was written and said about the legal status of the Public Health Declaration – much of it sought to ignore the public law realities of the document and grant it an extraordinary legal status.[661] Viewed from a legal standpoint, the Public Health Declaration will only constitute an original source of WTO law if it was granted such.[662] As the WTO does not accord ministerial declarations any specific legal status[663] it must be determined whether the consensus achieved at Doha has fulfilled any other requirements that afford binding consequences. Under the WTO Agree-ment and international treaty law the Ministerial Conference is empowered to make decisions

657 WTO Ministerial Declaration (20.11.2001) WT/MIN(01)/DEC/1 ('Doha Ministerial Declaration').

658 A similar course was used in both the Singapore and Geneva Ministerial Conferences. Cf. WTO Ministerial Declaration on Trade in Information Technology Products (13.12.1996) WT/MIN(96)/16, WTO Ministerial Declaration on Global Electronic Commerce (25.05.1998) WT/MIN(98)/DEC/2.

659 WTO Agreement Art IV, IX.

660 *Davey*, Institutional Framework in Macrory, Appleton and Plummer (eds) The World Trade Organisation: Legal, Economic and Political Analysis (Springer New York 2005) vol 1 p. 63, *Hestermeyer*, 37 GRURInt 3 (2004) p. 196. The EC and US view on the binding nature of the separate declaration was at times diametrically opposed. The then USTR Zoellick referred to the Public Health Declaration a 'landmark *political* declaration on the TRIPS Agreement and public health' (emphasis added). The EC on the other hand were initially unwilling to conclude a separate declaration on the grounds that an independent declaration might be assumed to have more weight than the principal Ministerial Declaration. Cf. EC in TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 58.

661 The political consequences of the Public Health Declaration are not doubt as important as the legal consequences. A political evaluation of the Public Health Declaration is however beyond the scope of this dissertation.

662 *Gregg Bloche*, 5 JIEL 4 (2002) p. 842, *Matsushita et al*, The World Trade Organization: Law, Practice, and Policy (2nd edn OUP Oxford 2006) p. 37.

663 *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 44.

that, depending on their nature, can either constitute an amendment,[664] a waiver,[665] an authoritative interpretation[666] and/or a new treaty.[667] There is no history that a ministerial declaration has, *ipso facto*, sought to amend,[668] waive or interpret a WTO provision. As the Public Health Declaration does not contain any express terminology indicating otherwise, there is no evidence that the Public Health Declaration intended to generate specific or direct rights or obligations.[669] However certain 'legal' consequences will flow from the Public Health Declaration. The *pacta sunt servanda* rule binds parties in good faith to the perfor-mance of the agreement they have concluded.[670] The Public Health Declaration is littered with terminology that reflects the agreement of the parties to the contents thereof.[671] This mass of consensus regarding the contents of the TRIPS Agreement can therefore not go unnoticed. However as the Public Health Declaration does not follow the formal route for the adoption of an authoritative interpretation, it must be concluded that it was not the parties intention to afford the agreement a formal interpretation.[672] Instead the Public Health Declaration will lend assistance to the interpretation of the TRIPS Agreement by the DSB and the Member States.[673] To this effect, Article 31(3)(a) of the Vienna Convention confirms that in interpreting treaties the subsequent agreements between the parties will be taken into account together as if it were part of the context of the original agreement.[674] This, according to *Abbott*, amounts to 'a very close approxi-

664 WTO Agreement Art X.
665 WTO Agreement Arts IX(3 and 4).
666 WTO Agreement Art IX(2).
667 Vienna Convention Art 9.
668 *Gregg Bloche*, 5 JIEL 4 (2002) p. 841.
669 *Van den Bossche*, The Law and Policy of the World Trade Organisation (CUP Cambridge 2005) p. 54, 123. The Public Health Declaration will unlikely meet the requirements for a new treaty as the parties' intention to create a new and separate treaty is lacking. By referring to the Public Health Declaration as a 'declaration' within the WTO context it is clear that the parties desired to limit themselves within the structure of the WTO and not create new obligations. Contrast *Hermann*, 13 EuZW 2 (2002) p. 42.
670 Vienna Convention Arts 5, 26, 31(3)(a). WTO *United States – Section* 211 (panel ruling) p. 85.
671 The Public Health Declaration is littered with the formulations 'we agree' and 'we recognise'. *Hestermeyer*, 37 GRURInt 3 (2004) p. 197, *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 131.
672 *Ehlermann and Ehring*, 8 JIEL 4 (2005) p. 817. Contrast *Hestermeyer*, 37 GRURInt 3 (2004) p. 197, *Kramer*, Patentschutz und Zugang zu Medikamenten (Carl Heymanns Verlag Cologne 2007) p. 69-70.
673 The Public Health Declaration confirms as much; Art 4 of the Public Health Declaration states that the TRIPS Agreement 'can and should be *interpreted* and *implemented* in a manner supportive of WTO Members' right to protect public health' (emphasis added).
674 This element is of particular importance as the Public Health Declaration seeks to clarify provisions that are in their current formulation flexible and thus subject to more than one interpretation. Further, there is also some merit to the Public Health Declaration been considered a 'subsequent practice' in terms of Art 31(3)(b) of the Vienna Convention. Cf. *Gregg Bloche*, 5 JIEL 4 (2002) p. 841. The fact that the Public Health Declaration was an agreement and not a practice tends to indicate that there is more merit to the 'subsequent agreement' view.

mation of an interpretation and, from a functional standpoint, may be indistinguishable'. [675]

C. *The effect of the Public Health Declaration on the TRIPS Agreement*

Being a 'subsequent agreement' the Public Health Declaration has the potential to shape the TRIPS Agreement like no other WTO Declaration or collective Member State agreement before it. The extent of this interpretational assistance will depend not only on the contents of the Public Health Declaration but also on the respective TRIPS Agreement provisions. The effects of the Public Health Declaration on the TRIPS Agreement are discussed in respect to the TRIPS scope and purpose, the TRIPS material obligation and the transitional period granted to LDCs.

I. The scope and purpose

According to the Vienna Convention on the Law of Treaties, the object and purpose help determine the ordinary meaning of the terms of the treaty.[676] In other words, clarity is brought to uncertain clauses and concepts through the use of the treaties object and purpose. As is evident in Chapter 5(B) Seite 47, the scope and purpose of the TRIPS Agreement play an important role in fleshing out the meaning of the numerous flexible provisions of the TRIPS Agreement. The difficulty with the scope and purpose of the TRIPS Agreement is that the provisions incorporating the scope and purpose are themselves flexible and permit a number of diverging, and yet arguably valid, conclusions to be drawn when interpreting the Agreement.[677]

As was intended the Public Health Declaration, as a subsequent agreement to the TRIPS Agreement, will have a vital role to play in clarifying and guiding the use of those provisions containing the scope and purpose of the TRIPS Agreement. The extent of this influence stems from the sometimes express references to the customary rules of interpretation of treaties, the reinforcement of the role of health and, last but not least, the confirmation of the provisions of Articles 7 and 8 of the TRIPS Agreement. These, and their effect on the implementation of the policy thoughts of the Public Health Declaration, are discussed independently below.

675 *Abbott,* 5 JIEL 2 (2002) p. 492. *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 44. *Straus* notes that part of the Public Health Declaration is to be viewed as an authentic interpretation and other parts as setting mandates for the Member States. Cf. *Straus*, Patentschutz durch TRIPS-Abkommen – Ausnahmeregelungen und –praktiken und ihre Bedeutung, insbesondere hinsichtlich pharmazeutische Produkte in Bitburger Gespräche Jahrbuch 2003 (CH Beck Munich 2003) p. 126.

676 Vienna Convention Art 31.

677 Compare WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 p. 3.

1. The customary rules of interpretation

The inclusion of a reference to the use of customary rules of interpretation made for little controversy in the negotiations leading up to the Public Health Declaration.[678] A draft of the Public Health Declaration dating back to the 27th of October 2001 included a paragraph stating that the interpretation of all the TRIPS provisions should be done in accordance with its objectives and principles, as required by customary rules of interpretation.[679]

The reason for the general acceptance of the use of the Vienna Convention[680] in the interpretation of the flexibilities of the TRIPS Agreement stems from the fact that the Member States had already accepted their use within the TRIPS Agreement[681] and that all Member States are nonetheless bound to the provisions in the Vienna Convention.[682]

The question that therefore arises is: why was a reaffirmation of the role of customary rules of interpretation necessary?

The answer lies in the political situation at the WTO in the late 1990s. There was an impression that the TRIPS Agreement was being implemented in a manner the Member States had not agreed upon. On the one hand developed countries pressed for a strict interpretation of the rules and on the other side the DSB ruling restrictively interpreted the exceptions worked into the TRIPS Agreement.[683] It was felt that insufficient regard was being given to the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement.[684] This, as it was felt, was contrary to the provisions of the Vienna Convention. Dissatisfied with the situations developing Member States energetically pushed to include a confirmation of the principles of

678 The Hong Kong representative stated that 'there should be no dispute that all provisions of the TRIPS Agreement should be read in the light of the objectives and principles as set forth in its Articles 7 and 8'. Cf. Hong Kong in TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 60

679 WTO General Council 'Draft Declaration on Intellectual Property and [Access to Medicines] [Public Health]' (27.10.2001) JOB(01)/155.

680 *Matsushita et al*, The World Trade Organization: Law, Practice, and Policy (2nd edn OUP Oxford 2006) p. 27.

681 DSU Art 3(2)

682 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 132.

683 The *Canada – Pharmaceutical* case is often cited in this regard. The opposition focused on the sentence that stated: 'The term "limited exception" must therefore be read to connote a narrow exception - one which makes only a small diminution of the rights in question'. WTO *Canada – Pharmaceuticals* p. 155. Brazil put its fear of the DSU as a method for interpretation of the TRIPS agreement bluntly when it said 'avoiding the … dispute settlement mechanism to enforce restrictive, unbalanced and, indeed, incorrect interpretations of the TRIPS Agreement'. Brazil in Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 9. Cf. *Abbott*, Quaker Paper 7 (2001) p. 22.

684 Compare WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 at 3, 5-6. Cf. *Abbott*, 8 JIEL 1 (2005) p. 83-84.

the Vienna Convention; their efforts were rewarded when it was agreed at the Doha Ministerial Conference that:

> 'In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.'[685]

By reiterating the role that the customary rules of interpretation of public international law play, Member States have further entrenched the importance of viewing the TRIPS Agreement in a context that includes references to public interest policies, social and economic welfare and the balancing of rights and obligations.[686] The result of paragraph 5(a) of the Public Health Declaration goes a long way in ensuring the policy objectives of the Public Health Declaration are noticed and applied.[687]

2. The Public Health Declaration and Articles 7 and 8 of the TRIPS Agreement

The role the Public Health Declaration plays is similar to the role of Articles 7 and 8 of the TRIPS Agreement. Like Articles 7 and 8, the Public Health Declaration reaffirms that health is a valid consideration factor when determining the meaning of a TRIPS provision. Both aid in creating the context in which a provision is interpreted. Both also refer to the importance of the protection of the public interest. As such the Public Health Declaration serves as a reminder of the core values behind the protection of intellectual property rights and ensures that these are not to be overlooked.

In addition to the reaffirmation of the role of the scope and purpose in interpreting the TRIPS Agreement, the Public Health Declaration makes a specific reference to the role of public health in the interpretation of the TRIPS Agreement; paragraph 4 reads:

> 'We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.'

685 Public Health Declaration para 5(a).

686 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 132. Although the Public Health Declaration is in principal limited to the role of public health in the interpretation and implementation of the TRIPS Agreement, the general formulation of the chapeaux to para 5 and the contents of pa 5(a) provide an impression that this is to apply to intellectual property rights as a whole. A further result of the inclusion of this provision is that it will likely dispel the role of customary international law as being an autonomous source of law, i.e. no merely as an interpretative tool. Cf. *Matsushita et al*, The World Trade Organization: Law, Practice, and Policy (2nd edn OUP Oxford 2006) p. 21.

687 The customary rules of interpretation are however eternally limited as they can only clarify what flexibility existed under the TRIPS Agreement. Compare Switzerland in TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 47.

By directly addressing the relationship between public health and intellectual property rights the Public Health Declaration has achieved something not previously accomplished; it rationalised intellectual property rights. Intellectual property rights, in particular patent rights, have generally been an autonomous area of law. Its restrictive effects were seen to be justified in the intellectual benefit it brought a country. This conclusion, mainly based on evidence from developed countries, was felt as being a global recipe for development and progress – at least this was one of the reasons given by developed nations to sweeten the acceptance of increased intellectual property rights by developing countries. It was the unfortunate combination of increased public health threats and tightened patent limitations that brought the world's attention to the relationship between public health and the TRIPS Agreement. In the eyes of the public at large it was inconceivable that patent rights could be equated with the right to health. Unable to counter such a vivid image of rich companies exploiting the poor and sick, developed Member States were compelled to react. Paragraph 4 is this reaction. It reflects the single most important 'victory' for developing Member States; they succeeded in shifting the weight of intellectual property rights in favour of the public interest. This political success can only be partially regarded as a legal success. A closer look at paragraph 4 shows that the TRIPS Agreement does not prevent a Member States from taking measures to protect public health. This statement reflects that this is not a new development. According to the Public Health Declaration, the TRIPS Agreement never prevented Member States from taking measures to protect the public health. If Member States felt that this was not the case they erred. From a legal point of view no new rights arise and no old obligations terminate. Notwithstanding this, the legal consequence is two-fold. Firstly, the flexibilities found in many TRIPS provisions can be exercised to the full.[688] This removes any doubt that interpretations limiting the extent of patent rights must be done restrictively. Secondly, paragraph 4 shifts the centre of balance in the interpretation of the TRIPS Agreement. The implementation of the TRIPS Agreement occurs as much from DSB rulings as from international pressure. Uncertain of the extent to which the flexibilities could be interpreted, many Member States succumbed to views held by other more influential Member States. The political consequence of the first sentence of paragraph 4 effectively grants Member States wishing to take advantage of the flexibilities in the TRIPS provisions a moral crutch to resist pressures requiring the contrary. The flexibilities – the wiggle room in the TRIPS Agreement – are also grey areas for the DSB. Uncertain of the extent to which the TRIPS negotiators intended their provisions to be used, the Public Health Declaration gives the DSB an additional body of evidence that will support an interpretation in a certain way. The Public Health Declaration states further in the second sentence in paragraph 4 that the interpretation of the TRIPS Agreement should, where applicable, support a Member State's measures to protect its citizen's health. This statement in the Public Health Declaration is likely to have an effect on

688 Public Health Declaration para 4, second sub-paragraph.

the DSB's policy of 'objective assessment'.[689] The DSB has maintained a rigid policy of assessing exclusionary and trade restrictive measures taken by Member States in a strict manner. Justifications presented by Member States defending their measures have been required to objectively substantiate their actions. In light of the Public Health Declaration's confirmation that the full flexibility can be exercised when taking measures to protect the public health, the DSB will be required to determine whether an objective assessment policy will limit the flexibilities to which the Member State is entitled. Bloche notes that the DSB has increasingly been willing to defer the decision regarding health and environmental matter to the Member States themselves, despite there being objective/scientific uncertainty regarding the measures taken.[690] This is increasingly likely to be the case in respect of measures taken to protect the public health.

The effect of paragraph 4 on the scope and purpose of the TRIPS Agreement can therefore be surmised as fortifying the role of Articles 7 and 8, reinforcing the autonomy of the Member States' public health policies and ensuring that flexibilities can be used to the full and will not be interpreted to the disadvantage of public health measures – all highly relevant aspects in applying the scope and purpose of the TRIPS Agreement. This however does not however alter any material obligations.[691] The proviso in the second sentence of paragraph 4 is a reminder that despite the swing to public interest, the obligations a Member State has under the TRIPS Agreement remain.[692]

3. The Public Health Declaration and the right to health

There is no express obligation in the TRIPS Agreement requiring Member States to protect human rights.[693] The TRIPS Agreement and the other WTO Agreements are trade agreements; their obligations pertain to measures to regulate the flow of trade between its members. The WTO obligations do however acknowledge that public interest issues – which by virtue of their scope encompass human rights – can play a role in the implementation and interpretation of the WTO obligations.[694] The Public Health Declaration however marked the first, albeit indirect, reference to the role of human rights, in particular the right to health, within WTO. It stated:

> 'We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the

689 *Gregg Bloche*, 5 JIEL 4 (2002) p. 831.
690 Also referred to as the 'precautionary principle'. Cf. *Gregg Bloche*, 5 JIEL 4 (2002) p. 834.
691 The Public Health Declaration has not altered the status of Arts 7 or 8. They remain general or non-operative provisions that assist in the understanding and application of other TRIPS provision. Cf. *Rott*, 25 GRURInt 2 (2003) p. 106.
692 The corollary of para 4 is that public health measures does not and should not prevent Member States from protecting intellectual property rights.
693 *Rott*, 25 GRURInt 2 (2003) p. 104.
694 Compare GATT Art XX, GATS Art XIV.

> TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.'[695]

This statement confirmed the developing Member States' position that domestic public health policies are not restricted by the TRIPS Agreement. This implies that a Member States is able to prioritise its public health measures over its intellectual property rights system. This does not mean that a Member States can ignore the implementation of its TRIPS obligations;[696] rather it means that in implementing the obligations, a Member States may validly favour an interpretation that prioritises health policies over stricter patent protection and may exercise the exceptions in the TRIPS Agreement to the benefit of health policies. This right to exercise the TRIPS Agreement to the benefit health measures or other public interest measures existed at the very beginning of the TRIPS Agreement. The Public Health Declaration is effectively an affirmation of old rights.

Public health is, as mentioned above, the duty a state has to its citizens to ensure their right to health is respected and performed. The reference in the Public Health Declaration to public health and not the right to health stems from the fact that the TRIPS Agreement concerns itself with the obligations Member States have amongst one another. The TRIPS Agreement cannot out of its own right impose domestic rules. Notwithstanding this the correlation between public health and the right to health is clear. Although perhaps ethereal in nature, the right to health and the tacit acknowledgement in the Public Health Declaration indicates that the TRIPS Agreement is not an island but can and should be to the greater good of mankind.

The role of the right to health will become even more important the more intellectual property rights become entrenched. The right to health, public health and other public interest considerations play an important role in balancing the obligations that flow from intellectual property rights.[697] The more a state is able to ensure the public interest is attended to the greater the chances will be that intellectual property rights will be deemed socially acceptable and better protected.

As a result of the Public Health Declaration and its references to public health, there has and will continue to be added attention to public health and its alter ego the right to health in international relations.[698] This is already evident in bilateral trade treaties, where the US's free trade agreements with Chile, Bahrain, Morocco and Oman all have references to the Public Health Declaration.[699]

695 Public Health Declaration para 4.
696 Art XXIII of the GATT Agreement and Art 64 of the TRIPS Agreement.
697 *Taylor*, 80 WHO Bulletin 12 (2002) p. 976, *Chapman*, 5 JIEL 6 (2002) p. 879.
698 *Gregg Bloche*, 5 JIEL 4 (2002) p. 847.
699 US/Chile FTA c 17 chapeau, US/Bahrain side letter to c 14 of the FTA, US/Morocco side letter to c 15 of the FTA, US/Oman side letter to c 15 of the FTA. For a discussion on the effect of the Public Health Declaration on bilateral trade treaties see Chapter 8(F)(II) below.

4. Conclusion

The Public Health Declaration has embellished the role of the scope and purpose of the TRIPS Agreement.[700] As a result there is more substance and form available for Member States to apply when interpreting the TRIPS Agreement. With the added clarity comes the confidence for Member States to actually apply the principles found in TRIPS Agreement's scope and purpose; especially in relations to patents and public health. The added certainty derived from the Public Health Declaration is likely to encourage Member States and the DSB to grant other social interests a greater role in the interpretation of the WTO Agreements. It can therefore be said that the Public Health Declaration has not only cemented the role of public health in the TRIPS Agreement but it has also created more awareness for the role of other rights and public interests in the interpretation and implementation of the WTO Agreements.[701]

II. The material obligations

The effect of the Public Health Declaration is not limited to the scope and purpose provisions of the TRIPS Agreement; it also provides guidance and clarification with respect to the material provisions of the TRIPS Agreement.

The Public Health Declaration makes references to two material obligations in the TRIPS Agreement: exhaustion (Article 6) and compulsory licenses (Article 31). The latter is dealt with in two sub-groups: the grounds for compulsory licenses (Articles 31 generally) and the prohibition on compulsory license for export purposes (Article 31(f)). Each of these points is discussed separately below.

1. Exhaustion

The exhaustion of intellectual property rights is, as set out in Article 6 of the TRIPS Agreement, the prerogative of the Member States.[702] Despite this and as mentioned in Chapter 5(C)(V) on Exhaustion Seite 149 above, the TRIPS provisions relating to exhaustion has provided much fodder for debate and disputes in the WTO arena. The discussions became more intense when certain Member States, thereunder the US, indicated their desire to restrict the extent to which Member States exercise their exhaustion regime. This 'attack' on the *ultra vires* role of exhaustion intimidated other Member States from exercising Article 6 of the TRIPS Agreement. This uncer-

700 *Gervais*, 1 JIPLP 4 (2006) p. 251.
701 *Gervais*, 1 JIPLP 4 (2006) p. 251.
702 Contrast *Straus and Katzenberger*, Parallelimporte: Rechtsgrundlagen zur Erschöpfung im Patentrecht (Schweizerische Eidgenossenschaft Munich 2002) p. 38-47

tainty motivated these Member States to reassert the role of Article 6 within the scope of the Public Health Declaration.

Like Article 6 and footnote 6 of the TRIPS Agreement, the Public Health Declaration makes it clear that the freedom to implement an exhaustion regime is not subject to challenge under the WTO.[703] Paragraph 5(d) of the Public Health Declaration says in no uncertain terms that 'the effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for exhaustion without challenge'.

It would be amiss to automatically limit the effects of the Public Health Declaration to the scope of public health. Although the Public Health Declaration states that the clarifications of the flexibilities in paragraph 5 are for the purpose of the Public Health Declaration, the phraseology of paragraph 5(d) itself does not limit itself to public health but instead refers in general terms to the all the 'provisions of the TRIPS Agreement' affecting exhaustion.[704] Despite the language used the context of paragraph 5 is intellectual property rights and public health. As such there is no definitive clarity whether or not paragraph 5(d) can be used outside the scope of public health.[705] It is foreseeable that Member States seeking to a grant universal application to paragraph 5(d) could argue that a restriction to a limited number of sectors could constitute a discriminatory act.

The Public Health Declaration is also likely to counter the view taken that Article 6 was merely procedural in nature. Paragraph 5(d) of the Public Health Declaration makes it abundantly clear that all TRIPS provisions relating to exhaustion do not diminish the Member States' right to implement its own exhaustion regime. Therefore, Articles 27 and 28 of the TRIPS Agreement do not, and will not, impose a restriction on the domestic rules pertaining to when a country will deem the rights of a intellectual property right holder to have been exhausted.

2. Compulsory licenses

The absence of rules or guidelines setting out when compulsory licenses could be used in a national patent system was one of the grounds why the TRIPS Agreement could actually be concluded. The wide variety of the national practices meant that the negotiating parties were unable to find sufficient common territory on the scope of application and the use of compulsory licenses.[706] Whereas the absence of a catalogue of grounds may have led to the TRIPS Agreement being adopted, it also

703 *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen (Nomos Baden Baden 2002) p. 249.

704 See Chapter 6(C)(II)(1) above.

705 Compare *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen (Nomos Baden Baden 2002) p. 249. Contrast *Hermann*, 13 EuZW 2 (2002) p. 42.

706 *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen (Nomos Baden Baden 2002) p. 279-280.

meant that there was legal uncertainty. This uncertainty was particularly evident when seeking to use compulsory licenses. The Public Health Declaration sought to clarify this uncertainty.[707]

The 'freedom' to apply the flexibilities of the Public Health Declaration ensures that a restrictive interpretation of the TRIPS provisions is no longer a requirement when interpreting the TRIPS Agreement.[708] In respect to compulsory licenses, the Member States identified two key flexibilities:

> '5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
>
> (a)…
>
> (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
>
> (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.'[709]

a) The flexibilities in paragraph 5 of the Public Health Declaration

In addressing the compulsory license flexibilities mentioned in paragraph 5 of the Public Health Declaration one must first consider what effect the *chapeau*[710] has on the provisions. WTO jurisprudence has held that the application of certain provisions must be done in compliance with the requirements of the *chapeau*.[711] The *chapeau* in paragraph 5 says that the flexibilities should be seen 'in light of paragraph 4', i.e. the protection of public health. At first glance it may appear that the flexibilities mentioned in the Public Health Declaration should now be applied in a manner that supports the protection of public health. This is not the case. Firstly, each TRIPS Agreement provision must be viewed in terms of its own *chapeau*. The flexibilities mentioned in paragraph 5 stem from express terms within the WTO Agree-

707 As mentioned in Chapter 6(A)(III) above, the Public Health Declaration also referred to Art 31(f). This effect is dealt with in more detail in Chapter 6(C)(IV) below.

708 This 'freedom' does not extend to overriding the good faith requirements set out in the WTO *United States – Section* 211 (panel ruling) p. 85 and Art 31 of the Vienna Convention.

709 Public Health Declaration para 5. Para 5 does not create a *numerus clausus* of flexibilities, it merely identifies some of those present.

710 The *chapeau* is the introductory sentence in a provision; its purpose is to avoid misuse or abuse of the remainder of the provision. Significant importance has been given to the *chapeau* in provisions in other WTO Agreement. Cf. WTO *US – Gambling* (panel ruling) p. 235 *et seq*, 262-265. In paragraph 5 of the Public Health Declaration the *chapeau* states: 'Accordingly, and in light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:'

711 WTO *US – Gambling* (Appellate Body ruling) p. 122.

ments. Accordingly, their respective *chapeau* will apply. Secondly, the paragraph 5 *chapeau* does not set any conditions, rather it indicates that the policy measures contained in paragraph 4 recognise that the TRIPS Agreement has flexibilities that can be used to realise the paragraph 4 policy measures. In other words paragraph 5 does not contain or alter any of the flexibilities, it merely identifies them. Thus, those flexibilities identified can be used as much to promote public health as other public interest policies.

For some Member States the confirmation that the flexibilities were available was insufficient;[712] they sought to expressly confirm the flexibilities of four provisions, two of which concerned the application of compulsory licenses:[713] the sovereign right to grant and determine the grounds for a compulsory license[714] and the right to determine what constitutes an extreme urgency.[715]

b) Paragraph 5(b) of the Public Health Declaration

The freedom to grant compulsory licenses and determine when and why they will be used is a significant clarification of the TRIPS Agreement. This 'freedom' marks a return to the general understanding of the TRIPS Agreement at its adoption in 1994[716] by removing certain misunderstandings that may have arisen in its first years of application. Hence, paragraph 5(b) ensures that Member States will no longer be able to impose their own compulsory license 'morality' or understanding on other Member States. Although the effect of paragraph 5(b) is first and foremost political, indirect legal effects are likely to flow. Member States will have the confidence to enact compulsory licenses in ways not considered or explored before. In other words, Member States are likely to be less conservative in the use of compulsory licenses and more willing to investigate the boundaries of what is legal. Further, there can be no contention that compulsory licenses may only be granted in extreme urgency situations, government use or to remedy anti-competitive acts.[717] Compulsory licenses granted to counter public health problems, whether extremely urgent or not, are fully compliant with the TRIPS Agreement.

Paragraph 5(b) of the Public Health Declaration refers to the right to grant 'compulsory licenses'. The TRIPS Agreement however refers to the 'use without the au-

712 As early as April 2001 the US had confirmed the right a Member State has to use the flexibilities in the TRIPS Agreement. Cf. US in the TRIPS Council Minutes (01.06.2001) IP/C/M/30 p. 69. Notwithstanding this recognition, they proceeded to challenge certain provisions of the Argentinean and Brazilian patent systems.

713 Zimbabwe on behalf of the African Group in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 5.

714 Public Health Declaration para 5(b).

715 Public Health Declaration para 5(c).

716 *Blakeney,* Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPs Agreement (Sweet & Maxwell Perth 1997) p. 91.

717 These three grounds for compulsory license are expressly referred to in Art 31 of the TRIPS Agreement.

thorisation of the right holder'.[718] The discrepancy in the choice of terms raised the question: is the Public Health Declaration limited to compulsory licenses? To answer this question requires an explanation of the use of terms in the negotiations preceding the TRIPS Agreement. The TRIPS negotiating parties had found that the term 'compulsory license' posed certain problems as it was not a universally accepted or applied term.[719] Further, a distinction had to be made to the limited exception, now found in Article 30 of the TRIPS Agreement.[720] The term used sought merely to provide the best common denominator for the use of a patent without the patentee's consent.[721] Notwithstanding the use of the term for convenience purposes, the question remains: did the Member States at the Doha Ministerial Conference specifically seek to make a distinction between the terminology they used and that in the TRIPS Agreement? If so, the result would be that the Public Health Declaration would not apply to the government use which, in a limited sense within the WTO, is not a compulsory license.[722] Such an intention is not immediately clear from the text of the Public Health Declaration. Paragraph 5(b) indicates that compulsory licenses can be granted for any reason. It is therefore plausible that 'compulsory license' is referred to in its wider sense and includes government use. The Public Health Declaration negotiating history indicates that the term compulsory license did not take a restrictive meaning but often included compulsory license in its wider sense, i.e. including government use.[723] The general use of the term 'compulsory license' by the Member States leaves the impression that they intended the contents of the Public Health Declaration to extend to all forms of use of the patent without the patentee's consent.[724]

718 TRIPS Agreement Art 31.

719 The US does not issue 'compulsory licenses'. It does however allow for the use of a patent without the patentee's consent in cases such as government use or instances to remedy anti-competitive acts. The NAFTA also contains a similar provision in Art 1709.10. Cf. *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 230 fn. 597.

720 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 461-462.

721 The use of the term by academics also tends to indicate that the 'use without the authorisation of the right holder' is a synonym for compulsory license. Compare *Straus,* Implications of the TRIPS Agreement in the Field of Patent Law in: *Beier and Schricker* (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 202, *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 230, *Abbott,* Quaker Paper 9 (2002) p. 8.

722 *WTO*, (2003) p. 4.

723 For example US, Cuba, Hungary, Hong Kong in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 38, 50, 55, 66.

724 *Correa* sees no significance in the use of the term compulsory license other than for the fact that it might encourage its use by government agencies. Cf. *Correa*, Quaker Paper 5 (2001) p. 15. *Nolff* refers to a compulsory license definition as being 'when a government allows a third party to make, use or sell a patented product'. This definition would thus, at the very least theoretically, incorporate government use within the definition of compulsory license. Despite this, *Nolff* himself comes to a contrary conclusion; how he does not explain. Cf. *Nolff*,

The inclusion of the non-authorised use of a patent by governments within the scope of the Public Health Declaration's compulsory licenses acquires further confirmation and endorsement by paragraph 5(c) which reaffirms the Member States' sovereign right to determine what an extreme urgency is. This is particularly relevant as public health problems most often require quick responses, especially from the government.[725] The appropriation of certain patent rights by a government without the patentee's consent, the so-called government use, is often the most appropriate way to respond to the public health problem. As such government use of a patent to protect the public health is a vital part of the measures taken to counter urgent civil illnesses.[726]

c) Paragraph 5(c) of the Public Health Declaration

The right to determine what constitutes an extreme urgency is, as discussed in Chapter 5(C)(III)(3)(d)(aa) Seite 113 above, a freedom and flexibility that existed prior to the Public Health Declaration. Like the right to determine the grounds of a compulsory license, the scope of an extreme urgency was called into doubt prior to the Doha Ministerial Conference. To clear any misconception that may have arisen, the Public Health Declaration expressly confirms that the grounds for extreme urgencies are a national prerogative. Although this has no direct effect on the material obligations under the TRIPS Agreement it does remove any degree of uncertainty as to what the Member States are entitled to do. The right to determine what constitutes an extreme urgency is insofar relevant in that Member States are not restricted to certain predefined examples or generally held ideas. The right is however, like the freedom mentioned in paragraph 5(b), not absolute or beyond review. Member States are required to ensure that the standards they have implemented to gauge an extreme urgency are not only done in good faith but also do not unjustifiably limit the rights of the patentee.

The scope of the right set out in paragraph 5(c) depends on the individual circumstances of the particular Member State. This relativity of the right is dependent not only on the extent of the emergency, but also on, *inter alia*, the amount of persons affected, the status and wealth of a state, the acuteness of the threat, the availability of treatment measures and the subjective perception of the threat by both the government or its citizens. The phrasing of the paragraph puts particular emphasis on the right of '[e]ach Member' to determine which domestic circumstances will be re-

86 JPTOS 4 (2004) p. 296. Should the use of the term 'compulsory license' be deemed to exclude the government use of patents, Member States could nevertheless argue that – like compulsory licenses – Art 31 does not limit the grounds for government use of patent rights.

725 The association between expediency and compulsory licenses is also found in the Decision of the General Council 'Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health' (30.08.2003) WT/L/540.

726 This approach is confirmed by para 4 of the Public Health Declaration which states that the TRIPS Agreement 'should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health'.

garded as an extreme urgency situation. This implies that what is regarded in one country as constituting an extreme urgency need not automatically mean it will be regarded as such in another. The independence of this concept – also present prior to the Public Health Declaration – seeks to ensure that Member States concentrate their measures on combating the urgency and not on deliberating if other Member States will agree or not. The importance of the independent evaluation can also be separately deduced from paragraph 4 where it is stated that not only are Member States not limited by the TRIPS Agreement when taking steps to protect the public health, but the TRIPS Agreement can and should be interpreted in a manner supportive of the right to protect the public interest. Notwithstanding the existence of this freedom, the Public Health Declaration made specific reference to the public health crises, including those epidemics: HIV/AIDS, malaria and tuberculosis. The term 'public health crises', like the term extreme urgency, evades a precise definition.[727] Notwithstanding the objective inability to define the scope of a public health crises, the WHO has stated that 45 countries are currently facing human health crises and/or emergencies.[728] This number is extended if public health crises affecting animals are included.[729] The Public Health Declaration assists in adding body to the meaning of 'public health crises'. It states that epidemics, such as HIV/AIDS, malaria and tuberculosis, will constitute a public health crisis or extreme urgency. The Public Health Declaration does however make it explicitly clear that epidemics mentioned are merely examples and could justify being classified an extreme urgency by a Member State.[730] Thus, despite the interplay between the concepts 'public health crises' and 'extreme urgency', Member States will be able to freely determine which situations it deems severely threatening to its citizens wellbeing. Although the Public Health Declaration does confirm the sovereign right to determine when an extreme urgency will exist, it will be bound under the general treaty obligation to exercise the TRIPS

727 The WHO cautions against making a list as 'any disease list could become obsolete the day after it was printed'. *WHO*, Global Crises – Global Solutions: Managing public health emergencies of international concern through the revised International Health Regulations (WHO Geneva 2002) p. 5.

728 They are: Afghanistan, Angola, Botswana, Burkina Faso, Burundi, Central African Republic, Chad, China, Colombia, Democratic Republic of the Congo, Republic of Congo, Côte d'Ivoire, Djibouti, Eritrea, Ethiopia, Ghana, Guinea, Haiti, India, Indonesia, Islamic Republic of Iran, Iraq, Lesotho, Liberia, Malawi, Mozambique, Niger, Nepal, Pakistan, Philippines, Russian Federation - North Caucasus (Chechnya), Rwanda, Serbia and Montenegro, Sierra Leone, Somalia, South Africa, Sri Lanka, Sudan, Swaziland, Tajikistan, Tanzania, Uganda, Venezuela, Zambia and Zimbabwe. 8 international regions are also classified as experiencing health crises or emergencies. Cf. *WHO* (2006).

729 *Nicoll et al*, 323 BMJ 7325 (2001) p. 1321. Examples only affecting the UK include foot and mouth disease and bovine spongiform encephalopathy (BSE). The transmissibility of certain diseases from animal to man and the social importance of domestic animals justify this position; severe acute repository syndrome (SARS) and the H5N1 avian flu strain are more recent example hereof

730 As the Public Health Declaration did not introduce any new provisions into the TRIPS Agreement it must be recalled that Art 31(b) only refers to extreme urgencies. The term 'public health crises' is not relevant to Art 31(b).

Agreement in good faith. In this regard it is important to recall that the Public Health Declaration refers to public health problems and crises. This qualification sets an objective assessment of the threat. In other words, a Member State must be experiencing a difficulty in countering the threat. Current resources must, in one way or the other, be insufficient to counter the threat. The difficulty need not be limited to a lack of financial resources but may also extend to a lack of material resources, as well as distribution and administrative difficulties. Such a restriction on the 'right' to determine what constitutes an emergency is a necessary and reasonable safeguard to ensure that Member States do not abuse the flexibilities found in the TRIPS Agreement.[731]

It is difficult to comprehend exactly why paragraph 5(c) was included in the Public Health Declaration. From an operational perspective the classification of a situation as being an extreme urgency will only enable a Member State to bypass the requirement of prior negotiations with the patentee. This circumvention of the prior negotiation requirement is also permissible when the use of the patent is authorised by the government. Not only is it permissible, but it can also be used when there is no extreme urgency; thus leaving Member States in the position of issuing compulsory licenses for government use but without having to determine or justify a situation as being an extreme urgency. Although government use permits a simpler way of achieving the same result, it does not make a direct impact on compulsory license applications by non-governmental and private persons or institutions. Such applicants will only be able to circumvent the prior negotiations requirement when there is an extreme urgency. This distinction is unlikely to cause too many problems in combating such extreme urgencies as the quickest reaction to an extreme urgency will come from the government. An example of this is the declaration of a national emergency. It thus follows that in such situations where the licensing of a patent is necessary it will predominantly be the government that authorises its use in its name, i.e. as government use.[732] The theoretical possibility still exists that a private compulsory license application will be made in an extreme urgent situation and therefore making paragraph 5(c) theoretically worthwhile. It would however be a poor reflec-

731 The 'problem' is not to be equated with the legal concept of impossibility (either objective or subjective impossibility). The Public Health Declaration does not require a Member State to redirect all its resources to counter a threat. The allocation of resources is a national prerogative and neither the TRIPS Agreement nor the Public Health Declaration imposes a limitation in this regard. Cf. Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 8.

732 This was expressly recognised by the Norwegian implementation of the tackling of public health problems will 'probably normally be subject to non-commercial use under the auspices of the public authorities'. This statement was made in reference to the para 6 of the Public Health Declaration but would effectively apply to most significant public health problems.

tion on a country's willingness to tackle an extreme urgency should such a license be applied for.[733]

d) Subsequent developments

The use of the flexibilities in the TRIPS Agreement was addressed twice by the General Council subsequent to the Public Health Declaration. In the first instance, paragraph 7 of the General Council decision on the 'Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health' (the 'Decision'),[734] the General Council sought to ensure that the system set up to resolve the dilemma referred to in paragraph 6 of the Public Health Declaration neither directly nor indirectly has the effect of restricting the flexibilities contained in the TRIPS Agreement. This statement reaffirms the position in the Public Health Declaration that the flexibilities contained in the TRIPS Agreement may be exercised to the full by the Member States and that the measures taken by the Member States do not limit this – unless expressly stated. The second instance where the issue of flexibilities was addressed was in the formalisation of the Decision by the General Council in December 2005 (Decision of the General Council 'Amendment to the TRIPS Agreement' (the 'Amendment').[735] This decision of the General Council amends the TRIPS Agreement by inserting a new article, Article 31*bis*. Paragraph 5 of Article 31*bis* is an *ad verbatim* transformation of paragraph 11 of the Decision. The consequence hereof is, upon the entry into effect of the Amendment, that Member States will be able refer to an express treaty provision that confirms that the flexibilities of the TRIPS Agreement remain unencumbered – save for the instances where they serve to permit Member States access to medicines under paragraph 6 of the Public Health Declaration. The presence of a formal confirmation that flexibilities remain free from limitation will surely reassure Member States taking steps to exercise the flexibilities to the full.

The correlation between paragraph 4 and 5 of the Public Health Declaration and the newly inserted Article 31*bis*(5) of the TRIPS Agreement is strengthened by the numerous references in the Amendment to the Public Health Declaration.[736] In addition hereto the interpretation of the Amendment will require the interpreter to assess its context, of which the Public Health Declaration forms an essential part.

733 The inability to adequately make utilise the TRIPS provisions may however be an indication of insufficient know-how and technical knowledge.

734 Decision of the General Council 'Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health' (30.08.2003) WT/L/540 ('Decision') para 9.

735 Decision of the General Council 'Amendment to the TRIPS Agreement' (08.12.2005) WT/L/641 ('Amendment') (Annex III hereto).

736 References are found in the preamble to the Amendment, the Annex and the Chairman's Statement.

Notwithstanding the additional references to the flexibilities in the Public Health Declaration, neither the Decision nor Article 31*bis* limit or extend the scope and application of the flexibilities found in the TRIPS Agreement.

e) Conclusion

Undoubtedly the contents of the Public Health Declaration will have settled the uncertainty surrounding some of the unclear and/or uncertain means of interpretation and implementation of compulsory licenses. Notwithstanding the clarification of these issues, the Public Health Declaration was, in respect to compulsory licenses, a mere reaffirmation of the norms existing in the agreement from its inception, and as such do not permit legal scholars no interpret new direct legal rights or obligations into the TRIPS Agreement.[737] With the exception of system enabling certain Member States to satisfy their domestic compulsory licenses in other countries, the newly adopted Article 31*bis* does not alter the current reading or understanding of the obligations under the TRIPS Agreement. Instead Article 31*bis* serves to confirm the sovereignty of the concept of the flexible interpretation of the TRIPS provision. As such, and in connection with the Public Health Declaration, both have an important role for the future implementation of international intellectual property rights and their effect on national legal systems. Member States, especially those uncertain or subject to international intimidation, will now have more ammunition to defend their desires to make meaningful use of their compulsory license system.[738]

III. The extension of the transitional period for LDCs

1. Paragraph 7 of the Public Health Declaration

In addition to reaching an agreement on the clarification of certain TRIPS provisions, the parties to the Doha Ministerial Conference agreed that the complete implementation of the TRIPS Agreement by certain Member States, initially set for 2006, would not be required until 2016. Paragraph 7 of the Public Health Declaration states:

> 'We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council

737 *Correa* notes that the Public Health Declaration, or parts thereof, merely state the obvious. Cf. *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 15.

738 An amendment to the Belgium patent system has introduced a compulsory license to be granted on public health grounds. During the adopting thereof express reference was made to the Public Health Declaration. See *Van Overwalle*, 37 IIC 8 (2006) p. 908-909.

for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.'

The reason for the inclusion of the extension of implementation duty arose as a result of Article 66 of the TRIPS Agreement. Article 66.1 states that LDCs were not required to im-plement the TRIPS obligations until 2006.[739] As this date was fast approaching and clearly in the minds of the LDCs during the negotiations leading up to the Public Health Declaration, these Member States sought to have their obligations further extended.

The transitional period in Article 66.1 was initially seen as a significantly long period of time for LDC Member States to create and implement a comprehensive and functioning intellectual property rights system. However, as the expiry date of the transitional period approached, LDC Member States began to question whether this period was in fact long enough.[740] The difficulties lay not only in enacting a comprehensive intellectual property system but also in implementing such a system and being sufficiently well versed in the system to ensure it is implemented in a manner that is conducive to social and economic welfare. Developed Member States viewed the transition period as being one of the core flexibilities available in the TRIPS Agreement.[741] The diverging views came to a head in the negotiations preceding the Public Health Declaration. The LDC Member States feared that the expiry of the transitional periods would require an intellectual property rights system that would accentuate poverty and dependency, especially with the advent of diseases such as HIV/AIDS, tuberculosis and malaria. In the light of these difficulties the LDCs pushed to have the implementation of these obligations delayed.[742] The TRIPS Agreement makes provision for the extension of the transition periods in Article 66.1 of the TRIPS Agreement and requires each LDC Member State to apply for the extension individually. The LDCs did not use this approach but instead chose

739 Art 66 of the TRIPS Agreement does however note that LDCs are nonetheless required to implement Arts 3 (national treatment), 4 (most-favoured nation treatment) and 5 (multilateral agreements). The implementation period is calculated in terms of the general transitional period of one year in Art 65.1 plus the 10 year transitional period foreseen by Art 66.1. Cf. *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 716.

740 Tanzania made reference to the obligation developed Member States have in respect of providing incentives to enterprises and institutions to promote and encourage technology transfers. Cf. Tanzania in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 30.

741 Compare US in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 at 36-37. The US representative is quoted as saying: 'I would like to remind delegations that among the most significant flexibilities contained in the TRIPS Agreement are the transition periods provided to developing and least-developed country Members'.

742 Compare WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 at p. 4. In the latter proposal Brazil calls for an extension of *5 years* on patents affecting the public health in both developing and least-developing Member States.

to proceed as a unit, requiring a general extension to all LDCs. Not only did a united front spread the burden but the TRIPS forum, swayed by the political momentum flowing from the HIV/AIDS crisis, presented a more opportune vehicle to acquire a blanket extension.

Unlike the extensive debates on compulsory licenses, Member States found it relatively easy to reach an agreement on the extension of the patent obligations for LDCs. A reason for this ease stems from the fact that the extension was limited to LDCs, as opposed to both developing and developed Member States, and to pharmaceutical products. [743]

The limitation on the countries eligible for the extension derived from Article 66.1 which limits the initial transitional period to LDCs. This limitation however was the key to the quick adoption of the paragraph 7 instruction. It is the LDCs that are on the one hand most susceptible to public health problems and on the other hand least able to respond to these problems. Further, the lack of technical knowledge and infrastructure means that LDCs pose little of a threat to pharmaceutical industry, either the developing countries or elsewhere.[744] The reason why this was not extended to benefit all developing Member States was the fact that a large portion of these countries already had functioning intellectual property systems and that a large number of these countries had both an operational pharmaceutical industry, a large market and thus the ability to exploit any extension.[745]

What was precisely meant by a 'pharmaceutical product' was not set out in the Public Health Declaration. Clearly however the reference to the product and not the type of patent implies that the product can derive from a product patent or a process patent.[746] Viewed within the context of the Public Health Declaration, in particular

743 Thus excluding pharmaceutical process patents.

744 Most LDCs lack a domestic pharmaceutical industry and thus rely on imports for more developed countries which, by reason, already have a viable pharmaceutical patent protection system.

745 Developing countries had however called for an extension in terms of Art 65.4 of the TRIPS Agreement. Cf. WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 p. 9.

746 A pharmaceutical product can be patented itself or be the product of a patented process. As the Public Health Declaration refers to pharmaceutical products and not to patents, it must be concluded that the pharmaceutical products, irrespective of how they are protected by patent rights, are excluded. Were the meaning to be limited to patented products alone it could lead to the situation where pharmaceutical manufacturers would patent the process only and in so doing 'fence-off' the pharmaceutical product. This would defeat the object of the Public Health Declaration. The reference in the second sentence of para 7 to 'rights' does not limit its application only to product rights in terms of Art 28.1(b). Hence it must be seen as a reference to the rights contained in Art 28 as a whole. *Correa* concurs and notes that the EC also agrees. He also notes that the US views this phrase as meaning all pharmaceutical patents. Cf. *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 38. The minutes of the TRIPS Council Meeting in which the Extension was granted do not reflect a dispute in this regard. The view taken by the LDC Member States – i.e. that it refers to both patented products and processes – was not contested by any

paragraph 6, it would appear that pharmaceutical products would refer to all products produced in the pharmaceutical sector. In the absence of any subsequent agreement by the Member States this approach will remain the most authoritative.[747] Although the extension is granted within the broader scope of public health problems the concept 'pharmaceutical product' will not be limited to pharmaceutical products necessary to protect the public health.[748] Paragraph 7 does not limit the products to those 'necessary'. The extension is absolute; any pharmaceutical product can be excluded from being patented in a LDC.[749]

Aside from the limitation to pharmaceutical products, paragraph 7 also limits the extension to the scope of patents and undisclosed information, Articles 27-34 and 39 respectively. This limitation corresponds to the demands made by the developing Member States in the negotiations prior to the Public Health Declaration. It was felt that not only could patents limit the access to affordable medicines but that also the expansive protection of undisclosed information could have a similar effect by limiting generic producers from relying on the original data supplied by the pharmaceutical producers in the process of obtaining market access for the pharmaceutical.[750]

of the other Member States at the TRIPS Council Meeting. Cf. TRIPS Council Minutes (18.07.2002) IP/C/M/36 p. 48-52.

747 The *India – Patent Protection* cases I and II the DSB was required to deal with pharmaceutical chemical products under Art 70 of he TRIPS Agreement. Both the panel and the Appellate Body avoided discussing the scope of the term. Cf. WTO *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products* Report of the Panel (05.09.1997) WT/DS50/R, WTO *India – Patent Protection II*.

748 The contrary argument that the only those pharmaceutical products can be excluded that are used to treat public health problems contains some merit. Firstly, Art 66.1 of the TRIPS Agreement is an exception to the material obligations contained in section 5 of the TRIPS Agreement and as such should be interpreted restrictively. Secondly, the context of the Public Health Declaration is generally limited public health problems. However these two points cannot rebut the ordinary meaning of the words in para 7 of the Public Health Declaration. It is plainly evident from para 7 as a whole that the exception of pharmaceutical products is not coupled to public health problems. With the exception of the limitation to patents, undisclosed information and pharmaceutical products, the phraseology used in para 7 is absolute.

749 It would make little difference if the products were limited to public health problems as the term public health itself is unlimited; hence the products used to treat them could not be limited.

750 Compare India in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 24, EC and Senegal in the TRIPS Council Minutes (18.07.2002) IP/C/M/36 p. 50-51.

2. The TRIPS Council decision extending the transition period

Paragraph 7 was formally adopted by the TRIPS Council on the 27th of June 2002 (the 'Extension').[751] The Extension is an opt-in system, in other words LDC Member States are not required to take advantage of the Extension but may do so. LDC Member States opting for the extension are only excluded from enforcing Sections 5 and 7 of the TRIPS Agreement, i.e. patents and undisclosed information respectively. The scope of the exemption extends to pharmaceutical products and will last until the end of 2015.

The Extension of the transitional period under Article 66.1 included a number of procedural irregularities that have brought certain issues into question. In the third preamble paragraph of the Extension it states that paragraph 7 of the Public Health Declaration 'constitutes a duly motivated request' for the extension of the transitional period.[752] This statement is factually unfounded as paragraph 7 contains no express statements explaining or justifying the need for an extension. No reference is made in the preamble to prior discussions or negotiations and as such do not form part of the request. Within the context of the Public Health Declaration as a whole, no mention is made to the LDCs' difficulties in implementing the TRIPS agreement or the problems that would arise in implementing the TRIPS Agreement. Thus, it must be concluded that paragraph 7 fails to establish a ground for the extension of the transitional period. Although a formal motivation is absent in both paragraph 7 and the Extension, it must be assumed that the Member States would not have consented to the extension of the transitional period unless they were convinced – in one way or the other – that the Extension was justified. An additional procedural inconsistency is the extensions decisions reference to paragraph 7 constituting a 'request'. Paragraph 7 however makes no reference to it being a request. It instead 'instructs' the TRIPS Council to give effect to the extension. No evidence has been found that a formal request was ever made.[753] Despite the procedural limbo in which the Extension stands, the Member States do not contest the validity of the legal instrument.

Paragraph 7 and the Extension, implementing a *de jure* relief for LDCs, constitute little more than a consolation prize in the ambit of the Public Health Declaration. The delay in implementation has little effect on the majority of the LDCs. In a study of thirty African Member States, only two have no pharmaceutical product protec-

751 Decision of the TRIPS Council 'Extension of the transition period under Article 66.1 of the TRIPS Agreement for least-developed countries for certain obligations with respect to pharmaceutical products' (27.06.2002) IP/C/25 ('Extension').

752 Art 66.1 of the TRIPS Agreement requires any extension request to be 'duly motivated'.

753 Other interesting results of para 7 are fact that there is no certainty as to which countries are deemed LDCs. The WTO does not contain a category or standards in terms of which states are formally determined to be either LDCs or not. It is however not a requirement of the waiver process that each Member State must individually apply for a waiver. Cf. WTO Secretariat note 'Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Information on Waivers' (24.10.2002) IP/C/W/387 p. 3.

tion and thus the only two immediately able to take advantage of the Extension.[754] As Article 66 of the TRIPS Agreement is not constrained by the 'freezing clause' contained in Article 65.5,[755] LDCs with patent protection for pharmaceutical products are entitled to amend their intellectual property system so as to exclude such pharmaceutical products from being patented.

The extent to which the Extension will be exercised is yet to be seen. A prime candidate for the use would have been Mozambique. In attempts to come to grips with its public health problems Mozambique, a LDC and a country struggling with HIV/AIDS, has decided not to exclude pharmaceutical inventions from being patented but have instead proceeded to grant a compulsory license, a choice that marks the easiest method to obtain medication currently.

Paragraph 7 of the Public Health Declaration and subsequently paragraph 2 of the Extension explicitly note that in addition to the agreed extension, LDC Member States are still permitted to apply for an extension to the transitional arrangements above and beyond those contained in paragraph 7 of the Public Health Declaration. The inclusion of this provision is to reaffirm that Member States are not prohibited from applying for additional extensions beyond the scope of the Public Health Declaration. Accordingly, LDCs are still able to apply for extensions to the implementation of other obligations arising out of the TRIPS agreement.[756]

3. The General Council waiver of Article 70.9

The lack of a reference in paragraph 7 of the Public Health Declaration to the exclusive marketing rights that accrue under Article 70's mailbox system posed a problem for LDCs negotiating the paragraph 7 extension.[757] The LDCs' problem with the mailbox system stemmed from the obligation on those Member States not granting pharmaceutical and agricultural chemical inventions patents to grant such inventions exclusive marketing rights for a period of 5 years after obtaining marketing approval. This restriction was interpreted as applying to those Member States wanting to exercise the paragraph 7 Extension. Were this obligation to apply it to LDCs this would effectively mean that the concessions obtained in the Public Health Declara-

754 The countries are Angola and Eritrea. Cf. *Thorpe*, CIPR Study Paper 7 (2002) p. 11. Other LDCs from other continents that might be able to take advantage of the Extension include Afghanistan, Cape Verde, Comoros, Lao PDR, Maldives and Sao Tome and Principle.

755 Art 1.1 of the TRIPS Agreement states that Member States are not required to implement an intellectual property rights system that is more extensive than is required by the TRIPS Agreement.

756 *Baker*, Process and Issues for Improving Access to Medicines: Willingness and Ability to use TRIPS Flexibilities in Non-Procuring Countries (Fretwells London 2004) p. 14.

757 TRIPS Agreement Arts 70.8 and 9. Cf. *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 41.

tion could be 'effectively blocked' by the inventors exercising a quasi-patent right and a 5 year market monopoly.[758]

The momentum that carried the adoption of the Public Health Declaration and the Extension was used to adopt a waiver of Article 70.9. The Article 70.9 waiver was formulated in a manner that would ensure it corresponded to the Extension. To this effect, the Article 70.9 will be waived until the 1st of January 2016. [759]

However, like the Extension, a LDC Member State is not obliged to exercise the Article 70.9 Waiver. Its use is voluntary and does not require a notification of its use to the TRIPS Council or any other WTO body. It is also noteworthy that the Article 70.9 Waiver is only for the obligations contained in Article 70.9 and not for Articles 70.8 and 70.9, as initially proposed by LDC Member States in the consultations undertaken prior to its adoption.[760] The Swiss representative questioned whether a waiver of both Article 70.8 and 70.9 were necessary. Switzerland took the view that whereas exclusive marketing rights (Article 70.9) might restrict the implementation of the Extension, the mailbox system itself would not limit a LDC Member State's ability to acquire, manufacture and/or sell pharmaceutical products.[761] In the 'spirit of compromise and cooperation' and the fear that the issue would drag on otherwise, LDC Member States settled on a waiver of Article 70.9 alone.[762] Therefore, the exclusion of Article 70.8 from the waiver requires all Member States not granting pharmaceutical product inventors patents to implement a system that would enable these inventors to acquire a filing date for their inventions. Aside from the administrative obligations that flow from the implementation of Article 70.8, LDC Member States are likely to profit from the mailbox system for a number of reasons: Firstly, the Member States could require registration fees. Secondly, the implementation of the mailbox will permit such states time and experience in a 'patent-like' system. This would likely assist such states to have a put into place a functioning registration system in place prior to 2016 and which can be used subsequently for patent applications. Lastly, such Member States will have access to the information disclosed at the time of the mailbox application. This information would automatically serve to enrich domestic know-how.

758 Compare *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 41.

759 The waiver was finally adopted by the WTO General Council on 8.7.2002. Cf. Decision of the WTO General Council 'Least-developed country Members – Obligations under Article 70.9 of the TRIPS Agreement with respect to pharmaceutical products' (08.07.2002) WT/L/478 ('Article 70.9 Waiver').

760 The Chairman and Senegal, on behalf of the LDC Member States, in the TRIPS Council Minutes (18.07.2002) IP/C/M/36 p. 48, 49.

761 Switzerland in the TRIPS Council Minutes (18.07.2002) IP/C/M/36 p. 48-49. This standpoint was also mirrored by the EC and the US, p. 50.

762 Uganda, on behalf of the LDC Member States, in the TRIPS Council Minutes (18.07.2002) IP/C/M/36 at 53. Cf. ICTSD 'TRIPS Council Agrees on Extension for LDCs on Pharmaceutical Patents' *Bridges Weekly Trade News Digest* (03.07.2002) p. 1.

IV. Member States without domestic pharmaceutical production facilities

There was a general willingness amongst the WTO Member States to find a solution to the inability some Member States had in exercising compulsory licenses where they had no domestic production facilities to exercise the compulsory license. This willingness to find a solution stalled at the question of how the solution should be structured. Despite numerous suggestions[763] no solution could be reached at the Doha Ministerial Conference. To ensure that the matter did not fall from the negotiating table the Member States agreed that the negotiations should proceed in order to 'find an expeditious solution to this problem and to report to the General Council before the end of 2002'.[764]

Although there are numerous grounds that can be attributed to why Member States were not able to reach a solution at the Doha Ministerial Conference, the reality of the matter was that the negotiations on the issue raised its head relatively late in the pre-Doha negotiations and, despite the complexity of the issue, were only superficially discussed.[765] This length of time was insufficient to enable the Member States to find a solution that would address what some Member States saw as a shortcoming of the TRIPS Agreement and what others saw as a potential dissolution of certain fundamental intellectual property issues.[766] The Member States were however able to agree that the dilemma, then set out in paragraph 6 of the Public Health Declaration,[767] required further negotiations.

763 WTO Communication from the EC 'The Relationship between the Provisions of the TRIPS Agreement and Access to Medicines' (12.06.2001) IP/C/W/280 at 3-4, Malaysia, Tanzania (on behalf of the LDCs), Hungary in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 18, 29, 56, respectively WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 p. 8.

764 Public Health Declaration para 6.

765 Norway stated in the pre-Doha negotiations that Art 31(f) 'raises many important questions, most of which cannot be dealt with in-depth at this stage'. Cf. Norway in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 at p. 17. The minutes of the TRIPS Council in September of 2001 also reflect the infancy of the discussions on the Art 31(f) dilemma.

766 The issues of territoriality, independence of patents (Art 4bis of the Paris Convention), exhaustion and safeguards all played a role in negotiating a solution to the para 6 dilemma.

767 Paragraph 6 of the Public Health Declaration states: 'We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.'

Chapter 7 The solution to the paragraph 6 dilemma

A. The identification of the paragraph 6 issues

Paragraph 6 of the Public Health Declaration is misleading in the impression it gives. A read of the text leads to the thought that a solution could not be far from being achieved: the problem was well defined, the 'culprit' identified and the intention to resolve the problem was present. What paragraph 6 did lack was the identification of the issues at stake. These issues and their potential consequences would lead to the negotiations being strung out and difficult to conclude.

I. The scope of paragraph 6

Paragraph 6 contains a number of issues that define its scope. Firstly, the problem is identified as being the ineffective use of compulsory license by some Member States without sufficient (or any) domestic production facilities. Secondly, there is no reference (and thus no restriction) to Article 31(f). Although the formulation of Article 31(f) may be the cause of the problem, there is no limitation in paragraph 6 that requires that it should also be the solution. Lastly, paragraph 6 does not limit the solution to public health problems. Instead it restricts the solution to the pharmaceutical sector.[768] This is a clear reference to one of the core Public Health Declaration goals: the access to medicines.[769]

Absent from paragraph 6 is the limitation of its application to LDCs and/or developing countries.[770] One reason for this absence is the fact that some developed countries also lack domestic production facilities.[771] It would have been unwise to limit the use of a paragraph 6 solution to LDCs and developing countries as one cannot rule out the possibility that a developed Member State might some day require the assistance of other Member States in treating a public health problem. The lack of a distinction posed the greatest hurdle to reaching a solution.

768 US in the TRIPS Council Minutes (22.03.2002) IP/C/M/35 p. 14.

769 Public Health Declaration para 4.

770 Whereas the para. 1 of the Public Health Declaration refers to the public health problems being experienced by LDCs and developing countries, para. 6 refers makes no such distinction. Instead it refers to Member States in general

771 Examples of wealthy states without any pharmaceutical production facilities are: Luxembourg, Lichtenstein, Iceland, Bahrain and Andorra. Examples of wealthy states with only the capacity to produce finished products are: Brunei, Hong Kong, Kuwait, New Zealand, Saudi Arabia, Singapore, Taiwan and the United Arab Emirates. Cf. *Balance et al*, The World's Pharmaceutical Industry: An International Perspective on Innovation, Competition and Policy (Edward Elgar Aldershot 1992) p. 8-9.

The mandate the Member States had given was limited to a system that would enable those Member States without an adequate domestic pharmaceutical sector to acquire help in exercising their compulsory license from abroad. The mandate did not authorise Member States to extend the scope to other sectors where Member States have no domestic manufacturing facilities. Further, the mandate did not call into question the application of patent rights for Member States without a domestic manufacturing sector. Despite the recognition that a problem exists in the TRIPS Agreement, the mandate in no way detracts from the basic tenet that implementation of an adequate and effective patent system, inclusive of the grant and limitation of rights, remains a principal obligation of each and every Member State.

II. Manufacturing capacity

In order to be able to determine when a Member State has an insufficient or no manufacturing capacity, there must be a common understanding on what 'manufacturing capacities' can encompass. The text of the Public Health Declaration permits two views: either there is a lack of production facilities or there is an inability to produce. The former refers to the physical absence of a pharmaceutical manufacturing facility and does not include the manufacture of components or chemical compounds used in the final production. If the Member States were to limit their interpretation to a portion of the pharmaceutical production process (i.e. the lack of one chain in the production process) it would effectively defeat the purpose of paragraph 4 of the Public Health Declaration by limiting the Member States right to take comprehensive measures to protect the public health.[772] Further, any attempt to identify which stages of the production process would have to be absent would ensure that such a solution would drown in bureaucratic regulation.

The latter however, the inability to produce, is broader in scope and refers to the inability to domestically produce any/all elements at any/all stages of production of a pharmaceutical product. This would therefore include all operations commencing at the purchase of materials and products, production, quality control, release, storage and distribution of pharmaceutical products and the related controls. It would also mean that any if any one stage could not be produced domestically that this stage alone could be fulfilled by a compulsory license. This approach would thus better reflect the object and context of the Public Health Declaration as it would allow the Member State ultimately to elect which portions of the manufacturing process it wishes to undertake and/or if it would rather import the finished pharmaceutical.[773]

772 *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002).

773 The WHO also takes this expansive view of 'production'. Cf. *WHO*, WHO Expert Committee on Specifications for Pharmaceutical Preparations Technical (WHO Geneva 2005) p. 63.

III. Insufficient or no capacities

Once it has been determined what manufacturing capacities encompass, it is necessary to determine when they are insufficient or absent. Like the manufacturing capacity, absence or insufficiency can be determined in two ways: the absolute non-existence of a pharmaceutical sector or, where such exist, the unwillingness of domestic producers to produce the compulsory license for the licensee. The Public Health Declaration, in particular the inclusion of the word 'insufficient', appears to require the Member States to find a solution to both, i.e. the problem exists not only where there is no production facilities but also where the existing facilities are unable (or unwilling) to assist in the production. This would imply that although there could be an ability to produce, factors prevent this from occurring. These factors are neither limited by paragraph 6 nor by the Public Health Declaration. Accordingly, there does not appear to be a limitation as to what causes the insufficiency. Provided the reason is a reasonable and justifiable ground and not a means to circumvent the protection of intellectual property rights.

IV. Pharmaceutical sector

The reference to the 'pharmaceutical sector' is relevant in that it reflects the context of the Public Health Declaration and ensures that the solution should not extend beyond this scope. One of the goals of the Public Health Declaration was to ensure that Member States were able to afford healthcare treatment. Limiting the solution to the pharmaceutical sector reflects this goal and ensures the solution is tailored to meet this goal and not to be misused for other purposes.

The ordinary meaning of 'pharmaceutical sector' implies that only that sector that prepares, preserves, compounds or dispenses drugs will be considered.[774] This would imply that instruments, testing machinery and other non-medicinal measures used to counter epidemics and other extreme urgencies would not be included.[775] This is, to some extent, reflected by the reference to access to medicines in paragraph 4 of the Public Health Declaration. Notwithstanding this, limiting the meaning to industries producing medicines would not reflect the general context of the Public Health Declaration, i.e. taking measures to protect the public health. Non-medicine products such as diagnostic kits for HIV/AIDS play a crucial role in the treatment of diseases. A narrow interpretation of the concept 'pharmaceutical product' would rule out

774 Webster's Third New International Dictionary (Merriam Chicago 1971) p. 1694.

775 *Correa* makes another proposal. He suggests that the 'pharmaceutical sector' may be interpreted to extend to all those products sold by a pharmacy. Cf. *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 21.

much of the necessary tools required to treat public health problems.[776] Supporting an expansive interpretation of pharmaceutical sector is the notion that chemical compounds, *per se*, would also be excluded from the definition of a pharmaceutical. An exclusion of chemicals would perpetuate the problem identified in paragraph 6 and would not bring about a real solution.

V. Effective use of the compulsory license system

Paragraph 6 of the Public Health Declaration identified the scope of the problem as being the 'difficulties in making effective use of the compulsory licensing under the TRIPS Agreement'. The inability to make use of a compulsory license system because of absent or inadequate pharmaceutical production capacities meant that the affected Member States were unable to make 'effective' use of the TRIPS Agreement. By making express mention of the effective use of compulsory licenses the Member States directed the solution to the use of compulsory licenses. This formulation did away with certain pre-Doha suggestions that the insufficient production capacities could be resolved, as Canada suggested, through 'other TRIPS flexibilities, such as parallel importation'.[777] Whilst this is indeed a possible solution the Member States clearly identified the problem as being the inability to make effective use of compulsory licenses. Hence, the solution should enable the effective use of compulsory licenses. Other tools that might alleviate the difficulties experienced under Article 31(f) thus bore no further relevance when seeking a solution to the paragraph 6 dilemma. For many Member States being able to use the compulsory license system effectively was one of the safeguards they had bargained for when negotiating the TRIPS Agreement. Being able to use this safeguard, as well as all other safeguards, was a 'right' they sought to exercise. Had the Canadian approach been followed it would have effectively resulted in the loss of a safeguard.

VI. Potential paragraph 6 solutions

A number of alternative solutions and/or justifications were proposed by Member States and academics alike.[778] The proposals made can be divided into 5 distinctive categories: a TRIPS Agreement amendment, an interpretative solution, a morato-

776 The access to medicines by way of compulsory licenses for patented products or processes would be equally affected should there be no domestic pharmaceutical industry. The Public Health Declaration accordingly applies to both patented products and patented processes.

777 Canada in the TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 42.

778 WTO Secretariat note 'Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation' (11.07.2002) IP/C/W/363, *Matthews*, 7 JIEL 1 (2004) p. 83-94, *Abbott*, Quaker Paper 7 (2001) p. 12-17, *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 25-35.

rium, an Article 30 solution and an Article 6 solution. It was also generally recognised that any solution would have to incorporate safeguards to ensure that the solution is used to resolve the problem identified in paragraph 6 and not as an indirect means to circumvent the TRIPS Agreement provisions.

The discussions on a solution proceeded slowly with Member States playing tug-of-war with the issue and using it to leverage movement in other WTO negotiations.[779] It was only 8 months after the 2002 deadline had passed – the 30th of August 2003 – that the Member States were able to reach a solution. The decision and its effect are discussed below.

B. The 30 August 2003 decision

The decision of the General Council on the 30th of August 2003 (the 'Decision')[780] was hailed as being a 'historic agreement for the WTO'.[781] Although this statement represents more wishful thinking than the legal reality of the solution reached, the Decision represented a milestone in that it introduced a system whereby Member States were empowered to help those fellow Member States without the domestic ability to help themselves.[782] Notwithstanding the Decision being a 'solution', it was by no means meant to be a final decision. It was for the majority an *ad hoc* solution to apply until the Member States could agree on a final decision. Upon a final solution being adopted the Decision would lapse.

The Decision, a 'temporary solution', comprised of 11 clauses and an annex qualifying certain issues therein. Its adoption was made on the premise of certain

779 -- 'Access to Medicines: WTO Members May Snatch Defeat out of the Jaws of Victory' (2002) 6 Bridges 8 p. 1-2.

780 Decision of the General Council 'Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health' (30.08.2003) WT/L/540 ('Decision') (Annex II hereto).

781 Director General Panitchpakdi, WTO Press Release Press/350/Rev.1. The DG was also quoted a saying that the 'final piece of the jigsaw has fallen into place' and that the decision was a completion of the Public Health Declaration. This comment was unfortunately somewhat premature as the decision was an interim solution. Whereas some Member States reiterated the DG's statement, some Member States were not so forthcoming with their complements. The Djiboutian representative stated that although he was pleased with the decision he was nonetheless 'not satisfied'. The representative from the Barbados 'felt obliged to register [their] disappointment and concern'. The Jamaican representative was 'dissatisfied' with certain elements of the text. These and other Member States felt that opposing the decision would do more harm than adopting it. See in this regard Cuba, Djibouti, Barbados and Jamaica in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 9, 11, 13.

782 *Abbott,* 99 AJIL 2 (2005) p. 327.

'shared understandings' incorporated in a statement made by the Chairman (the 'Chairman's Statement') preceding the adoption of the Decision.[783]

I. The legal effect of the Decision and the Chairman's Statement

1. The waivers in the Decision

Unlike the procedural 'irregularities' and uncertainty regarding the legal effect of the Public Health Declaration, there is no doubt that the Decision has taken the form of a waiver, at least parts thereof.[784] The procedures chosen to adopt the text correspond with those required by Article IX.1, 3 and 4 of the WTO Agreement for a waiver.[785] In addition, the Decision also expressly notes that there were sufficient 'exceptional circumstances' which justified the waiver of the obligations contained in Article 31(f and h) of the TRIPS agreement.[786] Further confirmation of its waiver format was the adoption of an annual review procedure, a waiver requirement.[787] These factors confirm that all requirements for a waiver in terms of the WTO Agreement were met. As waivers, the adoption of the Decision has the effect of temporarily suspending the identified provisions, i.e. Member States will not be re-

783 Contained in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 at 6-7. The Statement was read out prior to the adoption of the Decision on 30.08.2003. The Chairman's Statement was accompanied by a 'Best Practices' attachment.

784 *Correa*, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WHO Geneva 2004) p. 5, *Hermann*, 6 ZEuS 4 (2003) p. 601-602. The Decision actually incorporates three waivers: para 2 (the waiver of Art 31(f) for the importing Member States), para 3 (the waiver of Art 31(h), the waiver of the exporting countries obligation to provide adequate remuneration) and para 6(i) (the waiver of Art 31(f) with respect to custom unions and free trade areas). Contrast *Hestermeyer*, 37 GRURInt 3 (2004) p. 198-199. Despite *Hestermeyer's* contention that the Decision may constitute an amendment he concludes that the Decision should be seen as a waiver. *Kramer* also incorrectly views the Decision as an amendment. Viewing the Decision in its individual parts clearly indicates that the document is primarily comprised of a number of waivers. The structure and the contents thereof confirm this. Cf. *Kramer*, Patentschutz und Zugang zu Medikamenten (Carl Heymanns Verlag Cologne 2007) p. 143-144.

785 Decision preamble. The procedural progress of the waiver proceeded as follows: on 28.08.2003 the TRIPS Council approved a draft decision (IP/C/W/405) and had forwarded it to the General Council for adoption. The General Council is empowered by Art IV to carry out the functions of the Ministerial Conference in the intervals between its meetings. The requirements set by Art IX.4 of the WTO Agreement, i.e. exceptional circumstances, the terms and conditions, the review thereof and the termination are all dealt with by the Decision. Cf. Decision preamble, paras 2, 8, 11. Cf. *Nolff*, 86 JPTOS 4 (2004) p. 303.

786 The text contained in the preamble referring to the existence of exceptional circumstances was inserted subsequent to the Motta draft proposal in December 2002. Cf. WTO Draft Decision (16.12.2002) JOB(02)/217 p. 2.

787 WTO Agreement Art IX.4. An additional review mechanism was included in para 8 of the Decision.

quired to comply with the waived obligations, provided they comply with the terms and conditions governing the application of the waiver.[788]

The Member States included three waivers in the Decision to implement their paragraph 6 solution. The first sets out the circumstances when a Member State will be entitled to grant a compulsory license solely for export without infringing Article 31(f).[789] The second waiver was adopted to ensure that the requirement of having compulsory licenses in both the exporting and the importing Member State does not lead to a double remuneration for the patent holder.[790] The third waiver makes provision for establishing economies of scale within the context of the dilemma set out in paragraph 6 of the Public Health Declaration. In terms of the Decision, the limitations imposed by Article 31(f) will not apply within the context of a regional trade agreement. This effectively allows, under certain conditions, one of the parties in the regional trade agreement to produce the pharmaceutical products for the benefit of a fellow partner country in the regional trade agreement.[791]

2. The Decision's moratorium

In addition to the waiver the Member States included a moratorium whereby they agreed to forgo dispute settlement claims concerning the implementation of the waivers in terms of Articles XXIII(1)(b and c) of the GATT Agreement.[792] Decisions taken by the General Council should, unless indicated otherwise elsewhere, be concluded by consensus. This was the case with the adoption of the moratorium in the Decision.[793] The effect of this moratorium is that Member States will be unable to challenge measures taken in terms of the waivers that have the effect of nullifying or impairing any direct or indirect benefit accruing to a Member State. In the WTO *India – Patent Protection II* case, where an analogous set of facts was considered, the Appellate Body stated that the 'meaning of this provision is clear: the *only* cause of action permitted under the *TRIPS Agreement* during the first five years after the entry into force of the *WTO Agreement* is a "violation" complaint under Article

788 WTO Agreement Art IX.3(b). Cf. *Correa*, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WHO Geneva 2004) p. 5.

789 Decision para 2.

790 Decision para 3.

791 Decision para 6. A potential beneficiary of this provision is SACU.

792 Dispute settlement moratoriums do not have a formal procedure that must be fulfilled in order to become applicable and as such the adoption of a moratorium is to rest with the General Council, during the interim periods, and the Ministerial Conference when it sits. The Appellate Body has held that the TRIPS Council was authorised to decide upon the moratorium set out in Arts 64.2 and 3 of the TRIPS Agreement (WTO *India – Patent Protection II* p. 14). This delegation of powers to the TRIPS Council derives from Art IV.5 of the WTO Agreement. All other decisions not delegate remain in the General Council in terms of Art IV.2 of the WTO Agreement

793 WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 8.

XXIII:1(a) of the GATT 1994.'[794] In other words the DSB will only be able to hear a case challenging the non-conformity of a Member State's actions under the Decision. Hence, the waivers do not permit Member States *carte blanche* when implementing the Decision. The principles of *pacta sunt servanda* remain applicable and the Member States are bound to ensure that actions comply with the Decision.

The validity of non-violation proceedings under the TRIPS Agreement has been a contentious issue since the expiry of the provision suspending non-violation and impairment actions based on the TRIPS Agreement in the 1st of January 2000. Within the five year suspension the Member States were required to determine how the non-violation proceedings should apply to the TRIPS Agreement. An agreement has however been difficult to come by. Whilst an agreement has been out of reach, the Member States have agreed to stay any non-violation actions until a decision has been reached.[795] The moratorium contained in the Decision guarantees that the lack of definitive clarity under Article 64 (and any subsequent changes) will not affect the waivers contained in the Decision. The necessity of this provision is unclear. The Appellate Body had made it clear that neither it nor a panel is authorised to decide on the application of non-violation complaints; this authority was exclusively left to the TRIPS Council, which can only be altered by the consensus of all Member States. It stated in no uncertain terms that Article 64.3 of the TRIPS Agreement is '*not* a matter to be resolved through interpretation by panels or by the Appellate Body'.[796] The Appellate Body's clear positioning on Article 64 should have removed any doubt or misconceptions Member States could have had.

3. The Chairman's Statement

Immediately prior to the Decision being adopted in the General Council, the General Council Chairman, Ambassador Carlos Pérez del Castillo, was asked to read out a statement approved by the TRIPS Council.[797] The statement became known as the 'Chairman's Statement'.[798] As the WTO procedural structures do not make formal provision for such statements, it is unclear what legal consequences the Chairman's

794 WTO India – Patent Protection II. Original italics.

795 TRIPS Agreement Arts 64.2 and 3. The Hong Kong Ministerial Conference was not able to bring about a final decision on whether or not non-violation disputes may be brought under the TRIPS Agreement. Cf. Hong Kong Ministerial Declaration p. 8.

796 WTO *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products* Report of the Appellate Body (19.12.1997) WT/DS50/AB/R 14. Original italics.

797 The General Council Chairman notes that the Statement was forwarded to him 'on the approval of the TRIPS Council'. The General Council agreed however only 'taken note of' the Chairman's Statement.

798 The Statement was largely to appease US's demands that were not directly incorporated into the draft Decision. Cf. Third World Network, Comment on the Chair's Statement of Understanding of December 16, *Van den Bossche*, The Law and Policy of the World Trade Organisation (CUP Cambridge 2005) p. 149-150.

Statement is to be given.[799] As the WTO does not accord such statements any express legal standing, such a statement will bear any direct legal effect from the WTO rules. In the WTO arena, direct legal consequence will only flow from a decision made by the General Council or a Ministerial Conference and from a DSB decision. From a procedural perspective, the Chairman's Statement was not voted upon at the General Council meeting.[800] Instead the Chairman asked the General Council to 'take note' of the statement. The Chairman's Statement can therefore not be deemed to be a formal Council or Ministerial decision.[801] This lack of formal legitimacy does not imply that the Chairman's Statement is without any legal effect; by adopting the Decision 'in light of the Chairman's Statement' the Member States have acknowledged that the Chairman's Statement does have a limited relevance.[802] As an instrument of informal consensus, its role will serve to assist interested parties in determining the meaning of the Decision.[803] In terms of Article 31(2)(b) of the Vienna Convention, an instrument accepted in connection with an agreement by the parties to the agreement will set the context for determining the purpose of an agreement.[804] This role is justified when the Chairman's Statement is seen as a complementary act.[805] In the *US – Copyright Act* case the panel noted that 'uncontested interpretations given at a conference, e.g., by a chairman of a drafting committee, may consti-

799 The Decision, as set out in WTO Doc WT/L/540, contains a footnote wherein it refers to the Chairman's Statement. This footnote does not however form part of the original documentation and is instead an *ex post facto* editorial insertion by the WTO Secretariat. It has been expressly noted that the footnote 'was added without the consent or consensus of the Members'. Cf. WTO Communication by Rwanda and others 'The TRIPS Agreement and Public Health' (06.04.2005) IP/C/W/445 p. 2. Academics also diverge on the legal implications of the Decision. Cf. *Hestermeyer*, 37 GRURInt 3 (2004) p. 199-200, *Hermann*, 6 ZEuS 4 (2003) p. 604, *Oh*, 10 Bridges 1 (2006) p. 22.

800 The contents of the Chairman's Statement was largely due to the negotiations between the US, India, Brazil and South Africa. Cf. ICTSD 'WTO Members Expected to Agree on Health and TRIPS Pre-Cancun' *Bridges Weekly Trade News Digest* (28.08.2003) p. 2.

801 The approval of the Statement by the TRIPS Council confirms the intention of the Member States that the contents of the Statement be used for the interpretation of the Decision. However the Chairman's Statement was itself never the subject of a decision. The Chairman proposed at the 30.08.2003 General Council meeting that the 'General Council take note of the [individual Member State] statements and, in the light of the Chairman's Statement he had just read out, *adopt the draft Decision*' (emphasis added).

802 The General Council Chairman stated that 'in the earlier informal discussions and consultations no delegation had indicated any intention of preventing the adoption of the draft Decision of 16 December 2002 in the light of the proposed Statement by the General Council Chairman'. Cf. General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 at p. 4. Compare *Hermann*, 6 ZEuS 4 (2003) p. 604.

803 The body of law justifying the Chairman's Statement as an interpretational tool is disputed. Having regard to the informal nature of acceptance of the Chairman's Statement, only Art 31(2)(b) of the Vienna Convention is able to divest the statement of any legal relevance. Compare *Hestermeyer*, 37 GRURInt 3 (2004) p. 200.

804 *Aust*, Modern Treaty Law and Practice (CUP Cambridge 2000) p. 190.

805 *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 104. The authors also note that Chairman's Statement was 'a common understanding of all WTO Members'.

tute an "agreement" forming part of the "context"'.[806] Viewing the Chairman's Statement as an uncontested interpretation, and therefore as an agreement, would mean that its role as an interpretation tool would be guaranteed by Article 31(2)(a) of the Vienna Convention.[807] Similar acts have also recognised under public international law as constituting an agreement under Article 31(2)(a).[808] Whether classified under Article 31(2)(a) or 31(2)(b) of the Vienna Convention, the Chairman's Statement will qualify as a source of information when interpreting the Decision.[809] This is supported by the phraseology of the Chairman's Statement.[810] This therefore means that the Chairman's Statement will serve as an aid in interpreting the Decision.[811] The extent of their role as an interpretational tool will however be tempered

806 WTO *United Stated – Section 110(5) of the US Copyright Act* Report of the Panel (15.06.2000) WT/DS160/R 18.

807 *Ortino* critically notes that the Appellate Body in the WTO *United States – Gambling* case took a limited approach to determining which instruments served to establish the 'context' of a text (Art 31)and which served as a 'supplementary' means of interpretation (Art 32). Cf. *Ortino*, 9 JIEL 1 (2006) p. 127-132.

808 *Aust*, Modern Treaty Law and Practice (CUP Cambridge 2000) p. 189-191. *Aust* remarks that instruments, such as the 'Chairman's Statement' and 'Understandings' (both present in the context of the Decision), operate as a political tool in treaty making. He notes that a separate document read by the chairman may indeed form part of the treaty but was structures separately in order to make it more politically digestible. Compare EC in the TRIPS Council Minutes (31.01.2006) IP/C/M/49 at 37 where it states 'the Chairman's Statement constituted a shared agreement accepted by all Members and context for the interpretation of the Decision, it should continue to represent context for the interpretation of the amendment'. The EC, at p. 39, also viewed the Chairman's Statement as falling within the scope of Art 31(2)(a) of the Vienna Convention. The Chairman's Statement was 'noted' prior to the adoption of the Decision. The timing of the Chairman's Statement will not affect present any material doubt as to its status as Art 31(2)(a) of the Vienna Convention merely refers to agreements made 'in connection with the conclusion of the treaty'. As the Chairman's Statement clearly fits this description, the timing of its appearance is immaterial.

809 The role of the Chairman's Statement may further be justified under Arts 31(3)(b) and 32 of the Vienna Convention. Cf. India in the TRIPS Council Minutes (31.01.2006) IP/C/M/49 p. 40. Also a combination of the acquiescence and estoppel principles could potentially prevent a Member State from denying the role of the Chairman's Decision on the grounds that it did not protest or counter the validity or role of the statement at the time when it was presented. Cf. *Müller and Cottier*, Acquiescence in: *Bernhardt* (ed) Encyclopaedia of Public International Law (North-Holland Amsterdam 1992) vol 1 p. 14-16. This rule of public international law will apply should any of those Member States listed in the Chairman's Statement not consider itself bound by the opt-out.

810 The Chairman notes that the statement 'represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented'. Cf. General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 6.

811 The role of the Chairman's Statement to the Decision plays a similar, yet less, important role in the Public Health Declaration does to the TRIPS Agreement. The distinction between the two is that the Public Health Declaration was formally adopted by the Member States as a Ministerial Declaration. Contrast *USTR*, Special 301 Report (2006) p. 11, where the USTR views the Decision and Chairman's Statement as a single solution to be 'interpreted and applied' as such.

by the remarks made by the Member States after the adoption of the Decision.[812] In these remarks, a number of Member States voiced their understanding of the Chairman's Statement. These remarks, to the extent that they qualify certain issues in the Chairman's Statement, will serve to counter or confirm that there was consensus or a consensual understanding of an issue. Accordingly, the actual 'key understandings' in the Chairman's Statement can be inferred to as referring only to those issues that were not rebutted in the remarks made by the Member States after the adoption of the Decision.[813]

In order for an interpretational tool within the ambit of the law of treaties to function it must embellish or elaborate on the contents of the treaty it is being used to interpret. Applying this rule to the Chairman's Statement it is evident that certain provisions of the Chairman's Statement cannot be applied unreservedly. The reason is that certain provisions in the Chairman's Statement set out more detailed 'obligations' than the Decision itself.[814] The inclusion of 'new' provisions means that these provisions are unable to apply in interpreting the Decision. As the new provisions do not have an interpretational role the only other role they could potentially assume would be an amendment.[815] As the Chairman's Statement does not meet the formal requirement for an amendment and the Chairman himself is not authorised to act in such a manner, they will not have any legal value and/or be *ultra vires*. It does however seem evident that the negotiating parties did not intend the Chairman's Statement to alter the Decision.[816] Accordingly, the Chairman's Statement will present a limited means for interpreting the Decision but will not and cannot be used to implement rights and/or duties not contained in the Decision.[817] In addition to the Chairman's Statement playing a role in the interpretation of the Decision, the Public Health Declaration too will play an important role.[818]

812 The Chairman's Statement refers to 'shared understanding of Members'. This does not imply that *all* Member States agreed. The negotiating history of the Chairman's Statement reflects that the wording was negotiated almost exclusively between Brazil, India, South Africa and the US. Cf. *ICTSD* 'WTO Members Expected to Agree on Health and TRIPS Pre-Cancun' *Bridges Weekly Trade News Digest* (28.08.2003) p. 2.

813 *Vandoren* and *Van Eeckhaute* state: the Chairman's Statement 'confirms the common understanding of all WTO Members that the primary objective of the [Decision] is to protect public health and that it should be used in good faith'. Cf. *Vandoren and Van Eeckhaute*, 6 JWIP 6 (2003) p. 781.

814 *Slonina*, Durchbruch im Spannungsverhältnis TRIPS and Health: Die WTO-Entscheidung zu Exporten unter Zwangslizenzen in: *Tietje, Kraft and Sethe* (eds) Beiträge zum Transnationalem Wirtschaftsrecht (MLU Halle 2003) Heft 20 p. 14.

815 The new provisions could not be considered 'subsequent practice' in terms of Art 31(3)(b) of the Vienna Convention will not apply as the provisions are neither subsequent nor do they interpret provisions of the Decision – they introduce new provisions that are neither included in the TRIPS Agreement nor in the Decision.

816 *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 104.

817 *Vandoren and Van Eeckhaute*, 6 JWIP 6 (2003) p. 781.

818 Which will have more sway in interpreting the Decision is unclear. Whereas the Chairman's Statement is the more current document, the Public Health Declaration represents an unequivocal agreement between the Member States. Cf. *Hermann*, 6 ZEuS 4 (2003) p. 602.

By adopting the waivers and moratorium the Member States have created a skeleton for a system based on exceptions to international trade obligations. In order for this skeleton to function, Member State will be required to add the muscle, i.e. to implement the system – and its conditions – into domestic law.[819]

II. The scope of the Decision

The adoption of the Decision came as a direct response to the dilemma set out in paragraph 6 of the Public Health Declaration. The Decision's preamble clearly confirms this. Accordingly, the Decision must be seen within the scope of providing those affected Member States with a means to effectively make use of their compulsory license system when their domestic pharmaceutical sector prevents or inhibits this.

The scope of the Decision also makes it clear that the central feature of the Decision, the system resolving the paragraph 6 dilemma, is not unlimited but is instead a 'drug-by-drug, country-by-country, case-by-case system'.[820] The qualifications to this system play a key role and seek to limit the scope by ensuring the system is only used to benefit the needy countries and not to the advantage of other Member States. The barrage of safeguards confirms this.[821] In addition to the system and the safeguards, the scope of the Decision is characterised by issues not initially foreseen in the Public Health Declaration. Although not mandated, the Member States agreed that the issues were sufficiently connected and important to justify their inclusion.[822] These issues sought to further the transfer of technology[823] and to prevent dispute proceedings[824] in respect to the system. Despite the introduction of a system to resolve the paragraph 6 problem, the Member States did at no time prior to the adoption of the Decision intend the Decision to be the final system; its role was merely a

819 This is a prerequisite for the exporting country. Cf. *Correa*, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WHO Geneva 2004) p. 6, *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 105.

820 *Oh*, 10 Bridges 1 (2006) p. 22-23.

821 Compare Chairman's Statement which states that 'Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives'. Cf. General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 6. Further, the remaining Art 31 provisions will continue to apply. Cf. *Law*, 18 ELDB 3 (2006) p. 6.

822 General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 7.

823 Decision para 7.

824 Decision para 10, General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 7.

stopgap measure to ensure there was an interim solution whilst the Member States negotiated a final solution.[825]

III. The legal implications of the Decision

The Decision and the Chairman's Statement introduce a number of formal requirements for Member States, whether as exporter or importer, wishing to apply the solution. Member States will be required to determine when and what pharmaceutical products can be used, which countries are eligible, what safeguards are applicable and how technology transfer must be used to prevent the paragraph 6 problem. These legal implications are dealt with individually hereunder.

1. The pharmaceutical product

For the purposes of the Decision a pharmaceutical product is deemed to be 'patented product, or a product of a patented process, of the pharmaceutical sector'[826] that is needed to address a public health problem.[827] The definition of pharmaceutical product is qualified in numerous ways. Firstly, the product must be a patented product or result from a patented process. This qualification dispels any doubt that both patented products and patented processes can perpetuate the paragraph 6 dilemma. Secondly, the product must flow from the pharma-ceutical sector. This may seem self evident when dealing with pharmaceutical products, however in connection with the third qualification, those public health problems recognised in paragraph 1 of the Public Health Declaration, other sectors may have played a role in countering the public health problems. The nutritional sector for instance, may have patented products that help reduce certain health afflictions. An example hereof is the proposal to produce genetically engineered crops that can reduce allergic reactions or induce certain health effects.[828] Both the nutritional and agricultural sectors can play a significant part in reducing public health problems. In terms of the Decision these products will not fall under the definition 'pharmaceutical product'. This qualifica-

825 Decision para 11.

826 Decision para 1(a).

827 The Decision does not mirror the terminology used in the Public Health Declaration. Instead of referring solely to the pharmaceutical sector, the Decision limits the scope of the Decision to 'pharmaceutical products'. Although potentially viewed as a limitation of the Public Health Declaration its is in fact a better formulation for Member States as it resolves the problem of whether or not the Public Health Declaration scope includes certain medical devices. The choice of terms in the Decision also ensure a greater association with one of the core issues in the Public Health Declaration, the access to medicines set out in para 4 thereof. See Chapter 7(A)(IV) Pharmaceutical sector above.

828 Monsanto purports to have developed a soybean that can 'reduce or eliminate the amount of trans-fats in processed foods'. Cf. '*Monsanto*, (2006)'.

tion has a secondary consequence. Being a product 'of the pharmaceutical sector' implies that invention must have been patented by a person or company active in the pharmaceutical industry, or subsequently employed by the pharmaceutical sector. The result of this qualification is somewhat technical and unlikely to pose too much of a problem when the system is indeed implemented. Not-withstanding this, it may be relevant where a non-pharmaceutical company makes an invention that has secondary health improving consequences and/or where the patented invention is subsequently used in the pharmaceutical sector. In such situations, and where there is a genuine public health problem, the definition 'pharmaceutical product' will be flexible enough to incorporate such products.[829]

Thirdly, the pharmaceutical product itself must be *necessary* to address the public health problem.[830] The inclusion of the necessity test into the definition of the pharmaceutical product is both a logical extension of the *pacta sunt servanda* principle and a safeguard to ensure the system is not abused.[831] Here Member States will not be judged on the underlying policy decisions they make in respect to the pharmaceutical but as to whether the pharma-ceutical itself is the most appropriate medicine for treating the public health problem. Factors relevant in determining the most appropriate medication will include not only price, but also availability, usability, convenience and any other factor that would affect the usability of the pharmaceutical product.[832] In terms of the Decision this would include not only the finished product but also products used in the process of manufacturing the product and/or diagnostic kits used in the treatment of the public health problem.[833] This extension of the ordinary meaning of pharmaceutical product will have the consequence of extending beyond the term 'pharmaceutical' and apply to all products necessary to treat a public health problem. Whereas synthesised chemical products, microbicides, reagents and biologicals are likely to be readily accepted as falling within the definition of the Decision,[834] it is not clear whether this would be the case for medical machines or

829 A situation where this could apply set the prerequisites that there is no domestic industry able to (sufficiently) produce that product and it is used in good faith.

830 Paragraph 1(a) of the Decision limits the products to those '*needed to address* the public health problems' (emphasis added).

831 As mirrored by the good faith obligation in the Chairman's Statement.

832 Compare WTO *Korea – Beef* p. 49.

833 The Chairman's Statement states 'the provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients.'

834 *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 10. Correa, at p. 11, argues that the definition of pharmaceutical product in the Decision is wide enough to include vaccines. Compare, *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 35. Contrast Cuba in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 9.

instruments.[835] However, as acknowledged by the Appellate Body, the 'more vital or important those common interests or values are, the easier it would be to accept as "necessary".'[836]

Fourthly, the Decision refers to the patented product and not to the individual patent. Although this is a minor issue, focussing the attention on the pharmaceutical implies that a compulsory license for that pharmaceutical can be granted and refer to all patents, both product and process related, used to protect it. Accordingly, the Decision indirectly acknowledges that a compulsory license may relate to all patents necessary to produce the product.[837]

Lastly, pharmaceutical products must be used to address the public health problems recognised in paragraph 1 of the Public Health Declaration.[838] This qualification addresses the scope of diseases capable of benefiting under the system and posed the greatest hurdle for negotiators of a final decision.[839] The attempts by the US to restrict the scope of diseases in the pre-Decision negotiations did not materialise.[840] The main reason for this was the common position by the majority of the developing Member States that they would not accept an erosion of the scope of the diseases mentioned in the Public Health Declaration.[841] All attempts to implement a list of diseases were rejected. A South African non-paper phrased the developing Member States position on lists best when it stated it is 'neither practicable nor desirable to predict the pharmaceutical product needs of Members desiring to protect

835 Art 2(2) of the SPS Agreement will assist in identifying which measures are justifiable. The standard imposed by Art 2(2) does not however require the 'best' means; instead it requires Member States to be able to scientifically justify the measures they take. This, in light of the fact that appropriate pharmaceutical products will generally bring a scientific benefit, should not pose a problem to Member States implementing the Decision in good faith. Further, the Appellate Body implements this requirement

836 WTO *Korea – Beef* p. 49

837 *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 28.

838 Compare *Nolff*, 86 JPTOS 4 (2004) p. 295.

839 The scope of diseases was seen as the 'ultimate sticking point'. *WTO*, World Trade Report 2003 (WTO Geneva 2003) p. 168.

840 The scope of the diseases covered presented the greatest challenge to reaching a consensus and was the reason why the US blocked the acceptance of the Decision in December 2002. The US sought to limit the diseases and referred, *inter alia*, to those expressly mentioned in the Public Health Declaration, i.e. 'HIV/AIDS, malaria or tuberculosis or other infectious epidemics of comparable scale and gravity, including those that may arise in the future'. Cf. WTO Communication by the US 'Moratorium to Address Needs of Developing and Least-Developed Members with No or Insufficient Manufacturing Capacities in the Pharmaceutical Sector' (10.02.2003) IP/C/W/396/Corr.1 p. 2. Compare *Abbott*, 99 AJIL 2 (2005) p. 327-334, *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 10-11.

841 Neither the Public Health Declaration as a whole nor para 6 in particular contained *Abbott*, 99 AJIL 2 (2005) p. 328-330.

the public health by promoting access to medicines for all'.[842] The eventual acceptance by the US of the scope elicited in the Public Health Declaration has meant that each and every pharmaceutical product used to treat public health problems potentially falls within the ambit of paragraph 1(a) of the Decision.[843] In terms of this *any* pharmaceutical product has the potential to be licensed under the Decision, provided it is to treat a public health problem. In the *EC – Asbestos* case a risk can be 'evaluated either in quantitative or qualitative terms'.[844] This therefore allows Member States not only to classify health problems that affect thousands of persons as a problem but also isolated human *and* animal afflicted by a serious illness. This will generally be the case where the isolated disease has the potential to afflict significant amount of persons, such as the SARS and avian flu threats. The indiscriminate threat posed by the anthrax scare in the US in 2001 would also arguably fall within this definition of public health problem. Notwithstanding generally held views on what constitutes a public health problem, the final determination is and remains a domestic prerogative.[845]

2. Eligible countries

The factors determining which countries were eligible for the paragraph 6 solution was a major sticking point in the negotiations preceding the adoption of the Decision. Debates surrounded not only which Member States would be the beneficiaries of the system but also which Member States would qualify for exporting the pharmaceutical products. In what transpired to be the deal maker, a number of provisions, an explanatory annex and the Chairman's Statement were agreed upon to regulate and guide the determination of which Member States are eligible. Under the Decision eligibility is determined not only according to which countries can export and which can import but also when they may do either, i.e. compliance with both external and internal qualification requirements. This effectively forms the framework for applying the system.

a) The exporting Member State

The US sought early on in the paragraph 6 solution negotiations to limit the exporting countries to developing Member States with a sufficient pharmaceutical manufacturing capacity. The US's motivation was that in restricting the exporting Mem-

842 WTO Non-paper by South Africa 'Substantive and Procedural Elements of a Report to the General Council under Paragraph 6 of the Declaration on the TRIPS Agreement and Public Health' (05.11.2002) JOB(02)/156

843 Compare *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 11.

844 WTO *EC – Asbestos* p. 65.

845 *Abbott*, 99 AJIL 2 (2005) p. 332.

ber States to de-veloping Member States this would insert more momentum for technology transfers, limit competition from countries with a developed pharmaceutical industry and would ensure that developing countries became more independent of developed Member States.[846] This pro-posal was however rejected by the developing Member States on the grounds that the Public Health Declaration did not limit the states entitled to supply the needy countries.[847]

The Decision, which contains no limitation, means that the Decision's waiver of Article 31(f) permits *any* Member State to assist needy Member States.[848] The Decision does however lay certain conditions for a Member States to qualify as an 'exporting Member'. It must comply with both the Decision's restrictions and formalities[849] and ensure that they are, to the extent necessary, incorporated into their domestic legal system.[850] Of primary importance for the exporting Member State will be the need to establish a mechanism that will ensure that the conditions imposed by the Decision are implemented in a good faith manner.[851] This will require Member States to ensure that both the relevant governmental agencies and the local compulsory license holder comply with the formal procedural requirements set out in the Decision. Paragraph 5 of the Decision also reiterates that the Member States are to ensure that those TRIPS obligations requiring legal tools to control the importation and sale of intellectual property protected items are effectively enforced. In particular, special attention must be given to ensuring that these measures will prevent the diversion of the pharmaceutical products to unintended destinations. In addition hereto, the exporting Member State should ensure that the paragraph 6 solution does not become an 'instrument to pursue industrial and commercial policy objectives'.[852]

The Decision obliges the exporting Member State to limit the scope and extent of the compulsory license to what is necessary for the importing countries needs. Paragraph 2(b) requires that the exporting Member State's license is limited in quantity, is exclusively for export, the products produced under the license are marked as being produced under such a license (i.e. by way of specific labelling or markings, provided it is feasible) and requires the publication of the quantities and identification characteristics on a website. The exporting country does not have to acquire prior authorisation to grant the compulsory license from either the TRIPS Council or

846 WTO Communication by the US 'Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (09.07.2002) IP/C/W/358 p. 3.

847 WTO Secretariat note 'Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation' (11.07.2002) IP/C/W/363 p. 8.

848 *Matthews*, 7 JIEL 1 (2004) p. 96, *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 104.

849 Para 2 of the Decision sets out the requirements for the exporting country to be waived of its obligations under Art 31(f) of the TRIPS Agreement. For example, para 2(c) of the Decision which requires that any compulsory license grants made under the system be 'notified' to the TRIPS Council. The wording of the para 2(c) indicates that the notification can be *ex post facto*.

850 *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 105.

851 In particular paras 1(c), 2b), 2(c) and 3 of the Decision.

852 General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 6.

any other international or foreign body or organisation. The granting of a compulsory license remains the exporting country's prerogative, subject to it abiding by the abovementioned requirements.

The authorisation of a compulsory license by an exporting country must, aside from the waiver of Articles 31(f and h), comply with the requirements of Article 31. This infers that in terms of Article 31(b) the requirement to enter into prior negotiations with the patent holder remains, unless the compulsory license is based on a 'national emergency or other circumstances of extreme urgency or in cases of public non-commercial use'. However, as it is not the exporting Member State that suffers from the public health problem this may result in the exporting Member States requiring prior negotiations with the patent holder in the exporting country.[853] The territorial nature of patent rights on the one hand and Article 31(b) on the other give the impression that the urgency should be domestic in order to circumvent the prior negotiation requirement.[854] However, the extreme urgency mentioned in Article 31(b) is not limited to national emergencies and can, in theory, extend to urgencies beyond its border. As the TRIPS Agreement is silent on the origin of an extreme urgency and that there is, although indirectly, recognition that compulsory licenses can be used in limited circumstances for the benefit of foreign Member States, there does not appear to be any provision that would prevent a granting authority from fast-tracking the compulsory license process on the basis of a foreign extreme urgency. Mutual state respect would dictate that the use of an extreme urgency in one country in terms of Article 31(b) should be respected and where applicable applied where it is to that states benefit. This stance is supported by the Public Health Declaration's express statement that the TRIPS Agreement should be interpreted in a 'manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for *all*' (emphasis added).[855] As there is no reference to the recognition of foreign emergencies in terms of Article 31(b) in the Decision, the exporting Member States would be free to develop their own policies for reacting to a request under the system set out in the Decision.

853 *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 36.

854 Paris Convention Art 4bis. Art 31(b) of the TRIPS Agreement refers to 'national' emergencies. It is however to be noted that the territoriality of patents in Art 4bis of the Paris Convention refers to the *application, nullification or forfeiture* of the patent. It does not refer to their *limitation* under the compulsory licensing system. Further, emergencies in terms of Art 31(b) do not ground their licensing, they only form the basis for it fast-tracking the licensing process. Finally, the Paris Convention's concept of territoriality does not refer to the scope/territory of extreme urgencies.

855 Public Health Declaration para 6.

b) The importing Member State

Although every Member State is able to become an 'importing Member' under the Decision, the importing country may only import when two requirements are met. Firstly, it must be an 'eligible' country and secondly it must meet the requirements set for importation. As both are necessary to participate as a recipient in the system both requirements are discussed below.

Eligibility is easily met under the Decision. LDC Member States are regarded as automatically being eligible.[856] Other Member States are required to give notification to the TRIPS Council of their intention to use the system.[857] The notification by non-LDCs does not require the TRIPS Council's consent; it is simply a notice, there are no requirements regulating its contents and can be submitted at any time.[858] The notice does not oblige Member States to use the system. Accordingly, it can be made as a precautionary measure and need not be based on any existing or threatening emergency.

Although eligible, a Member State will only be able to import in a Decision-compliant manner when it has met the formal requirements set out in paragraph 2(a) of the Decision. Only when these requirements are fulfilled will there be compliance with the Article 31(f) waiver requirements. These requirements require all Member States (both LDCs and non-LDCs alike)[859] to notify the TRIPS Council of the following:

856 Decision para 1(b). Notwithstanding this Rwanda, a LDC, saw it necessary to notify the WTO of its intention to use the system. Cf. --, Rwanda Becomes the First Country to Try to Use WTO Procedure to Import Patented HIV/AIDS Drugs (2007) 11 Bridges 27 p. 4.

857 *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 17-18.

858 Decision fn. 2. The exporting Member State will however not be able to export the product until the notification has been made by the importing Member State. Cf. *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 17-18.

859 *Abbott* and *Correa* rightly note that the notification of the Member State's intention to use the system (para 1(b)) and the notification in respect to the scope of the use (para 2(a)) can be separate notifications. This would theoretically permit there to be two separate notifications: the one being a once-off notification in terms of para 1(b) and the other being a specific notification detailing what pharmaceutical product and how much thereof will be used. Practically, it is more likely that Member States will indicate their intention by way of a notification for the specific pharmaceutical, i.e. combining the two notifications into one. Cf. *Abbott*, 99 AJIL 2 (2005) p. 336, *Correa*, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WHO Geneva 2004) p. 15.

- the names and expected quantity of the pharmaceutical products required
- confirmation that a compulsory license has been, or will be, granted in respect of the pharmaceutical product, if it is the subject of a patent right[860] and
- confirmation that it does not have any or sufficient production facilities for the requested products.[861]

Whereas the first notification's role is questionable,[862] the second notification's purpose is not. As indicated above, the eligible Member States are required to notify the TRIPS Council of the amount and identity the pharmaceuticals required and, where applicable, issue a domestic compulsory license for the importation and use of the pharmaceutical product.[863] Where the eligible Member State is not a LDC it must 'confirm' that it has insufficient or no domestic pharmaceutical production capacities to meet its needs. The non-application of the latter requirement frees LDC Member States from having to *prove* its inability to produce the relevant pharmaceutical product domestically in sufficient quantities as it is deemed not to have such capacities.[864]

In order to meet the latter requirement non-LDC Member States are required to confirm one of two situations: either that it has no production capacities at all or that it has some production capacities however these are, at the time in question, insufficient to meet the production needs.[865] The question of available capacities is taken as at the time when the need arises and is specific to the particular pharmaceutical.[866] The Chairman's Statement expands on the Decision's requirements and requires that

860 Importing Member States are therefore required to comply with Art 31 as a whole, i.e. binding that importing country into determining the scope, duration, the remuneration and other conditions of the compulsory license. Para 4 of the Decision waives the Art 31(h) requirement for the eligible importing Member State enabling it, should it chose to do so, to refrain from granting remuneration to the patent holder. *Correa* notes that the importing Member States is not obliged to limit the quantity of the needed pharmaceuticals in its domestic compulsory license grant. It will however be required to set out the quantity in the notification to the TRIPS Council. As this notification sets out what is 'needed' by the importing Member States, this figure will be in establishing the necessity by the exporting Member State. Cf. *Correa*, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WHO Geneva 2004) p. 18.

861 Only where the Member States is not a LDC.

862 The purpose behind the two-stage notification system is unclear. Whereas the notification to be provided by the non-LDCs (paragraph 1(b)) will draw attention to their potential use of the system, the notice does not have any other practical value. As the second notification (paragraph 2(a)) also draws attention to the systems use – in this case in more detail and with substantiated contents –the first notification effectively becomes redundant.

863 Compare *Nolff*, 86 JPTOS 4 (2004) p. 300.

864 Compare *Nolff*, 86 JPTOS 4 (2004) p. 300.

865 Annex to the Decision.

866 *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 26. The Authors state that sufficiency will also be dependent on whether the costs to start production of the product are 'material' or not, the time frame for production of sufficient quantities meeting sufficient standards.

the notification also include information as to how the Member State reached its conclusion that it has no or insufficient production facilities.[867] It appears that the Chairman's Statement further allows other Member States to seek clarification about the conclusion through the Director-General or Chair of the TRIPS Council.[868] Despite this review mechanism it is clear that the establishment of insufficient or no production facilities remains a national prerogative.[869] This, together with the fact that the notification does not require the assent of the TRIPS Council, will mean that any challenge to the importing Member State's assessment of its domestic production capacities will not have a suspensive effect on the use of the system.[870]

Should the domestic production capacities improve sufficiently to allow domestic production, then the system will cease to apply, i.e. the waiver will no longer excuse the obligation under Article 31(f). This is somewhat of an unsatisfactory formulation because as soon as the 'capacity has become sufficient … the system shall no longer apply'.[871] If a compulsory license has been granted in terms of the paragraph 6 system, and it transpires that that country subsequently has a sufficient production capacity (e.g. due to a new production plant), then the Decision will require that the compulsory license be terminated. The termination of the compulsory license on the grounds of subsequent production capacities must be 'established'. What and when a production sufficiency is established should be determined either on the same grounds upon which the insufficiency was initially determined or by way of fulfilment of a set of pre-determined statutory, administrative or judicial conditions. Despite the apparent immediacy of the termination provision in the Decision, it does not pre-empt or waive the termination provisions set out in Article 31(g). As the Decision does not waive or suspend the application of Article 31(g) the termination of the compulsory license must also give due regard to the legitimate interests of the

867 General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 at p. 7. The information to be provided was clarified in the discussion following the adoption of the Decision. It noted that it 'had been clarified during the consultations that this did not involve provision of a great deal of technical or other information but only the brief and concise indication of the methodology for determination of insufficient capacity and the conclusions that were drawn on the basis of available data'. Cf. India in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 at 13. Compare *Abbott*, 99 AJIL 2 (2005) p. 336.

868 General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 at p. 7, *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 17-18. In this regards, the Chairman's Statement does not expand on the Decision and thus cannot be used as a means of interpretation. The statement may however be viewed as a preferred manner to resolve disputes in an informal way.

869 *Abbott*, 99 AJIL 2 (2005) p. 336, *Oh*, 10 Bridges 1 (2006) p. 22.

870 A DSU challenge to the 'eligibility' of a Member State, including the assessment of its domestic production facilities, will not be made against the importing Member States but against the exporting Member States as it is the eligibility that entitles the exporting Member States to use the waiver of Art 31(f) of the TRIPS Agreement. Accordingly, this circumstance may lead to a situation where the exporting Member State is found liable under the DSB for actions committed by the importing Member State.

871 Annex to the Decision para (ii).

licensee. This would enable the licensee the opportunity to recoup the investments made in connection with the compulsory license.[872]

A problem with certain paragraph 6 solutions proposed prior to the Decision was that they only concerned situations where there was a valid patent, and therefore a patent system, in the importing Member State. As a number of LDCs have no patent system they were not able to obtain the benefits considered under certain paragraph 6 proposals.[873] The Decision succeeded on averting this problem by regarding all Member States, regardless of whether it has a valid patent on the pharmaceutical product or not, as potential beneficiaries of the solution. In terms of the Decision the only difference between a Member State without a valid patent on the product and one with a patent is that the latter will be required to grant a compulsory license in its own territory for the importation of the licensed product. [874]

The definition of the eligible importing Member State in paragraph 1(b) of the Decision states that certain Member States had elected not to use the system as an importer either completely or in limited circumstances. This opt-out by certain Member States played a central role in bringing about a solution to the paragraph 6 problem. It gave the US the much needed 'security' it required to withdraw their blocking stance to the proposal made by Ambassador Motta. The 'note' in paragraph 1(b) of the Decision states:

> 'It is noted that some Members will not use the system set out in this Decision as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstance of extreme urgency'[875]

The significance of this opt-out is, legally speaking, complex.[876] The text in the Decision acknowledges that some Member States do not intend to use the system. The unwillingness to use a system indicates a voluntary[877] and unilateral act; it does not constitute an agreement. Instead the opt-out assumes the form of a 'renunciation' of rights, in this instance of substantive rights. The renunciation combined with the absence of any objection by the relevant Member States indicates that it is their in-

872 The lack of any financial security for parties exercising compulsory license will negate the desire on behalf of the pharmaceutical industry to exercise and apply for compulsory licenses. The lack of any willing participants would render the compulsory license system ineffective and permit anti-competitive behaviour on behalf of the patent holders.

873 A number of proposals made during the para. 6 solution negotiations acknowledged the eligibility of certain Member States without patent protection but who still had the need for a system that would permit the exportation of pharmaceutical products under a compulsory license. Cf. WTO Secretariat note 'Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation' (11.07.2002) IP/C/W/363 p. 6.

874 Decision para. 2(a)(iii).

875 Footnote omitted.

876 Compare *Fiedler,* Unilateral Acts in International Law in: *Bernhardt et al* (eds) Encyclopaedia of Public International Law (Elsevier Amsterdam 1981) vol 4 p. 1018-1023.

877 *Abbott*, 99 AJIL 2 (2005) p. 336.

tention to be bound by the renunciation.[878] The binding nature of the opt-out will, at the very least, be sufficient to create an estoppel and will prevent those Member States having declared their renunciation of the benefits under paragraph 1(b) of the Decision from acting contrary to their declared intention.[879] The opt-out, as a unilateral act, may however constitute binding public international law.[880] Having regard to the requirements for establishing the binding nature of the act, it seems highly likely that this will indeed be the case with respect to the countries mentioned in the Decision.[881] The binding nature of the opt-out may extend to those countries listed in the Chairman's Statement. The reason for this is that those countries 'acquiesced' to the limited opt-out by refraining from objecting to their inclusion. The passivity of those Member States and their involvement in the TRIPS Council and its negotiations all confirm the presence of their intention to refrain from the full use of the system.[882] The binding nature of unilateral acts is based, to a large degree, on the principles of good faith and *jus aequum*.[883] It follows therefore that those Member States who opted out of the system will only be able to withdraw their renunciation (without infringing another Member States interests) when they does so in good faith. In this regard, those listed Member States will be able to use the system where

878 The lack of an objection by the Member States opting out may constitute evidence of the unilateral act by way of acquiescence. Cf. *Schwarzenberger*, International Law (Stevens & Sons London 1957) vol 1 p. 552.

879 *Fiedler*, Unilateral Acts in International Law in: *Bernhardt et al* (eds) Encyclopaedia of Public International Law (Elsevier Amsterdam 1981) vol 4 p. 1020.

880 Unilateral acts have been afforded binding legal nature by the Permanent Court of International Justice. Cf. *Certain German Interests in Polish Upper Silesia (Germany v Poland) (Merits)* PCIJ Rep Series A No 7 at 13. Also *Matsushita et al*, The World Trade Organization: Law, Practice, and Policy (2nd edn OUP Oxford 2006) p. 21.

881 *Fiedler* notes that the country making the act must act in free will, the person/body performing the act must be competent to represent that country and the country must legally and factually be able to act in accordance with the act. Further factors include the intention to be bound and that the undertakings be unconditional and definitive. *Fiedler* also remarks that as 'notification is the most common from employed in international relations, it also seems as a rule most appropriate one for unilateral acts'. Cf. *Fiedler*, Unilateral Acts in International Law in: *Bernhardt et al* (eds) Encyclopaedia of Public International Law (Elsevier Amsterdam 1981) vol 4 p. 1021-1022.

882 Compare *Schwarzenberger*, International Law (Stevens & Sons London 1957) vol 1 p. 552. The list of Member States partially opting out of the system thus acquires more legal weight in relation to the rest of the Chairman's Statement (the remainder having an interpretive function). This conclusion reflects the reference made to these countries in para 1(b) of the Decision.

883 Compare *Fiedler*, Unilateral Acts in International Law in: *Bernhardt et al* (eds) Encyclopaedia of Public International Law (Elsevier Amsterdam 1981) vol 4 p. 1020-1021, *Schwarzenberger*, International Law (Stevens & Sons London 1957) vol 1 p. 551. To the extent that the opt-outs were agreed to between those opting out, i.e. by way of an informal bilateral or restricted multilateral agreement, the DSU has taken such agreements into account when done so within the framework of a WTO Agreement. The DSU has also made reference to 'tacit' agreements. Cf. Also *Matsushita et al*, The World Trade Organization: Law, Practice, and Policy (2nd edn OUP Oxford 2006) p. 41-42.

they are no longer able to counter a public health problem with domestically produced pharmaceuticals. Only where a genuine paragraph 6 problem is experienced by that country will it be able to revoke its renunciation.[884]

Whereas the definitive legal classification of the opt-out is not entirely clear, the effect is. An exporting Member State would not be able to rely on the waiver of Article 31(f) if it were to export pharmaceuticals to a country that had opted out of the system. In other words its exportation under the system would only comply with the Decision if it were to obey the opt-outs by those Member States concerned. An exporting Member State will however be required to distinguish between two types of Member States that opted out of the system. In terms of paragraph 1(b) of the Decision there are two opt-out categories of countries: those who will not use the system and those who will only use it in certain circumstances. The first group was initially made up of 23 Member States.[885] As of the 1st of May 2004 a further 10 Member States were added.[886] By opting out of the waiver, these Member States acknowledge that the legal restrictions referred to in paragraph 6 of the Public Health Declaration do not, and will not, negatively limit its domestic treatment of public health problems. The opt-out thus implies that those Member States subscribing thereto either have sufficient pharmaceutical production facilities and/or the prices of the importation of the products would not unduly constrain the domestic health care system. It is therefore understandable that those countries that have opted out are either OECD or EC members or are classified as high income countries.[887] Further, this group of countries not only constitutes the developed Member States at the WTO[888] but they also house the major pharmaceutical high-profit markets. This pledge by these states reassured the US and its pharmaceutical industry that it would not lose existing valuable markets to generic manufacturers producing under compulsory licensed rights.

The second group of Member States took a similar position to the first group; it acknowledged that their compulsory license system is effective. However, unlike the first group these Member States were unable to say categorically that their compulsory license system will remain 'effective' in *all* circumstances. The qualification of the general opt-out by these Member States sought to reserve the opportunity to use the system in situations that were exceptional. To this extent this group of Member States agreed only to use the system 'circumstances of extreme urgency [and] in

884 Contrast *Abbott,* 99 AJIL 2 (2005) fn. 130 p. 336.

885 They are Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

886 They are the countries that joined the EU on 01.05.2005 (Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia).

887 Of the Member States who have either completely or partially opted out, only three have no domestic pharmaceutical production capability – Iceland, Luxembourg and Qatar. Cf. WTO Secretariat note 'Available Information on Manufacturing Capacity for Medicines' (24.05.2002) IP/C/W/345 p. 13.

888 *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 104.

cases of public non-commercial use'.[889] This group of countries is made up of 11 Member States;[890] 9 of which are regarded by the World Bank as being 'high income' countries and two upper middle income countries.[891]

c) Conclusion

Determining eligibility goes to the core of the implementation of the policy issues identified in the Public Health Declaration. Not only does it seek to establish who the beneficiary of the system is but also which country, when and on what conditions, will be able to provide the assistance. The eligibility also ensures that the beneficiaries will be those countries unable to exercise the TRIPS Agreement in a manner that enables them to take full advantage of the tools provided within the patent system.

3. Safeguards

In any compulsory license system potential abuse may arise from both state and individual practices. The abuse potential is however amplified in a system that encompasses multiple parties in at a minimum two jurisdictions with countries. To prevent the abuse and misuse of the Decision's system the developed Member States demanded that comprehensive safeguard measures be created to ensure that, on the one hand, the benefits reach the needy country and, on the other, that the pecuniary loss felt by the patent holder is limited to the importing country's market. These safeguards, eventually adopted by the Member States, function on two levels. On the one level – that of the system itself – the safeguards ensure that the system is designed solely to benefit the needy country. To this effect safeguards were inserted to ensure the system remains transparent and accountable. The second level – general ancillary safeguards – require the exporting and importing countries to ensure that their general patent protection measures provide a sound legal basis for enforcing the system. The two approaches adopted are dealt with separately below.

889 Decision para 1(b).

890 These Member States are Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and the United Arab Emirates. 7 of these Member States (Hong Kong China, Israel, Korea, Mexico, Singapore, Chinese Taipei and Turkey) further verbally opted out of the public non-commercial use of the system. Not included in this number are the 10 EC accession states, who also opted out of the public non-commercial use during prior to their accession. Cf. WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 5-6.

891 Mexico and Turkey are classified by the World Bank as being 'upper middle income' countries. They are, together with Korea, also OECD members. Cf. *World Bank*, Country Classification (2005).

a) Safeguards inherent to the system

The Decision ensures that only when certain conditions, i.e. safeguards, are met will the waiver of Article 31(f) be effective. The safeguards in the Decision are therefore mandatory and require positive compliance. Phrased differently, the safeguards create the system. In order for the system to operate both importing and exporting Member States must abide and enforce certain protective measures.

The importing Member State must identify the needed pharmaceutical and the quantity it requires. This safeguard establishes and consequently limits the 'need'. Whereas the quantity is expressed and safeguarded in the notification, there is no express obligation compelling the importing Member State's compulsory license to quantify its license requirements – this is neither a mandatory nor regular requirement of standard compulsory licenses. Standard com-pulsory licenses are seldom limited in quantity as the consumed quantity is dictated by market demands. The Decision's compulsory license system does not create a standard compulsory license. The Decision states that the exporting state cannot grant a license that exceeds the actual needs of the importing country.[892] It is clear that this limitation seeks to safeguard against uncontrollable and unaccountable production amounts. This safeguard does not however require that there need not be a direct correlation between what is the *expected* need (i.e. what is set out in the notification) and what is the *actual* need (the limit that must be imposed by the exporting country), it is likely that the exporting Member States will draw this conclusion; thus making no distinction between what is expected and what is actually needed. As the Decision does not require an absolute quantity, Member States are entitled to qualify the quantity by making it dependent on variables.[893] The use of these safeguards in a flexible manner is essential to ensuring effective use of the system.[894] Both accountability and common sense understanding on what is understood under an 'expected quantity' will ensure that the system is effective for both the needy country and the patent holder.

As discussed above, the inability to provide self-help must also be established. This safeguard ensures that the system retains its legitimacy. The final system-bound

892 Para. 2(b)(i) of the Decision.

893 The quantification of the amount of pharmaceuticals 'needed' need not automatically be in absolute terms. Instead of just referring to a specified number of units it may also be possible to base the need on the number of patients or hospitals over a period of time. Cf. *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 112, *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 24. *Abbott* and *Van Puymbroeck* suggest that the importing country reserve a right to revise the quantity where it transpires that the expected needs no longer suffice.

894 In Rwanda's notification it reserved the right to alter the amounts it required as 'it is not possible to predict with certainty the extent of the country's health needs'. Cf. --, Rwanda Becomes the First Country to Try to Use WTO Procedure to Import Patented HIV/AIDS Drugs (2007) 11 Bridges 27 p. 4.

safeguard for the importing Member State is the 'reminder' that the existing non-waived compulsory license requirements in Article 31 must, to the extent applicable, be complied with. The documentation of compliance with these safeguards via the notification requirements ensures the system will remain accountable.

Not only do the majority of safeguards rest on the exporting Member State's shoulders but the Member State is also the party in the system that carries the liability for any non-compliance with the waiver and its conditions. As the exporting Member State is both the gatekeeper and the party carrying the liability for the system, it will be more engaged in ensuring that the system is used in a legitimate and compliant manner.

The overriding safeguard provision is the obligation to only grant a compulsory license 'to the extent necessary'.[895] This will imply in practice that the compulsory license in the exporting country will have to mirror the pharmaceutical and its quantity set out in the importing Member State's notification.[896] It does not however imply that the exporting Member State will have to validate the correctness or reasonableness of the importing country's notification.[897]

In addition to the general safeguards, the Decision sets specific domestic law conditions for the use of the system. These domestic safeguards require definitive action on behalf of the exporting Member States. To this effect the grant of the compulsory license must limit the compulsory license to the amount necessary to supply the needs of the importing country;[898] the pharmaceutical products must bear certain marks identifying them, either by labelling or marking, as being produced under the system; and the licensee must be required to inform, via a website, the quantities produced under the system, the destination of the products and the distinguishing features of the product.

The marking and labelling requirement in paragraph 2(b)(ii) of the Decision derives from practical experiences pharmaceutical exporters have had in attempting to control the diversion of their products to unintended destinations.[899] To avoid a situation whereby this safeguard would make the licensed products unaffordable or unfeasible to produce, a proviso was included which stated that this obligation would not apply where such a 'distinction is feasible and does not have a significant

895 Decision para 2.

896 It also goes without saying that the entire production manufactured under this system must be for export purposes.

897 Compare *Correa*, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WHO Geneva 2004) p. 17.

898 See Chapter 7(B)(III)(2)(b) above.

899 To this effect the 'Best Practices' referred to in the Chairman's Statement serve as an illustration. The Chairman's Statement notes that the 'Best Practices' will assist in preventing the diversion of the pharmaceutical product.

impact on price'.[900] This proviso was not to the liking of the US who called for the Chairman's Statement to acknowledge that it 'is the understanding of Members that, in general, special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals'.[901] This subsequent 'understanding' has effectively reduced the flexibility found in paragraph 2(b)(ii) of the Decision by affirming that packaging and shape changes will be necessary, unless there is clear evidence that the changes would lead to a significant increase in the price. It is unlikely that this requirement will pose an unreasonable restriction on the actual exercise of a license under this system. The reason for this is that this requirement could be met simply by confirming on the packaging that the product is under compulsory license. This alteration in the packaging would in most cases be necessary simply because the names given to most modern medications are subject to trademark protection and such names could not, without the right holder's authorisation, be used on the licensed product.[902] The distinguishing characteristic may however be unfeasible where the changes mean that the pharmaceutical must undergo new bioequivalence studies and/or marketing approval.[903]

The Decision also requires that notification must be given of the granting of a compulsory license under the system. In the notification to the TRIPS Council the exporting Member State must set out the conditions imposed on the grant of the compulsory license, include details pertaining to the identity and location of the licensee, the licensed product, the quantities to be produced, the destination of the products, the internet address of the notification and the duration of the license.[904]

A final safeguard that applies to and affects both the exporting and the importing Member States is that of remuneration. The Decision's system requires two compulsory licenses to be granted, one in the exporting country and one in the importing country.[905] This therefore leads to a potential situation where, in terms of Article 31(h), the patent holder is entitled to compensation in both countries.[906] As the notion of double remuneration ran against the spirit of the Public Health Declaration and the access to affordable medicines, the Member States were able to agree that payment of the remuneration should only be due in either the importing or exporting country.[907] A waiver of the Article 31(h) obligation presented little debate – the formulation however did. The problem that arose was: what standard is to be used to

900 Decision para 2(b)(ii). It is uncertain how active ingredients, usually sold in their basic form, will be changed to comply with this requirement. Also problematic are the alterations required for diagnostic kits. In this regard only superficial changes will be feasible.

901 General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 6.

902 Compulsory licenses are not permitted for trademarks. Cf. TRIPS Agreement Art 21.

903 Compare *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 113.

904 Decision para 2(c).

905 No requirement for a compulsory license in the importing country will exist where there is no valid patent in that country. Cf. Decision para 2(a)(iii).

906 *Nolff*, 86 JPTOS 4 (2004) p. 301-302.

907 This is effectively a safeguard against an abusive exploitation of the patent holder's rights.

determine the level of remuneration? This was eventually solved by waiving the importing Member State's remuneration obligation and requiring that the remuneration be paid in the exporting Member State. This remuneration is to be 'adequate' and is to 'take into account the economic value' of the use of the product in the importing Member State. By requiring the exporting Member State to provide for the remuneration of the patent holder the Member States have safeguarded the patent holder's right to remuneration. By shifting the onus of paying the remuneration to the exporting country, the system has ensured that the level of remuneration, although most likely lower than a 'standard' compulsory license in the exporting country, will be more likely and higher in value than in the importing countries jurisdiction.[908] Before a Member State can take advantage of the waiver of Article 31(h) the importing Member States will be required to amend their domestic laws to this effect. As the waiver may only be used within the context of the Decision, such Member States will be required to make a distinction in their domestic law between compulsory licenses granted within the scope of the Decision and compulsory licenses granted under other circumstances. Whether or not a Member State would be entitled to make a zero remuneration award instead of adopting the waiver is not certain. As the system effectively couples the license granted in the importing country with the license granted in the exporting country it, can be said that they form one 'case'.[909] Further, as the Decision already requires *adequate* remuneration to be paid in the exporting country the adequacy requirement in the importing country could be said to have been met. The Decision reinforces this by requiring the exporting country to base the adequacy of the remuneration on factors prevailing in the importing country.

b) General safeguards

Leading up to the adoption of the Decision, developed Member States expressed their fear that a potential solution could easily be used to divert those pharmaceutical products produced under the system. To avoid this, the developed Member States

908 *Nolff* states that when the export Member State does not grant any remuneration the importing country will be required to grant adequate remuneration. This view does not arise from the wording of the Decision. Neither the Decision nor Art 31(h) require that remuneration be given in every instance. Both require *adequate* remuneration. If the exporting Member State finds zero remuneration sufficient this does not oblige the importing Member State to once again re-evaluate the issue. Even if it does, and this may indeed be the case where there is no domestic rule waiving Art 31(h), it may also come to the conclusion that a zero remuneration rate is adequate. Cf. *Nolff*, 86 JPTOS 4 (2004) p. 302 fn. 26. Compare *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 38.

909 Article 31(h) states that remuneration should be 'paid in the circumstances of each case'. This is supported by the fact that both share the same object and purpose, i.e. alleviating a particular public health problem.

sought anti-diversionary safeguards to be included into the Member States' domestic laws, instituting a positive obligation to act. Whereas the developing Member States did not oppose anti-diversionary obligations, they were cautious to commit to requirements that would prove too burdensome for their limited resources. The problem was resolved by requiring anti-diversionary measures to be taken subject to the Member State's means. In other words, an importing Member State must take measures that would prevent the imported licensed products from being re-exported. However, where the importing Member State has limited resources, such measures need only be 'within their means [and] proportionate to their administrative capacities'.[910] The developed Member States for their part committed themselves to providing assistance (both technical and financial) to the importing Member State to facilitate their compliance with this requirement.[911] The assistance is to be provided upon request by the importing Member State, on terms and conditions acceptable to both parties. The principal assistance is likely to come in the form of an improved national customs system. Incorporated within this system may be specific procedures whereby the customs authorities (or other government officials) are able to monitor both the importation and distribution of the pharmaceutical products.

The Decision goes one step further in paragraph 5. It requires, in addition to measures preventing the re-exportation, measures to prevent the importation of those products licensed under the system to markets to which they were not intended. This secondary safeguard seeks to protect the interests of both the importing country as well as the patent holder by ensuring that the products reach the needy and do not harm the patent holder in other markets. The safeguard requires from all Member States the 'availability of effective legal means to prevent the [unlawful] importation into, and sale in, their territories of products produced under the system'. This obligation does not specifically require new protection measures, rather it requires that those measures already required by the TRIPS Agreement are implemented and, more importantly, effectively enforced. The proper enforcement implies that Member States will have to permit civil actions (providing for injunctions[912] and damages[913]) by the patent holder. The enforcement of patent protection under the TRIPS Agreement is, unlike copyright and trademarks, principally a civil law matter and the enforcement of patent remains a duty of the patent holder.[914] Accordingly and as provided for in Articles 41 to 50 of the TRIPS Agreement, Member States are to ensure that national courts and/or administrative officials are able to enforce the patent holder's rights contained in Article 28 of the TRIPS Agreement.

910 Decision para 4 first sentence.
911 Decision para 4 second sentence.
912 TRIPS Agreement Art 44.
913 TRIPS Agreement Art 45.
914 Arts 51-60 of the TRIPS Agreement provide for specific procedures for inspection, seizure and destruction of goods that infringe copyrights and trademarks. Art 60 of the TRIPS Agreement requires that Member States enforce criminal sanctions for trademark counterfeits and copyright pirates.

The Public Health Declaration provided Member States with the confirmation that those flexibilities available within the TRIPS Agreement could be used, to the full, to address public health issues.[915] Concerns had arisen that the provisions in the Decision could extend beyond Articles 31(f and h) of the TRIPS Agreement and limit the application of the use of these flexibilities. To safeguard against the spilling over of the Decision, the Member States confirmed that the contents of the Decision should not be used beyond its scope, i.e. the paragraph 6 problem.[916]

4. Transfer of technology

In its attempt to resolve the paragraph 6 problem, the solution indirectly perpetuates the state of affairs that led to the problem by increasing the importing Member State's reliance on foreign producers. Aware of this paradox the Member States sought to specifically encourage the transfer of technical know-how and capacity building in the pharmaceutical sector.[917] This was specifically to be realised by and between the exporting and importing Member States.[918] The manner in which this objective will be realised is somewhat unclear. It appears from the contents of paragraph 7 of the Decision that the exporting country should promote the transfer of technology to the importing country. If this is indeed the case importing Member States would only acquire limited know-how which, in the scope of pharmaceutical production, would bring about little tangible and sustainable technology transfer. Further, if the licensee in the exporting Member State is itself burdened by this obligation it would dissuade many producers from providing assistance. In terms of the Decision the international obligation to provide technology transfers within the ambit of the system will rest with the exporting Member State itself.[919] Leaving the obligation with the Member State itself – and not the actual producer – would make for a more effective and less burdensome system.

The obligation to promote the transfer of technology and capacity building under paragraph 7 of the Decision makes an important break from the TRIPS Agreement obligations in Article 66.2: it requires that the assistance extend to all importing Member States, regardless of their status. This does not substitute the Article 66.2

915 Public Health Declaration para 4.

916 Decision para 9. The Decision relates only to one issue mentioned in the Public Health Declaration (para 6). It would be amiss to allow the *lex specialis* (i.e. the Decision) to limit those elements of the *lex generalis* (i.e. the Public Health Declaration) to which it does not relate.

917 The Public Health Declaration also recognised the importance of technical transfers. Para 7 states: 'We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2'.

918 Decision para 7.

919 Par 6(ii) of the Decision obliges developed Member States to provide technical cooperation to those developing Member States wishing to adopt a regional patent system.

obligation nor does it indirectly extend Article 66.2 to all Member States. The assistance is limited to those who actually require it.

The Decision also draws the attention to the direct obligations found in Article 66.2. It requires the Member States, in performing their obligations under Article 66.2, to pay 'special attention to … the pharmaceutical sector'.

IV. Procedure for the adoption of a final solution

The interim nature of the Decision, confirmed in paragraph 11 of the Decision, instructs the TRIPS Council to negotiate and adopt an amendment that would replace the Decision's solution. Until such time, the provisions of the Decision would apply.[920]

The process of finding a final solution should be 'based, where applicable, on this Decision'.[921] This infers that the final solution should derive from the Decision and not paragraph 6 of the Public Health Declaration. This limitation meant that the scope of the entire solution was already incorporated into the Decision. Hence, issues not found in the Decision would not fall within the scope of the final solution mandate. As such the Decision effectively limited the scope of the final solution to how the Decision could – in form and structure – be transposed into an amendment. The Member States did however recognise that there may be other extraneous issues that would have to be included in the final solution. The contents of paragraph 11 did however indicate that there would be an onus on proving that the 'new' issues would be necessary. This view was not shared by all Member States. Rwanda, for instance, stated on behalf of the African Group that:

> 'The ordinary meaning of the sentence "the amendment will be based, where appropriate, on this Decision" indicates that it was never the intention of the Members to use the entire August Decision as the amendment. Only the parts of the 30 August 2003 Decision that are appropriate are to be used'[922]

For these and other Member States, the final solution was supposed to constitute a more comprehensive and thought-out decision that made for an effective and operational solution to the paragraph 6 dilemma. They rejected any assertion that the Decision and the Chairman's Statement should be incorporated in their entirety into the final solution.[923] These Member States sought a solution based upon the Public Health Declaration and paragraph 6 thereof. In addition, emphasis was put on the system itself as being unable to achieve its intended goals. This dispute was aggravated by the potential role the Chairman's Statement might play in interpreting the

920 Para 11 serves as a resolutory condition: upon the occurrence/adoption of an amendment the obligations under the Decision will terminate.

921 Decision para 11.

922 WTO Communication by Rwanda and others 'The TRIPS Agreement and Public Health' (06.04.2005) IP/C/W/445 p. 2.

923 Contrast US in the TRIPS Council Minutes (31.01.2006) IP/C/M/49 p. 36.

contents of the Decision. Those developing Member States fearful of a restrictive interpretation of the scope of paragraph 11 sought to downplay the role and application of the Chairman's Statement.

One of the problems that led to the Decision being temporary and not final was the dispute over the legal form of the solution.[924] It is therefore surprising to read that paragraph 11 of the Decision expressly refers to a solution that will *amend* the TRIPS Agreement.[925] By referring to an amendment the Member States effectively ruled out solutions on the basis of authoritative interpretations of Article 30, waivers in terms of Article IX.3 of the WTO Agreement and moratoriums. The choice of the word amendment steered the course for future discussions.

C. Article 31bis of the TRIPS Agreement

The negotiations for a final solution to the paragraph 6 dilemma made little headway after the adoption of the temporary Decision. Member States were at logger heads over the scope of the final solution. Some Member States, mainly developing countries, sought to readdress and correct the shortcomings in the Decision in order to ensure that the final system become an effective solution to the paragraph 6 dilemma.[926] These plans were viewed sceptically by developed Member States who saw the Decision as being the raw form for the final amendment.[927]

The Member States' inability to resolve the final solution weighed on the other WTO negotiations. It was the pressure to remove this obstacle and the resignation that a better deal was unlikely to be struck that spurred the Member States to finalise the solution to the paragraph 6 dilemma.

The final solution, adopted on the 6th of December 2005 by the General Council, is a direct transformation of the Decision; merely its format was altered.[928] The decision of the General Council (the 'Amendment') provides for the insertion of a new provision into the TRIPS Agreement: Article 31*bis*.[929] Only upon the entry into ef-

924 *Oh*, 10 Bridges 1 (2006) p. 22.

925 The Decision notes that the final solution, the amendment, should be based on the Decision. As the Decision is a combination of waivers it seems apparent that 'based' refers not to form but rather to content.

926 Compare WTO Communication by Nigeria and others 'Implementation of Paragraph 11 of the 30 August Decision' (10.12.2004) IP/C/W/437, *Oh*, 10 Bridges 1 (2006) p. 22.

927 ICTSD 'TRIPS Council Considers Public Health, Biodiversity' *Bridges Weekly Trade News Digest* (08.12.2004) 1.

928 *Law*, 18 ELDB 3 (2006) p. 4.

929 The TRIPS Council submitted IP/C/41 to the General Council as a proposal for the amendment of the TRIPS Agreement. This proposal was considered and was adopted by consensus by the General Council on 06.12.2005 (Decision of the General Council 'Amendment to the TRIPS Agreement' (08.12.2005) WT/L/641 ('Amendment')). The Amendment contained an attachment titled 'Protocol Amending the TRIPS Agreement' (the 'Protocol'). Para 1 of the Protocol states that, upon its entry into force, Art 31*bis* will be inserted after Art 31 into the TRIPS Agreement. The Annex to the TRIPS Agreement will be inserted after Art 73. Para 4

fect of Article 31*bis* and the Annex will the provisions of the Decision be officially substituted. The reason for the delay in the operation of the Amendment is the fact that the Amendment constitutes an alteration to the TRIPS Agreement and as such needs the ratification of the Member States. Only once the Protocol Amending the TRIPS Agreement found in the Amendment (the 'Protocol') is validly ratified will Article 31*bis* come into operation. Until this occurs the system set out in the Decision will remain in effect.[930] Hence, the Amendment will only take effect when it is ratified by all the Member States, alternatively, the 1st of January 2007, whichever is the latest. If all the Member States have not ratified the Protocol prior to the 1st of January 2007, the Protocol will only come into operation when two-thirds of the Member States have ratified the Protocol and only apply to those Member States who have ratified the Protocol.[931] Thereafter the Protocol will apply to each Member State upon its ratification.[932]

The entry into force of the Protocol will formalise the rights and obligations contained in the Decision and will be equal in weight to the other rights and obligations found in the TRIPS Agreement. The scope of the obligations will mean that effect of the obligations and rights are limited to the paragraph 6 dilemma.[933] As with the Decision, any Member States wanting to exercise the exclusions mentioned in Article 31*bis* will be required to adopt the same into the national legal system.

Although the Amendment does not amount to a change to the provisions of the Decision, its format differs from that in the Decision. The reason is purely functional; whereas the Decision implemented waivers, Article 31*bis* creates exclusions.[934] Article 31*bis* consists of 5 sub-paragraphs, structured as follows:

- Article 31*bis*(1) excludes the operation of Article 31(f) for an exporting Member State exporting pharmaceutical products in accordance with the system[935]

states that the Protocol will come into force in terms of Art X.3 of the WTO Agreement, having the effect that the Art 31*bis* and the Annex will become operational on 01.20.2007 or as soon thereafter as two-thirds of the Member States have ratified the Protocol. Cf. WTO General Council 'Annual Report (2005)' (07.12.2005) WT/GC/101 p. 6-7.

930 Para 11 of the Decision states that the Decision 'shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member'.

931 The US notified the WTO on 10.12.2005 that it has accepted the Protocol. Cf. *USTR*, Special 301 Report (2006) p. 11.

932 Protocol para 3, WTO Agreement Art X.3.

933 Art 31*bis*(5) ensures that the rights, obligations and flexibilities in the TRIPS Agreement remain unaffected by the Amendment, save where expressly stated otherwise.

934 For example the Decision uses the wording 'shall be waived'; the Amendment states 'shall not apply'. Compare Decision paras 2, 3, 6 and Art 31*bis*(1-3) respectively.

935 Art 31*bis*(1) states: 'The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement'.

- Article 31*bis*(2) excludes the operation of Article 31(h) preventing the double remuneration of patent holders in the exporting and importing Member States[936]
- Article 31*bis*(3) states that Article 31(f) shall not apply to Member States within a regional trade agreement made up of at least 50% LDC Member States[937]
- Article 31*bis*(4) constitutes an entrenched moratorium on non-violation complaints under Article XXIII of the GATT Agreement[938] and
- Article 31*bis*(5) serves to confirm that the Amendment shall not serve to restrict the flexibilities found in the provisions of the TRIPS Agreement (excluding Articles 31(f and h)).[939]

The contents of Article 31*bis* form the normative skeleton of the system. This legal foundation is augmented by the Annex to the TRIPS Agreement, a document essentially incorporating the bulk of the provisions that create the framework for the system. Together these documents constitute the entire text of the Amendment. Like the Decision before it, the interpretation of the system incorporated therein is subject to the contents of the Chairman's Statement. As was done prior to the adoption of

936 Art 31*bis*(2) states: 'Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member'.

937 Art 31*bis*(3) states: 'With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question'.

938 Art 31*bis*(4) states: 'Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.'

939 Art 31*bis*(5) states: 'This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f)'.

Decision, the 'new' Chairman's Statement was taken 'note of' by the General Council and 'in the light of this statement' prior to the adoption of the Amendment.[940]

The uncertainty that surrounded the legal status of the Chairman's Statement will, as a result of the repeated approval by the TRIPS Council and the absence of any objections to the reading of the Chairman's Statement in light of the Amendment, be somewhat lessened. The repetition and the inclusion of the same material elements of the original Chairman's Statement support the view that the document forms part of the context of the Amendment.[941] As the TRIPS Council approved the contents of the Chairman's Statement for a second time it would be difficult for a Member State to deny that the statement exhibits qualities and characteristics of an agreement. From an interpretational perspective, the result is that the Chairman's Statement under the Article 31*bis* system may, upon its adoption, prove to be the 'main, if not sole, supplementary means of interpreting it'.[942] Notwithstanding this, the Chairman's Statement is not unencumbered. The General Council agreed to reaffirm the statements made by certain Member States after the adoption of the Decision.[943]

The new Chairman's Statement differs in one relevant point. It inserts a new sentence explaining that Article 31*bis*(4) is without prejudice to the question of whether the application of Articles XXIII(1)(b and c) of the GATT Agreement applies to the TRIPS Agreement as a whole.[944] The inclusion of this sentence seeks to ensure that Article 31*bis*(4) does not influence the ongoing discussion on, and to what extent, non-violation challenges will apply to the TRIPS Agreement.[945]

The Member States that agreed to opt-out of the system under the Decision and Chairman's Statement confirmed that they would continue to either fully or partially opt-out of the system under the Protocol. This was achieved by 'choreographed' unilateral undertakings, either in writing or by way of a statement, made by the relevant Member States.[946]

940 WTO General Council 'Annual Report (2005)' (07.12.2005) WT/GC/101 at p. 7, WTO General Council Minutes (27.03.2006) WT/GC/M/100 p. 12. The TRIPS Council 'approved' the forwarding of the statements to the Chairman. It was read out in the General Council and the proposal to take note of the statements was formally adopted. The statements made by certain Member States after the adoption of the 30 August Decision were also formally reaffirmed.

941 ICTSD 'Members Strike Deal on TRIPS and Public Health; Civil Society Unimpressed' *Bridges Weekly Trade News Digest* (07.12.2005) p. 2.

942 ICTSD 'Members Strike Deal on TRIPS and Public Health; Civil Society Unimpressed' *Bridges Weekly Trade News Digest* (07.12.2005) p. 2-3.

943 WTO General Council Minutes (27.03.2006) WT/GC/M/100 p. 12.

944 The statement concerning Art 31*bis*(4) followed the identical procedure to the Chairman's Statement. Cf. WTO General Council Minutes (27.03.2006) WT/GC/M/100 p. 8-9.

945 The Hong Kong Ministerial Declaration mandated the continued 'examination of the scope and modalities for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 and make recommendations to our next Session. It is agreed that, in the meantime, Members will not initiate such complaints under the TRIPS Agreement'. Cf. WTO Ministerial Declaration (22.12.2005) WT/MIN(05)/DEC ('Hong Kong Ministerial Declaration') p. 8.

946 ICTSD 'Members Strike Deal on TRIPS and Public Health; Civil Society Unimpressed' *Bridges Weekly Trade News Digest* (07.12.2005) p. 2.

The first country to make a notification in terms of the paragraph 6/Article 31*bis* system was Rwanda.[947] On 19 July 2007 it notified the TRIPS Council that it would import TriAvir from a Canadian generic manufacturing company.[948]

An observation of the system put in place by the Decision could lead to the conclusion that the developed Member States prevailed in securing their interests. The system to be enforced by the Article 31*bis* is complex, bureaucratic and does not provide the easiest solution for Member States seeking access to medicines. Instead the developed countries were able to maintain a system that paid more attention to safeguards than to efficiency – the initial goal of paragraph 6 of the Public Health Declaration.

Despite the unattractiveness of the system as a whole, the spread of diseases and the limited supply of pharmaceuticals have multiplied the amount of countries unable to counter public health threats adequately with domestically produced pharmaceuticals. This has been highlighted in particular by the avian influenza threat where the producer of a medication identified as being the most effective, Roche, released a statement stating that despite concerted efforts to stockpile the medication Tamiflu in advance, orders made for the medication at the beginning of 2006 would only have been produced in 2008.[949]

947 WTO Notification from Rwanda 'Notification Under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (19.07.2007) IP/N/9/RWA/1.

948 WTO Notification from Canada 'Notification Under Paragraph 2(C) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (05.10.2007) IP/N/10/CAN/1. The Canadian counter notice accordingly fulfilled the formal requirements for the Article 31*bis* system by adding the pharmaceutical (a combination of lamivudine, nevirapine and zidoudine), the authorised manufacturer (Apotex Inc.), the website for information, the amount (15,600,000 tablets) and the duration (2 years).

949 --, Roche Completes Tamiflu Stockpile for WHO *Agence France-Presse* (19.04.2006). In the case of Tamiflu, Roche has granted 11 voluntary licenses to pharmaceutical producers around the globe in order to assist it in meeting the needs of society. Taiwan has however issued a compulsory license for the production of a generic version of Tamiflu. Cf. *Hille*, Taiwan employs compulsory license for Tamiflu Financial Times (25.11.2005).

Chapter 8 The realisation opportunities afforded by the Public Health Declaration

The waivers of Articles 31(f and h) of the TRIPS Agreement (found in the Decision) and the Article 31*bis*[950] mark an exception from the minimum patent standard required by the TRIPS Agreement. This means that a Member State with a TRIPS-conform intellectual property system will have to amend its domestic law before it will be able to make use of the system.[951] Hence, a Member State seeking to export pharmaceutical products under a compulsory license in terms of Article 31*bis*(1) will be required to amend its compulsory license system before it can authorise the compulsory license for export purposes. This applies *mutatis mutandis* to the exceptions in Articles 31*bis*(2 and 3). The actual methods used by Member States to implement the Amendment are left to the Member States themselves to regulate, subject to the relevant safeguards being effectively implemented.

A number of Member States were quick to take up the task of legitimising Article 31*bis* in their domestic legal systems. The measures taken, or in the process of being taken, are selectively discussed below.

A. Norway

Norway was actively involved throughout the paragraph 6 negotiations. With the adoption of the Decision Norway went about swiftly implementing the Decision into domestic law.[952] Despite the large domestic support from the implementation of the Decision, including from the Norwegian Association of Pharmaceutical Manufacturers, it was not anticipated that the relatively small number of Norwegian pharmaceutical manufacturers would be able to make a significant contribution to assisting those countries with inadequate domestic pharmaceutical production capacities.[953]

950 For convenience sake, subsequent references made to the provisions contained in the Decision will be done in terms of Art 31*bis*. Where applicable, the footnotes will make a corresponding reference to the specific location of the original source of the provision in the Decision.

951 *Law*, 18 ELDB 3 (2006) p. 6.

952 The implementation of the provisions of the Decision into the Norwegian Patent Act enacted by Act of 19.12.2003 no 127 and Royal Decree of 14.05.2004 and entered into force on 01.06.2004. Cf. WTO Communication by Norway 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (17.09.2004) IP/C/W/427.

953 WTO Communication by Norway 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (17.09.2004) IP/C/W/427 p. 2. Norway notes that all parties consulted, including the Association of Pharmaceutical Manufacturers expressed a 'strong general support' for the amendment.

The implementation of the Decision in Norway was achieved by an amendment of the Patent Act. The solution was founded on the Norwegian King's authority to permit a deviation to the rule that a compulsory license 'shall be issued mainly with a view to supplying the domestic market'.[954] In terms of the amendment, a Norwegian pharmaceutical producer is entitled to apply for a compulsory license in order to manufacture pharmaceutical products for their export. In order to obtain a license, the producer may only export the products to the eligible importing countries. The Norwegian amendment defers to the Decision for determining what a 'product', an 'eligible importing State' and inadequate production capacities are.[955] In addition, the amendment extends the scope of the eligible importing country to all LDCs designated as such by the UN.[956] Where the conditions for a license have been fulfilled, the producer has a 'legal right' to the license.[957]

The Norwegian approach to the implementation of Article 31*bis* is characterised by a respect for the sovereignty of the decisions made by the importing Member States. As such, the Norwegian system will not second-guess a Member State's assessment with respect to its inadequate domestic production capacity nor will it question the volume of pharmaceuticals requested.[958] Only where there 'are specific indications that the public health needs of the importing state have been inaccurately described' will an importing Member State's acts be questioned.[959] Where such evidence is absent to this effect, 'a compulsory license should normally be issued'. The Norwegian system accordingly places the onus on the party opposing the license grant to disprove the importing Member State's claims. Accordingly and unless there is evidence to the contrary, the compulsory license granting authority (either the Competition Authority or the courts) will presume the information provided to be true.

The details of the Norwegian system echo those of Article 31*bis*. The reason for this is that the amendment is less specific than the system set up in terms of Article 31*bis*. Norwegian legal practice will ensure that where the statute is inadequate or unclear interpreters will look to the founding public international rules for assistance.[960] The Norwegian system does however incorporate the essential requirements of Article 31*bis*, for example:

954 Norwegian Patent Act sec 49 (fifth paragraph).
955 Norwegian Patent Act secs 108(2) and 107(1) respectively.
956 Norwegian Patent Act sec 107(1).
957 Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 7.
958 Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 9.
959 WTO Communication by Norway 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (17.09.2004) IP/C/W/427 p. 3.
960 WTO Communication by Norway 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (17.09.2004) IP/C/W/427 p. 2.

- a notification by the importing country to the TRIPS Council[961]
- it must confirm that it intends to use the system (unless it is a LDC)
- it must include the name and intended amounts of the product it requires
- it must state that it has insufficient or no production facilities for the production of the product[962] and
- it must confirm that it has granted a compulsory license for the product in its own territory or intends to do so.

The Norwegian compulsory license applicant must base the application on the notification[963] and:

- the compulsory license applicant must have attempted to obtain a voluntary license from the patent holder[964]
- the product is a pharmaceutical product, an active ingredient or a diagnostic kit
- it is produced solely for the export to the eligible importing country and
- the product must not be patented in the importing country or it must be subject to a compulsory license or is in the process of being compulsory licensed.

The attempt to acquire a voluntary license forms a significant part of the Norwegian system. The potential licensee must seek to obtain a voluntary license on reasonable commercial terms and conditions. This obligation is however tempered by the qualification that the reasonable license fees should also take into account the 'economic value to the importing State of use of the invention'.[965] Notwithstanding this obligation, the Norwegian authorities are clear that most of the requests for assistance will come from the governments of the importing countries. Recognising this, the Norwegians have allowed their compulsory license system to recognise the foreign grounds for the compulsory licenses in their own compulsory license system.[966]

The Norwegian system, characterised by relative simplicity, avoids overcomplicating the Article 31*bis* system. This 'minimalist' approach is evident not only in amendment being 'less detailed' than Article 31*bis* but also ensuring that the discre-

961 Where the importer is a WTO Member State.

962 The determination of an insufficient manufacturing capacity is made in terms of the Annexure to the Decision.

963 Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 9. The quantity is limited to the 'current need' of the importing country. Accordingly, a compulsory license could not be increased without bringing a new application for a license.

964 The Explanatory Note confirms that this will not be necessary where the license is based on extreme urgencies or non-commercial use grounds. Cf. Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 8.

965 Norwegian Patent Act sec 108.

966 Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) 8, *Abbott*, 99 AJIL 2 (2005) p. 342.

tionary provisions remain discretionary under Norwegian domestic law. Article 31*bis*(2)(b)(ii)[967] states that the supplier 'should', where 'feasible', make a distinction in the production of the products. The language used by the Member States indicates that the obligation, although important, remains discretionary.[968] This flexibility is transposed into the Norwegian system by giving the granting authority the ability to compel these requirements.[969] The Norwegian system also abstains from limiting when the system can be used (i.e. the public health problem), it does not limit the scope of diseases[970] and from imposing any time restriction on the license duration. Further evidence of the minimalist approach is the absence of any time restriction on the license duration and Norwegian quality or admission requirements. The Norwegian system intelligently avoids imposing such requirements and leaves the obligation to determine safety and efficacy to the importing country.[971]

The Norwegian implementation of the Article 31*bis*(3)[972] obligation – to remunerate the patent holder according to the economic value of the license to the importing Member State – does not mention the possibility that the importing Member State may have provided for the remuneration of the patent holder itself. It is however assumed that the requirement to take into account the 'economic value' of the license will have due regard for the remuneration granted by the importing Member State and adjust the Norwegian remuneration accordingly.

The protection against the diversion of the licensed products is sensibly resolved by the Norwegian system: when the licensor learns that the products are not being

967 Decision para 2(b)(ii).

968 The Explanatory Note expressly states that these 'provisions are based on paragraph 2(b)(ii)' of the Decision. As the Regulation does not include the grounds for the conditionality of provisions in the Decision it is assumed that they will nevertheless be required to consider these factors in determining the discretionary nature of the provisions. The Explanatory Note also states that the Regulations purpose is to allow the granting of export licenses 'in accordance' with the Decision. Notwithstanding this, it is clear from the Explanatory Note that the principal concern of the granting authority is to prevent the unauthorised use of the compulsory license. Cf. Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 9-10.

969 Norwegian Patent Act sec 108. These include: (i) the packaging, including its container, should be distinguishable form the original packaging in Norway or other states in which the patent holder markets its product; (ii) the packaging must identify that they have been produced under a Norwegian compulsory license and that they are destined for a specific market. The discretionary nature of sec 108 is contradicted by the Explanatory Note which states, in reference to the relevant provisions in sec 108, that the 'grant of a compulsory license *must* include conditions to guard against its unauthorised use' (emphasis added). Cf. Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 9.

970 Compare *Abbott*, 99 AJIL 2 (2005) fn. 130 p. 333.

971 Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 9. Manufacturing requirements will however remain applicable.

972 Decision para 6(i).

used, to an 'appreciable degree', in accordance with the grant of the license, the manufacture and export of the products shall cease.[973] This obligation to cease is however a discretionary requirement that the granting authority may impose. Similarly well resolved is the question of actions available to the patent holder in terms of the paragraph 4 to the Annex.[974] Instead of making special arrangements or remedies the Norwegian system makes reference to existing remedies under patent law.[975] The transparency in the Article 31*bis* system will ensure that the patent holder has sufficient information to overview the compliance with the system and the license requirements.

The Norwegian system refrains from any direct reference to the Chairman's Statement. This absence once again confirms the Norwegian approach to only implementing the essentials of Article 31*bis* system. Where the system is found to be lacking, interpretation will be sought in Article 31*bis* and potentially the Chairman's Statement. As the latter does not impose any direct obligations it will only play a role when the domestic rules and Article 31*bis* are unable to provide sufficient clarity.[976]

The Norwegian system is, from a policy standpoint, an ideal system to resolve the paragraph 6 dilemma. It is less complex than the Article 31*bis* system, it is stripped of unnecessary limitations spawned by policy thoughts in the Article 31*bis* system[977] and it only legislates those rules necessary for the effective operation of the system.[978] The approach taken by Norway represents an adoption of the spirit of the Public Health Declaration and the TRIPS Agreement at large. It is free of prejudgemental policy issues and ensures that only the essential operational issues are implemented. The remaining issues and fears as to the abuse of the system and the diminution of patent protection are not shifted to the operation of the system between the actual users and producers but left to the government to address – either between itself and other Member States on a government level or between the organs of government.

973 Norwegian Patent Act sec 108.

974 Decision para 5.

975 Norwegian Explanatory Notes: Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a)) p. 9.

976 The clear formulation of the Norwegian system indicates that the use of the Chairman's Statement will only likely be with regards to influencing the labelling restrictions. As the 'Best Practices' Guidelines are merely illustrative, the domestic licensee would be able to other labelling practices if it is able to show that the measures it adopts are more effective or more feasible.

977 Notions of 'good faith', 'pursue industrial and commercial policy', the definition of 'public health problem' and the scope of diseases are not regulated by the Norwegian Patent Act.

978 An example of the effectiveness of the system is the ability of a licensee to produce, under one license, pharmaceutical products for exports to more than one importing state. This permits cost reduction and avoids unnecessary bureaucratic obstacles.

B. Canada

The Canadian implementation of the Article 31*bis* system differs substantially from the Norwegian approach. Critics would claim that the Canadian system puts more emphasis on formalities, forms and solemn declarations than on a simple and efficient system to aid Member States without adequate domestic pharmaceutical production capacities.[979] Proponents would counter that the formalities are safeguards that will deter the abuse and circumvention of the patent system. Either way, the system implemented by the Jean Chrétien Pledge to Africa Act (the 'Act')[980] on the 14th of May 2004 is substantially more exhaustive than the Norwegian system.[981] Instead of examining the entire system, the examination of the Act concentrates on the material scope, system and safeguard differences that distinguish it from the Norwegian approach and discusses to what extent the Canadian system has adopted the underlying policy considerations of Article 31*bis*, the Public Health Declaration and the TRIPS Agreement.

The Canadian approach differs from the scope of Norwegian approach in a four noticeable ways. Firstly, the comprehensive nature of the system has made it necessary for both the Patent Act and the Food and Drug Act to be amended and the creation of a new system for the similar regulation of medical devices.[982] Secondly, the Canadian legislators have limited the scope of the system to a finite number of pharmaceutical products.[983] In terms of Schedule 1 of the Act, only 56 pharmaceutical products are considered potential exportable pharmaceutical products.[984] Thirdly,

979 The legislators themselves acknowledge that their system is 'quite detailed'. Cf. Regulatory Impact Analysis Statement to the Use of Patented Products for International Humanitarian Purposes Regulations to the Patent Act SOR/2005-143 p. 1151.

980 The Jean Chrétien Pledge to Africa Act, Bill C-9, assented to on 14.05.2004, amending the Patent Act and the Food and Drugs Act. The Act brought about amendments to the Patent Act and the Food and Drugs Act that were to 'facilitate access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis malaria and other epidemics'. Although the Act was assented to prior to the Norwegian Regulation it only came into force on the 14th of May 2005.

981 An agreement was reached with the US to ensure that the NAFTA provisions will not impede the implementation of the Amendment. Cf. *USTR*, Special 301 Report (2006) p. 11.

982 Regulations Amending the Medical Devices Regulations (Developing Countries) SOR/2005/142, Regulatory Impact Analysis Statement to the Regulations Amending the Food and Drugs Regulations (1402 – Drugs for Developing Countries) SOR/2005-141 p. 1117.

983 Canadian Patent Act RSC 1985 c P-4 sec 21.02. The *numerus clausus* list for the pharmaceuticals was rejected by the Member States during the para 6 negotiations. The Canadian list excludes certain AIDS combination medication recommended by the WHO. Cf. *t'Hoen*, (2005) p. 5.

984 Sec 21.03 of the Canadian Patent Africa Act states that additional patented products can be added to the list provided it is recommended by the Minister and the Minister of Health and is used to address health problems afflicting many developing and LDC Member States. On 21.09.2006 oseltamiv phosphate (Tamiflu) was added to the list. Noteworthy is the inclusion

Schedules 2 and 3 to the Act list the countries eligible to take advantage of the system, either as a LDC or as a developing Member State.[985] Excluded from the lists are those Member States that have chosen to opt-out of the system or only to use it in emergency situations.[986] Lastly, although the Canadian system serves to implement the Article 31*bis* system, its focus lies on the 'humanitarian' assistance.[987] Whereas this may be the effective result of the system, the Article 31*bis* system serves to enable the effective use of the patent system.[988]

The system adopted in Canada sets more onerous measures on the licensee than the Norwegian system and more onerous than is required by Article 31*bis*.[989] This implementation of the Article 31*bis* system signals the Canadian intention to keep a tight control on the use of the system. To this effect, the Canadian system requires:

- a solemn or statutory declaration verifying that the prior negotiations were unsuccessful, were not carried out over a period of less than a 30 days and had provided the patent holder with essentially the same information as is set out in the compulsory license application[990]
- a solemn or statutory declaration verifying that the importing country is a WTO Member State, the patent status of the pharmaceutical product in that Member State and that it is identified in the schedules to the Act (either as a LDC, a developing Member State or a Member State having partially opted out of the system)[991]

of vaccines in the Canadian list, as set out in schedule 1 to the Jean Chrétien Pledge to Africa Act. The list includes the dosage form, the strength and the route of administration of the 56 pharmaceuticals. Absent from the list are, at present, medical devices. Cf. Regulatory Impact Analysis Statement to the Regulations Amending the Food and Drugs Regulations (1402 – Drugs for Developing Countries) SOR/2005-141 p. 1117

985 A number of countries have however been excluded from the list: for example East Timor, Turkmenistan and Vietnam. Like the list identifying the eligible pharmaceutical products, the list of countries may be amended either to include or exclude country. The amendment is done by the Governor in Council on recommendation from the Ministers of Foreign Affairs, International Trade and International Cooperation. In the case of a LDC, the status must have been determined by the UN. Cf. Canadian Patent Africa Act sec 21.03(1)(b). Like the list for the eligible products, the list for countries has also been criticised as an unnecessary restriction on the Art 31*bis* system. Cf. *t'Hoen*, (2005) p. 5.

986 Those countries that have agreed to a limited opt-out are identified in schedule 4.

987 Sec 21 of the Canadian Patent Act is now titled 'Use of Patents for International Humanitarian Purposes to Address Public Health Problems'.

988 Public Health Declaration para 6.

989 Elliot refers to the Canadian system as a 'TRIPS-plus' entitlement for Canadian patent holders. Cf. *Elliott*, 7 Bridges 8 (2003) p. 21.

990 Canadian Patent Act RSC 1985 c P-4 sec 21.04(3)(c).

991 This condition, *inter alia*, prevented MSF from obtaining a compulsory license under the Canadian system. Cf. --, Rwanda Becomes the First Country to Try to Use WTO Procedure to Import Patented HIV/AIDS Drugs (2007) 11 Bridges 27 p. 5.

- the production of a certified copy of the notice sent to the WTO setting out its intention to use the system[992]
- the submission of a solemn or statutory declaration to the granting authority and the patent holder setting out the number of pharmaceutical units are to be sold and their monetary value
- prior to the exportation of the product, the creation and maintenance of a website disclosing the particulars of the license[993]
- the payment of royalties, within a prescribed period, to the patent holder in accordance with the prescribed formula
- the identification of the quantity, product, importing country and all known persons handling the shipment of the product to the importing state.[994] This information is also required to be furnished to the patent holder, the importing country and the purchaser each time a shipment of products is exported.[995]
- the licensee must carry records that would enable the audit of the licensee's exercise of the compulsory license and
- the compulsory license is granted for a period of two years.[996]

The Canadian system is strewn with safeguards. Each solemn declaration and form deters the unlawful use of the system and increases the accountability of the licensees. Not only is the misuse of the system by the licensees deterred; the Canadian system sets certain requirements that – directly and indirectly – limit the 'full' use of the system by the importing Member State. Thus for example, the inability to acquire a compulsory license without the prior negotiations being conducted with the patent holder has meant that Canada is unwilling to acknowledge foreign circumstances of extreme urgency or public non-commercial use in their license applications.[997]

992 992 Where the importing country is not a WTO Member State, the Canadian system requires a certified copy of the notice sent to the Canadian Government requiring assistance.

993 Cf. --, Rwanda Becomes the First Country to Try to Use WTO Procedure to Import Patented HIV/AIDS Drugs (2007) 11 Bridges 27 p. 5.

994 Further, the Canadian Intellectual Property Office will contain a link to the website. Cf. Canadian Patent Act RSC 1985 c P-4 secs 21.04(2) and 21.06(1).

995 Failure to comply with these requirements results in the prohibition of exportation of the products. Cf. Canadian Patent Act RSC 1985 c P-4 sec 21.16(2). An earlier Canadian proposal sought to give the patent owner a 'right of first refusal' allowing it to assume the role of the generic producer in a supply contract. This proposal was however dropped. Cf. ICTSD 'Canadian Drug Patents Law for Poor Countries Released for Comment' *Bridges Weekly Trade News Digest* (13.10.2004) 5, *Abbott*, 99 AJIL 2 (2005) p. 341-342.

996 Canadian Patent Act RSC 1985 c P-4 sec 21.09. The duration may be extended if the license holder pays an additional license fee and states under oath that the products exported were less than was authorised in the license. All other requirements set out for the initial application must be repeated for the renewal. Only one renewal may be granted. Cf. Canadian Patent Act RSC 1985 c P-4 sec 21.12.

997 Cf. *Abbott*, 99 AJIL 2 (2005) p. 342.

The pecuniary safeguard of the patent holder's interests is expressly regulated in the Canadian system.[998] The Act speaks of a mandatory obligation on the licensee to compensate the patent holder. In determining the amount of remuneration the granting authority, the Governor in Council, must take into consideration the humanitarian and non-commercial reasons behind the license. These grounds are seen to be effectively incorporated into a formula used in the Canadian system to calculate the remuneration. The formula multiplies the monetary value of the pharmaceutical supply agreement by an amount which fluctuates according to the basis of the importing countries standing on the UN Human Development Index (the 'UNHDI'). In terms of the formula the royalty rate will not be lower than 0,02% and not more than 3,6% of the monetary value of the supply agreement. [999]

If it transpires that the agreement between the producing party and the importer is 'commercial in nature' a court is permitted to terminate the compulsory license. In terms of the Act, an agreement is commercial where the cost of the product is more than a quarter of the price of the patent holder's product.[1000] In other words, if the licensed product is less than 75% cheaper than patent holder's prices the patent holder can apply to have the license cancelled or the royalty rate increased.[1001] The Canadian legislators justify this provision on the 'good faith' clause in the Chairman's Statement.[1002] By limiting the opportunities licensees have to profit from the Article 31*bis* system the Canadian approach prevents the system from potentially becoming an 'instrument to pursue industrial or commercial objectives'.[1003]

998 Canadian Patent Act RSC 1985 c P-4 sec 21.08(1).

999 Hence, the calculation for Nigeria, which was ranked number 151 of 177 countries in the UNHDI in 2004, would be as follows: [(1+177-151)/177] x 0.04 = 0.0061 or 0.61% of the value of the pharmaceutical supply contract. Cf. Regulatory Impact Analysis Statement to the Use of Patented Products for International Humanitarian Purposes Regulations to the Patent Act SOR/2005-143 p. 1149.

1000 Determining that the price of the pharmaceutical product is 25% or more of the equivalent patented brand name pharmaceutical in Canada is a prerequisite for determining if the use of the license is commercial in nature. Cf. Regulatory Impact Analysis Statement to the Use of Patented Products for International Humanitarian Purposes Regulations to the Patent Act SOR/2005-143 p. 1150.

1001 A court tasked with considering such an application must take into account the need for the producer to make a reasonable return on the production, that ordinary profit is permissible and the international prices for humanitarian medication. The courts must however deny a termination on these grounds where the producer can prove that the price being charged is not more than the direct supply cost plus a mark-up of 15%. Cf. Canadian Patent Act RSC 1985 c P-4 secs 21.08(7) and 21.17(2, 5 and 6). In terms of sec 21.14(f) the license may also be terminated where, with the knowledge of the licensee, the products are being re-exported contrary to the Art 31*bis* system.

1002 Regulatory Impact Analysis Statement to the Use of Patented Products for International Humanitarian Purposes Regulations to the Patent Act SOR/2005-143 at 1150, 1155. The statement expressly notes that it does not consider the Chairman's Statement's 'good faith clause' to set a requirement for the implementation of the Art 31*bis* system.

1003 It is also theoretically possible for the pharmaceutical producer to frustrate a license (or bring about its termination) by lowering its prices resulting in the price difference being less than the required 75%.

In addition to safeguards protecting the patent system and the rights of the patent holder, the Act also inserts safeguards securing the quality of the product. In this regard the Act prohibits the exportation of the pharmaceutical product if it does not meet the Canadian efficacy, safety and quality standards.[1004] The Act does not detail exactly what tests will be required and how long they would take to complete.[1005] It would however be expected that this process be restricted to a chemical and quality analysis as the Canadian system already sets out what pharmaceuticals and in what dosage will be permitted.[1006] The list must be assumed to constitute a list of pharmaceuticals that are – in their specified state – effective and safe. As the admission of a pharmaceutical is generally the task of the country in which the product is consumed this requirement effectively requires two quality assurance tests.

To safeguard against the licensed product being diverted and used in the Canadian market the Canadian system requires both the label and the product itself must bear the marking 'XCL', be a 'significantly different' colour to the Canadian original pharmaceutical product and the label of the product contains an export tracking number and the wording 'FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA'.[1007] With these requirements the Canadian regulations seek to deter the diversion of the products by making the licensed products clearly distinguishable from the same product sold in Canada. Only if the product is distinguishable will it be permitted to be sold.[1008]

With the multitude of provisions, conditions and formalities found in the Canadian Act, there is the potential that either dogmatic administrative acts or judicially active patent holders will be able to frustrate or delay the granting or exercise of a compulsory license.[1009] The Canadian HIV/AIDS Legal Network noted that the Act

1004 Canadian Patent Africa Act sec 21.04(3), Regulatory Impact Analysis Statement to the Regulations Amending the Food and Drugs Regulations (1402 – Drugs for Developing Countries) SOR/2005-141 p. 1118.

1005 Sec C.08.002 of the Canadian Food and Drugs Regulations C.R.C. 870 requires, *inter alia*, tests and clinical evidence that establishes the efficacy, potency, purity, stability and safety of a new drug. This would apply to a new drug under the Art 31*bis* system. Cf. Regulations Amending the Food and Drugs Regulations (1402 – Drugs for Developing Countries) SOR/2005-141 sec C.07.004(b). Medicines that are not new must comply with sec C.07.003(c). A Canadian representative at the WTO noted that the licensed products will be subject to the same health and safety review as products for domestic consumption, however, the licensed products would be afforded preference by way of a special expedited queue. Cf. Canada in the TRIPS Council Minutes (15.09.2005) IP/C/M/48 p. 25.

1006 Jean Chrétien Pledge to Africa Act schedule 1.

1007 Canadian Regulations Amending the Food and Drugs Regulations (1402 – Drugs for Developing Countries) SOR/2005-141 sec C.07.008. The export tracking number is assigned by the Minister of Health.

1008 Canadian Regulations Amending the Food and Drugs Regulations (1402 – Drugs for Developing Countries) SOR/2005-141 sec C.07.007.

1009 The Act and is supplementary regulations makes provision for 7 different solemn or statutory declarations and a number of certifications and notifications with regards to the exportation system. Cf. Use of Patented Products for International Humanitarian Purposes Regulations to the Patent Act SOR/2005-143 at 1131-1137, *Canadian HIV/AIDS Legal Network,* press re-

contains 'unnecessary and unjustified hurdles to using it, and could undermine it'.[1010] Whereas the Canadian system sought to implement a local solution to the paragraph 6 dilemma, its conditions do not represent a 'liberal' or expedient implementation of the Public Health Declaration's policies. Hence, the Canadian approach lays more emphasis on comprehensive control mechanisms than on enabling the full use of the flexibilities permitted in the Public Health Declaration.[1011] The Canadian approach cannot however be accused of not reflecting the Public Health Declaration policies; it has taken measures to adopt a solution and has ensured that intellectual property rights are effectively and adequately protected in a manner it deems most appropriate.[1012]

Notwithstanding the formalist approach taken by Canada, it is more likely that it – and not Norway – will play a meaningful role in providing assistance to needy countries.[1013] This is not a result of the system created in Canada but rather a result of the more extensive generic pharmaceutical sector found in Canada.[1014] Not only do the generic producers have the capacity to help, they are also able to look back on a 'rich' compulsory license and generic production history in Canada.[1015] This experience, the ability and the resulting competitive advantage may make Canadian generic producers the first stop for needy countries – notwithstanding the rigid and bureaucratic system.[1016] A first step in this direction has already been taken.[1017]

lease from 13.05.2005. MSF has spent more than 2 years seeking to get a compulsory license under the Canadian system. It has called the system 'very "long" and "resource intensive"'. Cf. ICTSD 'Members Strike Deal on TRIPS and Public Health; Civil Society Unimpressed' *Bridges Weekly Trade News Digest* (07.10.2005) p. 3.

1010 Canadian HIV/AIDS Legal Network, (2005).

1011 It has been referred to as being 'just for one country, for one product and for a limited period'. Cf. --, Rwanda Becomes the First Country to Try to Use WTO Procedure to Import Patented HIV/AIDS Drugs (2007) 11 Bridges 27 p. 5.

1012 Compare TRIPS Agreement preamble, Art 1.1.

1013 Canada has become the first country to respond to a formal request to supply HIV/AIDS drugs under the Article 31*bis* system. *ICTSD*, Canada Issues Compulsory Licence for HIV/AIDS Drug Export to Rwanda in First Test of WTO Procedure (2007) 11 *Bridges Weekly Trade News Digest* 32 p. 4-5.

1014 The Canadian output of pharmaceuticals is approximately 10 times that of Norway. Cf. WTO Secretariat note 'Available Information on Manufacturing Capacity for Medicines' (24.05.2002) IP/C/W/345 p. 4.

1015 *Reichman and Hasenzahl*, Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA (ICTSD/UNCTAD Geneva 2003) p. 19.

1016 The history and make-up of the Canadian generic market and the compulsory license tools available have led to the first notification made to the WTO for the production and supply of a HIV/AIDS drug. *ICTSD*, Canada Issues Compulsory Licence for HIV/AIDS Drug Export to Rwanda in First Test of WTO Procedure (2007) 11 *Bridges Weekly Trade News Digest* 32 p. 4-5.

1017 WTO Notification from Canada 'Notification Under Paragraph 2(C) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (05.10.2007) IP/N/10/CAN/1.

C. The Netherlands

Section 57(1) of the Patent Act for the Kingdom of the Netherlands states:

> 'The Minister may, if he considers it in the public interest, grant a license under a patent, the content of which shall be described precisely by him, to a person designated by him'.

By structuring and expanding his authority under section 57(1) of the Patents Act to grant compulsory licenses the Minister of Economic Affairs was able to create a system whereby Article 31*bis* could be implemented into Dutch law in a relatively simple manner. In terms of the Dutch 'Policy Rules on issuing compulsory licenses pursuant to WTO Decision WT/L/540' (the 'Policy Rules')[1018] the Minister sets terms and conditions for the interpretation and application of the public interest compulsory licenses pursuant to Article 31*bis*.[1019]

In the Explanatory Notes to the Policy Rules the Minister expressly stated that section 57(1) 'may be interpreted as including the addressing of a public health problem in another WTO Member or in one of the least developed countries'.[1020] This amounts to a global appreciation and understanding that the concept of 'public interest' is not merely a national issue but that it can extend beyond borders.

Under Dutch law a policy rule 'lays down a general rule for weighing interests, determining facts or interpreting statutory regulations in the exercise of a power of an administrative authority'.[1021] It does not carry the weight of a statute but instead provides the structure for the implementation of a statute, in this case section 57(1) of the Patent Act. As such, the Policy Rules serve to guide the Minister's powers in terms of section 57(1). The Explanatory Notes to the Policy Rules further make it clear that, in exercising the 'policies' the aims thereof must be borne in mind. As such not only do the Policy Rules ensure that there is a balance between the rights of the individuals affected by the system but also that the Policy Rules reflect the aims of Article 31*bis*.

The simplicity of the Dutch system derives principally from its close resemblance to the Article 31*bis* system. Thus it is that the scope of the Dutch system derives directly from the Article 31*bis* system and that the term 'pharmaceutical product', 'importing state' and 'countries within a regional trade agreement' all directly derive their meaning from Article 31*bis*. As such the scope of the Dutch system mirrors that of the Article 31*bis* system. There is however no mention in the Dutch system to the Chairman's Statement. Further, the Dutch system does not make express mention of the concepts of 'good faith', 'industrial or commercial policy objectives' or 'best practices'. The lack of reference to the Chairman's Statement indicates that

1018 Policy Rules on issuing compulsory licenses pursuant to WTO Decision WT/L/540 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, under section 57, subsection 1 of the Kingdom Act on Patents of 1995, Staatscourant (21.11.2004) nr. 246/p. 11 ('Policy Rules').

1019 General Administrative Law Act Art 4:81.2.

1020 Policy Rules Explanatory Notes.

1021 General Administrative Law Act Art 1:3.4.

only when the Policy Rules and Article 31*bis* are unable to establish the meaning of a certain provision will there be a potential need to consult the contents of the Chairman's Statement.

In addition to the scope of the system, the actual licensing system created by the Policy Rules adopts major portions of the procedural rules incorporated into Article 31*bis*.[1022] The Dutch system does however exceed Article 31*bis*'s scope by allowing the export of pharmaceuticals under a compulsory license to non-WTO Member States, provided the country has an inability to produce sufficient pharmaceuticals itself and has taken steps to prevent the diversion of the licensed products once they enter their borders.[1023] The Dutch system does however note that the decision to allow or deny a compulsory license will be based on the principle of proportionality. In other words the license must be 'commensurate' with the public health problem.[1024] Thus it follows that the Minister, the granting authority, will evaluate whether or not the importing Member State's license will be acknowledged and 'respected' in the Netherlands.[1025] Although this could theoretically lead to a review of the importing country's decisions there is an assumption that the importing country's actions are in accordance with the Article 31*bis* system.[1026] It thus follows that only where the Minister is in the possession of information that rebuts the presumption or when the prejudice suffered by the patent holder is unreasonable will the Minister be able to limit or even deny the compulsory license.[1027]

The Policy Rules adopt a pragmatic approach to safeguarding the interests of the patent holder. In terms of the General Administrative Law Act and the Policy Rules the system can only be exercised to the extent that it seeks to solve the public health problems'.[1028] Accordingly, where this is not the case a compulsory license would no longer be in proportion to the aims of the Policy Rules.[1029] Aside from the general safeguard provision, the Dutch system has a number of other safeguards. For instance, section 57(1) of the Patent Act requires the prior negotiation with the patent holder for a voluntary license, although this may however be waived in times of ur-

1022 Policy Rules Arts 2(2 and 3), 3(2, 4 and 5), 4, and 5.

1023 Whereas the Norwegian Regulation uses the UN designation for determining which countries are deemed to by LDCs, the Dutch policy rules makes no reference to a specific list for determining which states would be eligible as importing Member States.

1024 Policy Rules Explanatory Note to Art 2. Art 4:84 of the Dutch General Administrative Law Act requires the 'administrative authority shall act in accordance with the policy rule unless, due to special circumstances, the consequences for one or more interested parties would be out of proportion to the purposes of the policy rule'.

1025 The commentary to the Policy Rules state that once a notification has been made to the TRIPS Council by the importing country it will be presumed to have met the requirements. Cf. Policy Rules Commentary to Art 4.

1026 Policy Rules Explanatory Note to Art 6

1027 Dutch General Administrative Law Act Art 3:2.

1028 The Explanatory Note to Art 3 of the Policy Rules makes it clear that the license may only be exercised 'as part of the solution to the public health problems of the importing country'.

1029 Dutch General Administrative Law Act Art 4:84.

gency.[1030] A patent holder is entitled to contest the compulsory license application. Whether or not the opposition would suspend the implementation of the license remains up to the Minister to decide.[1031]

The Dutch system places more specific obligations on physical safeguards. Thus, the obligation to make the licensed products more distinctive rests on the licensee. Only if the licensee is able to justify why the measures relating to labelling, colouring and packaging are unfeasible or too costly will the Minister grant the license without anti-diversion safeguards. The liability for the diversion of the pharmaceutical products is resolved as follows under the Dutch System: the importing country must take measures to prevent the re-export or diversion and the Dutch licensee will be liable under criminal law where he is 'wholly or partly responsible for the trade diversion'.

The pecuniary safeguards are contained in Article 5 of the Policy Rules. In terms hereof the remuneration shall be adequate, taking into account the value of the order in the importing country. This reflects a lowering of the standard Dutch remuneration level so that 'the pharmaceutical products should be affordable to everyone in the importing country'. This therefore implies that the remuneration will not use the average income as a basis for calculating the remuneration but a level that would ensure that the remuneration does not impede the access to the pharmaceuticals by the poor.

Upon the adoption of an EC Regulation to implement an Article 31*bis* system (see Chapter 8(E) Seite 238 below) the Netherlands will, to the extent necessary, harmonise the EC rules.[1032]

In comparison to Norway and Canada, the system adopted by the Netherlands may prove to be the most effective. The reason for this is not only the relatively simplicity of the system but also the substantial domestic pharmaceutical market. The Dutch pharmaceutical sector exports more pharmaceuticals than both Norway and Canada combined.[1033]

D. India

The Indian Patents (Amendment) Act, adopted on the 4th of April 2005 (the 'Amendment Act') took a major step in bringing its patent system in line with the TRIPS Agreement.[1034] Included in the Amendment Act was a new provision, section

1030 Patent Act for the Kingdom of the Netherlands sec 57(1).

1031 Policy Rules Art 6. Generally the review of an administrative decision will suspend the operation of the license; however, the Policy Rules presupposes the urgency of applications made under the Art 31*bis* system, thus preventing an appeal from suspending the operation of a license. Cf. *AIPPI*, Questionnaire No. 4 (2005) p. 3.

1032 Policy Rules Explanatory Notes.

1033 WTO Secretariat note 'Available Information on Manufacturing Capacity for Medicines' (24.05.2002) IP/C/W/345 p. 8.

1034 Indian Patents (Amendment) Act, Act 15 of 2005 ('Amendment Act').

92A, to permit a compulsory license 'for the export of pharmaceutical products in certain circumstances'. Section 92A is comprised of 3 subsections and one explanation. In comparison to all the above implementations of Article 31*bis*, the brevity is remarkable.

It would be fair to say that section 92A represents the absolute minimum in provisions necessary to transpose the Article 31*bis* system. Section 92A(1) sets the scope by allowing compulsory licenses for:

> 'The manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India'.[1035]

The nature of the tool used to adopt the Article 31*bis* system is, like the Norwegian and the Canadian systems, a formal statutory amendment. Similarly, all three systems rely on the traditional patent system and not the public non-commercial compulsory license for the license grant.[1036]

No reference is made in the Amendment Act to either Article 31*bis* or the Public Health Declaration.[1037] In respect of the object of the compulsory license, the pharmaceutical product, the explanation to section 92A defines it in a manner that is largely a reflection of the definition in paragraph 1(a) of Article 31*bis* Annex.[1038]

Section 92A(2) states that, in addition to the situations when compulsory licenses can be granted, the granting authority, the Controller, can specify and publish terms and conditions for the license as he sees fit. This *carte blanche* is, regardless of whether one is a patent holder or a license applicant, somewhat disconcerting. As India does not have experience with regards to compulsory licenses for pharmaceutical products,[1039] there is no reference as to which conditions could be applied. Despite the present lack of legislative guidance a further review of the Patent Act may bring some light into this dark corner.[1040]

The lack of additional rules or regulations may also be seen as an attempt to permit the granting authority the flexibility to adopt measures best suited to the request

1035 Indian Patents (Amendment) Act, Act 15 of 2005 ('Amendment Act') p. 14.

1036 The Norwegian system does however provide for the competition authority to grant a license in terms of Art 31*bis*.

1037 An Indian representative to the WTO did however note that it intents to exercise its amendment of the Patent Act 'in conformity with the Decision'. Cf. India in the WTO Report to the General Council 'Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the Trips Agreement and Public Health' (03.11.2005) IP/C/37 p. 1.

1038 The only difference lies in the omission of the reference to the health problems 'recognised in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2)'.

1039 'Industry Says Indian Drug Law Violates WTO, But No WTO Case Seen' *Inside US Trade* (15.04.2005).

1040 Cf. *Abbott*, 99 AJIL 2 (2005) p. 333 fn. 115.

for assistance made by the needy country.[1041] Rather than providing for an 'effective' system, the lack of guidance will more likely add to the uncertainty and absence of clarity. The existence of a large generic pharmaceutical sector in India and their supply of low cost generics have proven to be of great assistance to countries, in particular LDCs. Perhaps this track record will spur countries without an adequate pharmaceutical sector to seek assistance in India.

C. EC

Patent law is a national prerogative within the EC. Notwithstanding this, the EC is required to ensure that national legal systems do not bring about the distortion of competition between the common market Members and reserves the right to make appropriate rules with the unanimous consent of the EC Council.[1042] Upon this basis and the representative role the EC plays for its Member countries in the WTO the EC Commission decided to draft a regulation that would regulate and harmonise the implementation of the Article 31*bis* system into the domestic legal systems of all EC Members.[1043]

On the 17th of May 2006 the EC Regulation No. 816/2006 on 'compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems' was adopted (the 'EC Regulation').[1044] Being a regulation applies directly and overrides EC Member law.

The EC Regulation represents an uneasy balance between the facilitation of the Article 31*bis* exceptions and the protection of patent rights. The unease with the exception to Article 31(f) is evident in the introduction and solidification of comprehensive safeguard measures. In doing so the EC Regulation keeps close affinity to the terminology used in Article 31*bis*. Despite the adoption of definitions and concepts, the EC Regulation does not make reference to the Chairman's Statement.[1045] Notwithstanding this, the EC centres the regulation around the good faith use of the system.

1041 Compare India in the TRIPS Council Minutes (15.09.2005) IP/C/M/48 p. 26.

1042 The EC justified its intervention on Arts 95 (providing for the approximation of laws) and 133 (creation of a common commercial policy). Cf. EC Commission Proposal for a Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems COM(2004)737 (29.10.2004) ('EC Proposal') 5-6, *Hilf*, 6 EJIL 2 (1995) p. 245.

1043 The use of the regulation as a tool to implement the system was chosen to expedite the implementation of the system. Had the EC Members have been required to transpose a directive, the system would have required far longer to become operational. Cf. *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 105.

1044 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation').

1045 *Cornides*, 10 JWILP 1 (2007) p. 71.

The EC Regulation responded to criticisms[1046] of its proposal presented in 2004[1047] and adopted a system that more aptly reflects the spirit and intention of Article 31bis and the Public Health Declaration. To this extent the eligible beneficiary countries were not limited to WTO Member States.[1048] EC Member States may implement additional requirements for the granting of a license however these additional requirements may not place unnecessary costs or burdens of the license applicant.[1049] Unlike the Canadian approach, the EC Regulation permits the prior negotiation requirement to be waived in instances of extreme urgency and public non-commercial use.[1050] In other instances the negotiation period is limited to 30 days. The distinction between licenses granted for extreme urgency or public non-commercial use ground and other licenses is also relevant to the calculation of the remuneration. In the former instances the remuneration is limited to 4% of the total price paid.[1051] The EC Regulation also adopts a system that is better able to react to every-day changes. Hence, the extension of a license on the grounds that the amount permitted under the license is no longer sufficient is permitted under the EC rules.[1052] Absent from the EC Regulation is an obligation to question or review the necessity or authenticity of the importing country's request.[1053] Further practical provisions include the 'compulsory licensing' of supplementary protection certifi-

1046 *t'Hoen*, (2005).

1047 EC Commission Proposal for a Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems COM(2004)737 (29.10.2004) ('EC Proposal').

1048 In terms of Art 4(a and c) of the EC Regulation any LCD and low income country (with a gross national product per capita of US$ 745 and included in the OECD Development Assistance Committee's list) may partake in the EC system. Art 5 thereof sets out the procedures required in order for such countries to participate. Excluded from the EC Regulation is the obligation that the prior negotiations be conducted on 'reasonable commercial terms'. Compare *Cornides*, 10 JWILP 1 (2007) p. 72.

1049 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 6(4).

1050 The EC Proposal did not contain a waiver. Instead it merely permitted a shorter negotiation period for extreme urgencies.

1051 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 10(9). The conditions for determining the amount of remuneration appears to permit license fees in excess of 4% for licenses not granted within the scope of government use or extreme urgencies. Recital 15 states further that the 4% should be used as a 'reference point' when deliberating adequate remuneration, i.e. also during the prior negotiation. Compare *Cornides*, 10 JWILP 1 (2007) p. 72.

1052 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 16(4). The simplified extension procedure only relates to the amount and only to a maximum of 25% more than was initially requested.

1053 This may however occur in an indirect manner. Art 10(2) limits the amount necessary to the importing country's needs – not its request. Accordingly, it is possible that a granting authority could question whether the needs are indeed being fulfilled.

cates. This ensures that licenses are not hindered by the supplementary rights afforded to certain pharmaceutical patent holders. A further practical measure is that the licensee 'may avail' himself to the European safety and efficacy procedures.[1054] The option to use this system may be of significant assistance where the importing state has insufficient means to do so itself. In this vein, the EC Regulation also permits license holder to circumvent certain EC regulations concerning the production and sale of pharmaceuticals within the EC (e.g. proof of pre-clinical trials).[1055] To the extent that the producer can demonstrate that his product is a generic of a pharmaceutical already subjected to clinical trials and tests and authorised for marketing, the producer will be able to avail himself to the data presented by the original producer. Accordingly, the EC Regulation implicitly extends the compulsory license to undisclosed information protected under Article 39 of the TRIPS Agreement.[1056]

The EC Regulation is however a more restrictive system than that permitted by Article 31*bis*.[1057] In terms of the application requirements for a license, the applicant must provide a specific request from the government of the needy country or its representatives (this including NGOs and international UN or health bodies). Accordingly, private requests from the needy country will not be able to benefit under the EC system. The EC system is also limited to pharmaceuticals for human treatment.[1058] This restriction is not required by Article 31*bis*. Further, a license may not be granted for an unlimited period.

The Commission was unwilling to create a process whereby it would eliminate the patent holder from the license process. In this regard, the requirement of prior negotiations was expressly dealt with and, where deemed unnecessary, the EC Regulation obliges the licensing authority to notify the patent holder of a license application for the relevant patent and grant the patent holder the opportunity to make a comment. Additional safeguards for the patent holders' rights are evident in the form of a comprehensive oversight system by the relevant customs authorities. The EC Regulation establishes a detailed procedure for dealing with diverted licensed products. Not only are the customs authorities required to suspend or detain products, they are also obliged to provide verify the source, its purpose and provide opportuni-

1054 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 18.

1055 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 18(2).

1056 Cf. *Cornides*, 10 JWILP 1 (2007) p. 72.

1057 The EC Regulation bases this strict approach on a desire to 'create a secure legal framework and discourage litigation'. Cf. EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation' recital 6.

1058 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 2(1).

ties for the interested parties to provide information in regard to the shipment.[1059] The EC Regulation also permits the granting authority to oblige the license holder to maintain records and books that will verify the shipment process and prove that the products have arrived in the importing country.[1060] These recordkeeping requirements would be aimed at ensuring the license conditions are fulfilled.

Although these and other provisions regulate issues not expressly dealt with in Article 31*bis* they merely provide additional structure to the somewhat abstract system set out in Article 31*bis*.

The EC Regulation states that the termination of the license may be ordered where the license conditions have not been met. In the EC Proposal the termination was qualified and only required when the circumstances that led to the license grant are 'unlikely to recur'. The removal of this element of discretion indicates a departure from the Article 31(g) of the TRIPS Agreement and less protection for the license holder. This omission is an erosion of the license holder's safeguards and confirmation that the EC has adopted a strict system of ensuring that the licensed products are not diverted. Further safeguards are implemented by the granting authority. In this regard the authority must ensure that the amount stated in the importing country's request is not duplicated in other EC Member States. This control mechanism is coordinated in conjunction with the EC Commission.

The EC Regulation lays particular emphasis on ensuring that the license is used for the purposes intended in Article 31*bis*. This is no more evident in the sentence '[t]he license shall be strictly limited to all acts necessary'.[1061] This safeguard is directed not only at the product but also at the quantity, manufacture, distribution and destination. Although these requirements flow from Article 31*bis*, they give the impression that no latitude will be tolerated. To this extent the Dutch system may be required to apply its Article 31*bis* system in a more restrictive manner.

As the EC Regulation serves to establish 'a procedure for the grant of compulsory licenses' in relation to Article 31*bis*, all EC Member States will be obliged to grant such licenses in accordance with the EC Regulation. The effect is therefore that the market for producers of pharmaceutical products in accordance with Article 31*bis* has extended to the entire EC.

1059 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 14.

1060 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 10(8).

1061 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 10(4).

F. Related measures taken to reflect the Public Health Declaration

The reaction to the Public Health Declaration and the subsequent TRIPS decisions has been multifarious. National governments have taken steps to alter their domestic policies and legislation, countries interacting with one another have reflected the policies of the Public Health Declaration either expressly or tacitly and international bodies have recognised the contents in one way or the other. A brief sampling of the measures taken is dealt with below.

I. International and multilateral policies and measures

International bodies such as the WHO Assembly and the UN Commission on Human Rights have been vocal on propagating the use of the TRIPS flexibilities.[1062] In the May of 2004 the WHO Assembly, whilst taking into account the Public Health Declaration and the Decision, urged countries as 'a matter of high priority':

> 'to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights;
>
> …
>
> to encourage that bilateral trade agreements take into account the flexibilities contained in the WTO TRIPS Agreement and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health'.[1063]

International bodies have also taken the view that the Public Health Declaration has clarified the use of compulsory licenses and that Member States can take compulsory license measures without fear of threats or reprisals from industry or foreign governments.[1064]

II. Bilateral policies and measures

The move towards more comprehensive bilateral trade relationships has resulted in the negotiating parties often including obligations on intellectual property rights. This has especially been evident in bilateral free trade agreements involving the

1062 WHO World Health Assembly Resolution 'Global Health-sector Strategy for HIV/AIDS' (28.05.2003) WHA56.30 at 2, UNCHR Res 2004/26 'Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria' (16.04.2004) UN Doc E/CN.4/2004/L.11/Add.3 p. 58.

1063 WHO World Health Assembly 'Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS' (22.04.2004) WHA57.14 p. 3-4.

1064 *WHO/WTO*, WTO Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat (WTO Secretariat Geneva 2002) p. 16.

US.[1065] The US has progressively sought to negotiate commitments from the other parties that exceed the obligations found in the TRIPS Agreement.[1066] These so-called 'TRIPS-plus' obligations were criticised as a tactic by the US to achieve its goal of higher intellectual property protection through direct pressure.[1067] Critics, including the UN special human rights Rapporteur Paul Hunt, warned that the conclusion of such TRIPS-plus agreements would 'water-down internationally agree health safeguards'.[1068] In some cases activists campaigning for access to health felt that the TRIPS-plus FTAs could dissolve current HIV/AIDS medication programmes.[1069] The opposition to the TRIPS-plus commitments reached such a level that some countries negotiating FTAs with developed countries have suspended or refused to conclude such trade agreements containing intellectual property obligations in excess of the TRIPS Agreement.[1070] To allay these concerns, the US has agreed to enter into a 'side letter' or 'understanding' with the relevant FTA partner wherein the parties recognise their commitment to the Public Health Declaration and the Article 31*bis* provisions.[1071] The agreements note that the FTA chapter on intellectual property rights 'do not affect a Party's ability to take necessary measures to protect public health by promoting access to medicines for all'.[1072] Further, the FTAs expressly state that they will not prevent a party to the FTA to make effective utilisation of the Decision.[1073] The supplementary agreements do not however mean that the FTA intellectual property provisions are subservient to the provisions and poli-

1065 Compare *Correa*, GRAIN (2004) p. 3-9.

1066 For example the application of the utility requirement as addressed in the US-Australian FTA. Cf. *Straus*, TRIPS, TRIPS-plus oder TRIPS-minus – Zur Zukunft des internationalen Schutzes des Geistigen Eigentums in: *Ohly et al* (eds) Perspektiven des Geistigen Eigentums und Wettbewerbsrechts (CH Beck Munich 2005) p. 206-207.

1067 ICTSD 'IP Standards in US-Peru FTA to Affect Talks with Columbia and Ecuador?' *Bridges Weekly Trade News Digest* (25.01.2006) p. 4.

1068 ICTSD 'Concerns Raised Over Access to Medicines Under Trade Treaties' *Bridges Weekly Trade News Digest* (14.07.2004) p. 4.

1069 Human Rights Watch, (2002).

1070 For example South Africa who refused incorporate TRIPS-plus obligations in a FTA with the EFTA. A group of minister representing 10 South American countries issued a joint declaration in which they committed themselves to avoid TRIPS-plus commitments in bilateral and regional trade agreements. They were Argentina, Bolivia, Brazil, Chile Columbia, Ecuador, Paraguay, Peru, Uruguay and Venezuela. Cf. *Khor*, South American Ministers Vow to Protect Access to Medicines IRC Americas Program Report (15.06.2005).

1071 The US has concluded 7 FTA s since 2002; those with Singapore and Australia do not contain any references to the Public Health Declaration. The remaining 5 do; either as a side letter or understanding or references are made within the body of the FTA. They are Bahrain, Chile, the CAFTA states (Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras and Nicaragua), Morocco and the Oman. The side letters and understanding are almost identical in content. Only the US/Chile FTA refers to the Public Health Declaration in the preamble of the chapter on intellectual property rights. This FTA was singed in 2003 and predates the Decision. Compare *Roffe*, 8 Bridges 7 (2004) p. 17-18.

1072 CAFTA Understanding Regarding Certain Public Health Measures (05.08.2004).

1073 The US/Chile FTA also expressly permits Bolar-type exceptions. Cf. *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 444-445.

cies of the Public Health Declaration and Article 31*bis*. The FTAs instead contains limits that restrict the application of the TRIPS Agreement and the Public Health Declaration.[1074] As an example, the title of the US/central American FTA understanding on public health clearly states that it only applies to 'certain public health measures'.[1075] Further, the FTAs refer to the Decision/Article 31*bis* and the Chairman's Statement as being 'the TRIPS/health solution'.[1076] The US's desire to afford the Chairman's Statement as being an integral part of the Decision is evident in its FTAs. In addition to the specific references to the Public Health Declaration in supplementary agreements, the US has also sought to reduce the flexibilities permitted in the TRIPS Agreement. To this extent the US has sought, *inter alia*, better/TRIPS-plus protection for undisclosed data,[1077] fewer patentability exclusions, patent protection for new uses of known patents, patent term extensions, the exclusion of parallel imports and limited grounds for compulsory license.[1078] Commenting on the US's use of these provisions, *Abbott* stated that:

> 'the provisions relating to patents and regulatory approvals with respect to medicines … are intended to restrict the flexibilities inherent in the TRIPs Agreement, Doha Declaration and Decision on Implementation of Paragraph 6… They appear designed to negate the effective use of compulsory licensing by blocking the marketing of third party medicines during the term of patents'.[1079]

Not all states in negotiations for a FTA with the US have succumbed to the pressure and appeal of the FTA. In some cases they have stalled the negotiations, as is the case with SACU. SACU officials doubted whether the high-level US intellectual property standards they were 'appropriate' for developing countries.[1080]

1074 *Abbott*, 99 AJIL 2 (2005) p. 352.

1075 The USTR Special 301 Report notes that although the US supports the flexible interpretation of the TRIPS Agreement they should only be used to 'address *serious* public health problems' (emphasis added). Cf. *USTR*, Special 301 Report (2006) p. 10.

1076 Compare *USTR*, Special 301 Report (2006) p. 11.

1077 Not all data exclusivity provisions in the US FTAs are subject to public health understandings. Cf. ICTSD 'IP Standards in US-Peru FTA to Affect Talks with Columbia and Ecuador?' *Bridges Weekly Trade News Digest* (25.01.2006) 5.

1078 *Straus*, TRIPS, TRIPS-plus oder TRIPS-minus – Zur Zukunft des internationalen Schutzes des Geistigen Eigentums in: *Ohly et al* (eds) Perspektiven des Geistigen Eigentums und Wettbewerbsrechts (CH Beck Munich 2005) p. 206, *Abbott*, 99 AJIL 2 (2005) p. 350.

1079 *Abbott*, Quaker Paper 14 (2004) p. 12.

1080 ICTSD 'Southern African Countries Reject 'TRIPS-Plus' Demands in FTA Negotiation' *Bridges Weekly Trade News Digest* (09.03.2005) 5. *Abbott* notes that there is growing concern about the US's approach to including intellectual property rights in bilateral FTAs. Cf. *Abbott*, 99 AJIL 2 (2005) p. 349. *Abbott* also remarks that whilst the US FTA standards reflect US legal standards, they fail to include the safeguard provisions found in US law. Cf. *Abbott*, UNCTAD-ICTSD Issue 12 (2005) p. 20. The EC has also called upon the US to refrain from impinging on the Public Health Declaration's provisions in bilateral agreements. Cf. -- 'EU criticizes USA TRIPS+ drive' *E-Drug* (15.07.2004).

III. National policies and measures

The first developed Member State to adopted measures that reflect the Public Health Declaration was Belgium. In 2004 the Belgium legislature introduced for the first time a compulsory license to remedy possible access problems in the field of health care. The public health compulsory license made express reference to the TRIPS Agreement and the Public Health Declaration.[1081] Its scope reflects a liberal reading of the TRIPS Agreement and makes use of the flexibilities found therein. The compulsory license does not however extend to compulsory licenses for export to countries without their own production facilities.

An example of the consequences the TRIPS Agreement and the Public Health Declaration has had on developing countries can be seen in the case of Ghana. With the expiry of the transitional periods in the TRIPS Agreement Ghana brought its patent system in line with the TRIPS standards.[1082] Simultaneously, Ghana took advantage of the flexibilities mentioned in the Public Health Declaration to ensure the patent system would not ultimately stand in the way of its public health measures. Measures legislated include:

- The parallel importation of pharmaceuticals put onto any market with the patent holder's consent (i.e. international exhaustion system)[1083]
- Compulsory licenses to remedy abusive patent practices and excessive prices[1084]
- Compulsory licenses for insufficient local working of the patent[1085]
- Administrative guidelines for determining 'adequate remuneration' for compulsory licensed patents[1086] and
- Shortened the compulsory license process by entitling licenses to be granted by ministerial authorisation.[1087]

Other Member States have taken more direct measures to gain access to compulsory licensed pharmaceuticals. Zimbabwe, for example, declared a state of emergency allowing the state or its authorised agent to domestically 'make or use any patent … used in the treatment of persons suffering from HIV/AIDS'.[1088] The state of emergency further permits the importation of any generic drug for these pur-

1081 *Van Overwalle*, 37 IIC 8 (2006) p. 908-909.
1082 Ghanaian Patent amendment act no. 657 of 2003. Ghana, for example, did away with the powers to temporarily exclude the patenting of pharmaceuticals (formally sec 8) and licenses of right (formally sec 54).
1083 *Cohen et al*, 1 Globalization and Health 17 (2005) p. 5-6.
1084 *Cohen et al*, 1 Globalization and Health 17 (2005) p. 5.
1085 Adequate importation will also fulfil the local working requirement. Cf. *Cohen et al*, 1 Globalization and Health 17 (2005) p. 5.
1086 *Cohen et al*, 1 Globalization and Health 17 (2005) p. 4.
1087 *Cohen et al*, 1 Globalization and Health 17 (2005) p. 5.
1088 Declaration of Period of Emergency (HIV/AIDS) Notice 2002 (24.05.2002) sec 2(a). The emergency was declared for a period of 6 months.

poses.[1089] The approach taken by Zimbabwe was applauded as the first move to apply the Public Health Declaration.[1090] The view that Zimbabwe's actions derive from concessions made in the Public Health Declaration indicates the continued lack of understanding for the TRIPS Agreement. Although Zimbabwe's actions may have been motivated by the swell in public and political support flowing from the Public Health Declaration for such action, the provisions of the TRIPS Agreement never prevented Zimbabwe or any other Member State from taking such action.

Zambia,[1091] Mozambique,[1092] Namibia,[1093] Indonesia,[1094] Taiwan[1095] and Malaysia[1096] have also issued compulsory licenses with express reference to the Public Health Declaration or for the treatment of epidemics referred to in the Public Health Declaration. Thailand is another country making use of compulsory licenses to provide additional access to medications. The Thai policy of 'universal access to medicines' has however extended beyond medication to treat HIV/AIDS and has encompassed medication to treat heart diseases.[1097]

Brazil, a proponent of pre-empting intellectual property rights with health policies, has also acted on the swell in international support for the use of compulsory licenses to make use of the compulsory license system, either directly[1098] through a grant or indirectly as a negotiating ploy, to reduce pharmaceutical prices.[1099] Like the Zimbabwean measures, the entitlement to carry out such action does not flow from the Public Health Declaration; it is an entitlement contained in the TRIPS Agree-ment.

The adoption of a modern competition law system in South Africa has provided a platform for individuals to challenge the practices of certain pharmaceutical companies. To this effect the South African competition officials have heard complaints concerning excessive pricing, refusal to license and the lack of access to technology

1089 Declaration of Period of Emergency (HIV/AIDS) Notice 2002 (24.05.2002) sec 2(b).

1090 ICTSD 'Zimbabwe becomes the First Country to Invoke Declaration on TRIPS and Public Health' *Bridges Weekly Trade News Digest* (12.06.2002) 15. At present the WHO recognises a further 45 countries as suffering from health crises or emergencies. Cf. *WHO*, (2006).

1091 Zambian Compulsory License No. CL 01/2004 (21.09.2004).

1092 Mozambican Compulsory License 01/mic/04 (05.04.2004).

1093 -- 'Namibia uses TRIPS to make anti-AIDS drugs' *TRALAC* (24.06.2003).

1094 Indonesian Decree of the President Regarding the Exploitation of Patent by the Government on Anti-Retrovirals 83/2004 (05.10.2004)

1095 ICTSD 'Taiwan Issues Compulsory License For Tamiflu' *Bridges Weekly Trade News Digest* (30.11.2005) p. 11-12.

1096 Malaysian Authorisation for the Exploitation of Patented Invention (29.10.2003).

1097 Thai authorities have based their compulsory license for Clopidogrel on cost grounds. Their calculation is that the use of generic versions would enable the Thai healthcare system to afford 10 times the amount of medication. *Ministry of Health (Thailand)*, Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand (Sangsue Thailand 2007) p. 15.

1098 *Stewart*, WSJ (2007), *Ministry of Health (Brazil)*, Efavirenz (2007).

1099 *Abbott*, 7 Bridges 2 (2003) p. 22, *CIPR*, (2002) p. 43,

essential to pharmaceutical production.[1100] The use of the competition system, as done in the US and the EU, is a TRIPS-conform and a TRIPS-advocated process; it is not a procedure that stems from the Public Health Declaration.

The spread of intellectual property protection that has occurred with the expiry of the transitional periods under the TRIPS Agreement has reduced the number of states not required to enforce or implement pharmaceutical patents. This has prompted leading Indian generic pharmaceutical producers to consider shifting their operations to Bangladesh where they would be able to take advantage of its status as a LDC and continue to produce generic versions of pharmaceuticals patented in non-LDC countries.[1101]

G. Conclusion

In addition to Switzerland a number of other countries have briefly mentioned that they are considering implementing the Article 31*bis* system into domestic law.[1102] None of these countries have identical systems; whereas some are similar others differ considerably. This mixture of rules and procedures will make comparisons between the manufacturers seated in the various countries extremely difficult. The lack of universal transparency and the 'hidden' potential to subvert or delay the process further hinders the systems use. The lack of an active demand for the pharmaceuticals from the needy country will not encourage manufacturers to actively enter the market, thus preventing competition and knowledge of how the systems will function. The national implementation of the Article 31*bis* system has thus further complicated an already formalistic system and has as a result further distanced itself from the original goals of providing an expeditious solution to the problems caused by insufficient domestic pharmaceutical production capacities.

Although the systems are themselves a hurdle to solving the paragraph 6 dilemma and will most likely deter their use, the success of the system can only truly be determined once it is used. The unwillingness to use the system infers that either the current public health problems are not sufficiently serious or the existing avenues for acquiring assistance are adequate for the needy countries situations. [1103]

1100 *Baker,* Process and Issues for Improving Access to Medicines: Willingness and Ability to use TRIPS Flexibilities in Non-Procuring Countries (Fretwells London 2004) p. 45-46.

1101 *Matthews*, 7 JIEL 1 (2004) p. 106.

1102 For example China, France, Indonesia and Korea.

1103 Roche has licensed the sanquinavir patents and know-how to 3 African generic pharmaceutical producers. This measure is part of Roche's policy of not filing or enforcing its patents in LDCs or sub-Saharan Africa. Cf. -- 'Roche gibt Know-how für Aids-Generika frei' *NZZ* (23.09.2006).

Chapter 9 Definitive consequences of the Public Health Declaration

The policy thoughts contained in the Public Health Declaration have not amounted to much in a formal or objective sense. Despite the fact that the TRIPS Agreement has been amended to include an exception to the Article 31(f and h) problem expressed in paragraph 6 of the Public Health Declaration and the fact that the transitional periods for LDCs have been extended for pharmaceutical products there has been no further tangible incorporation of the Public Health Declaration's policy thoughts into the international intellectual property system. Why is this so?

To answer this question a distinction need be made between the changes in the international legal forum and those in the domestic legal system. On the international level the TRIPS Agreement – as discussed above – objectively required little changes. The TRIPS Agreement is a well balanced and flexible treaty that permits Member States to structure the manner in which they seek to implement the TRIPS provisions. The problem many Member States had with the TRIPS Agreement was their lack of confidence to interpret the agreement in ways that – although correct – were contrary to the views held by other Member States. In other words, the problem lay not in the TRIPS Agreement but in its application. The result is that the Public Health Declaration helped to redress the values that underlined the interpretation of the TRIPS Agreement; no real or substantive amendments were required to the core rules underpinning the protection of patent rights.[1104]

On a domestic level there was also little legislative action that flowed directly from the Public Health Declaration.[1105] Aside from certain Member States legislating laws to facilitate the Article 31*bis* system, there have been few attempts to amend domestic laws to take advantage of the flexibilities the TRIPS Agreement permits and the Public Health Declaration confirms. The absence of any significant statutory reaction to the Public Health Declaration further reinforces the position that the policy thoughts in the Public Health Declaration were not significant enough to necessitate legislative amendments.

The lack of formal consequences flowing from the Public Health Declaration does not mean that the Public Health Declaration has been without consequences. Consequences, subjective in nature, flowed *en masse* from the Public Health Decla-

1104 The para 6 dilemma identified in the Public Health Declaration represents the only real problem that required the TRIPS Agreement obligations to be reconsidered. The extension of the transitional periods for LDCs reflects a concession that will in a practical sense have effect on the relevant Member States.

1105 The much publicised court action in South Africa concerning the introduction of a compulsory license system permitting international exhaustion system for pharmaceuticals in certain circumstances was settled prior to the Public Health Declaration.

ration. At an international level Member States have agreed that the TRIPS Agreement permits diverging yet valid interpretations. This so-called flexibility has been anchored in the Public Health Declaration and forms the central achievement in the Public Health Declaration. This policy of permitting and accepting flexible interpretations has spread beyond the scope of the TRIPS Agreement. Analogies have been made to other WTO Agreements and to future developments in the WIPO. The Public Health Declaration has also had an effect on free trade agreements and their negotiations. FTAs that call for additional intellectual property protection – 'TRIPS-plus' protection – are often accompanied by 'side-letters' that reaffirm that the provisions agreed to in the FTA do not run contrary to the Public Health Declaration. In some FTA negotiations a final agreement seems unlikely because of calls for TRIPS-plus provisions. These consequences derive primarily out of the better understanding Member States have acquired of the TRIPS Agreement through the Public Health Declaration and their negotiations. This increased knowledge has boosted the confidence of the Member States seeking more flexibility and has resulted in them being more self-assured in their views and more assertive in negotiations in the WTO.

The course that the Public Health Declaration took created well-defined opponents. The access to healthcare brought developing Member States together and helped to form a united front against the positions held by the developed Member States. As a unit the developing Member States were able to bundle resources and influence to bring about results better suited to themselves. Holding the banner of better health the developing Member States were able to take the moral high ground against the perceived profit-driven developed Member States. The added knowledge, confidence and assertiveness have influenced most WTO negotiations that followed and, arguably, that will follow.

In addition to the added weight the Public Health Declaration has given to public interest concerns in negotiating and implementing treaties there have also been calls for this to be better recognised in dispute proceedings. This was one of the indirect consequences developing Member States had hoped would flow from the Public Health Declaration. The necessity of this was debatable. Although the WTO *Canada –Pharmaceuticals* case required exceptions to be interpreted restrictively, the DSB has largely respected public interest policies when evaluating measures taken under WTO law. Nevertheless, the uncertainty spurred developing Member States to reinforce already existing and accepted interpretative tools used by the DSB. Despite the fact that neither DSB panels nor the Appellate Body will undertake any paradigm shift purely because of the contents of the Public Health Declaration, it will nevertheless assist the DSB in interpreting the TRIPS Agreement in the future. This, together with the display of unity in the Public Health Declaration will likely reduce the threat of challenges under the DSB. In this sense, the Public Health Declaration has affirmed the right to use the TRIPS flexibilities in full; meaning that different views on the interpretation of a flexible provision need not automatically mean that one of the parties is infringing the TRIPS Agreement. Hence, the threat of chal-

lenges has been minimised. This has the effect of making the TRIPS Agreement less oppressive for developing countries and more amenable to peculiar domestic factors.

Matthews notes that '[o]n the face of it, the TRIPS Agreement deals adequately with the issue of patents, access to essential medicines and the public health crises'.[1106] This dissertation extends *Matthews*' comment by confirming that, subject to the abovementioned exceptions, the TRIPS Agreement is not only superficially adequate but also substantively capable of coping with current concerns; the 'problem' lies in the way in which it is interpreted and implemented.[1107] This therefore confirms the US's statement that 'the TRIPS Agreement has struck a proper balance between offering incentives for innovation and ensuring that there is access to needed medicines'.[1108]

The conclusion of the Public Health Declaration, the extensions given to the implementation of certain TRIPS obligations and the Article 31*bis* system have removed the real and perceived legal barriers that stood in the way of access to medicines have been removed. Whether or not the Member States calling for the changes are willing to act on their demands remains to be seen. Current circumstances indicate that for the vast majority of the countries, their pleas for assistance were merely rhetoric.

1106 *Matthews*, 7 JIEL 1 (2004) p. 76.

1107 *Anderson and Wagner*, 9 (JIEL) 3 (2006) p. 708.

1108 US in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 at p. 36.

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Annex I: Public Health Declaration

WORLD TRADE ORGANIZATION

WT/MIN(01)/DEC/2
20 November 2001

(01-5860)

MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 - 14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the

TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Annex II: 30 August 2003 Decision

WORLD TRADE ORGANIZATION

WT/L/540
2 September 2003

(03-4582)

IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Decision of 30 August 2003*

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

* *Secretariat note for information purposes only and without prejudice to Members' legal rights and obligations*: This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

1. For the purposes of this Decision:

   (a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included[1109];

   (b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification[1110] to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members[1111] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

   (c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to

1109 This subparagraph is without prejudice to subparagraph 1(b).

1110 It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

1111 Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s)[1112] has made a notification2 to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed[1113];

(ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision[1114];

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products

1112 Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

1113 The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

1114 This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement

themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website[1115] the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and

- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify[1116] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[1117] The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on

1115 The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

1116 It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

1117 The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the

TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

ANNEX

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

Annex III: The Article 31*bis* Amendment

WORLD TRADE ORGANIZATION

WT/L/641
8 December 2005

(05-5842)

AMENDMENT OF THE TRIPS AGREEMENT

Decision of 6 December 2005

The General Council;

Having regard to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in the proposed amendment of the TRIPS Agreement, the importance of a rapid response to those needs consistent with the provisions of the proposed amendment of the TRIPS Agreement;

Recalling paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;

Having considered the proposal to amend the TRIPS Agreement submitted by the Council for TRIPS (IP/C/41);

Noting the consensus to submit this proposed amendment to the Members for acceptance;

Decides as follows:

1. The Protocol amending the TRIPS Agreement attached to this Decision is hereby adopted and submitted to the Members for acceptance.

2. The Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.

3. The Protocol shall take effect in accordance with the provisions of paragraph 3 of Article X of the WTO Agreement.

ATTACHMENT

PROTOCOL AMENDING THE TRIPS AGREEMENT

Members of the World Trade Organization;

Having regard to the Decision of the General Council in document WT/L/641, adopted pursuant to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Hereby agree as follows:

1. The Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") shall, upon the entry into force of the Protocol pursuant to paragraph 4, be amended as set out in the Annex to this Protocol, by inserting Article 31*bis* after Article 31 and by inserting the Annex to the TRIPS Agreement after Article 73.

2. Reservations may not be entered in respect of any of the provisions of this Protocol without the consent of the other Members.

3. This Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.

4. This Protocol shall enter into force in accordance with paragraph 3 of Article X of the WTO Agreement.

5. This Protocol shall be deposited with the Director-General of the World Trade Organization who shall promptly furnish to each Member a certified copy thereof and a notification of each acceptance thereof pursuant to paragraph 3.

6. This Protocol shall be registered in accordance with the provisions of Article 102 of the Charter of the United Nations.

Done at Geneva this sixth day of December two thousand and five, in a single copy in the English, French and Spanish languages, each text being authentic.

ANNEX TO THE PROTOCOL AMENDING THE TRIPS AGREEMENT

Article 31bis

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f).

ANNEX TO THE TRIPS AGREEMENT

1. For the purposes of Article 31bis and this Annex:

   (a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included[1118];

   (b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification[1119] to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ("system") as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members[1120] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

   (c) "exporting Member" means a Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The terms referred to in paragraph 1 of Article 31bis are that:

   (a) the eligible importing Member(s)[1121] has made a notification2 to the Council for TRIPS, that:

1118 This subparagraph is without prejudice to subparagraph 1(b).

1119 It is understood that this notification does not need to be approved by a WTO body in order to use the system.

1120 Australia, Canada, the European Communities with, for the purposes of Article 31bis and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.

1121 Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 3 of Article 31bis on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

(i) specifies the names and expected quantities of the product(s) needed[1122];

(ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Articles 31 and 31bis of this Agreement and the provisions of this Annex[1123];

(b) the compulsory licence issued by the exporting Member under the system shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website[1124] the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and

- the distinguishing features of the product(s) referred to in indent (ii) above;

1122 The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

1123 This subparagraph is without prejudice to Article 66.1 of this Agreement.

1124 The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to the system.

(c) the exporting Member shall notify[1125] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[1126] The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

4. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under this Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

5. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31bis should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of this Agreement, including in conjunction with other relevant intergovernmental organizations.

6. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Mem-

1125 It is understood that this notification does not need to be approved by a WTO body in order to use the system

1126 The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

bers undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS.

7. The Council for TRIPS shall review annually the functioning of the system with a view to ensuring its effective operation and shall annually report on its operation to the General Council.

* * *

APPENDIX TO THE ANNEX TO THE TRIPS AGREEMENT

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

or

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

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Annex IV: Examples of royalty rates in compulsory licensing & related cases

Country	Case	Royalty rate/Remuneration
United States	Rocket engine patents (World War II era)	US$ 1 million - 0.01%
United States	Microsoft protocols	0.05-1%; maximum of 5% total for use of 100 protocols
Canada	Medicine exports under WTO waiver of Article 31(f)	0.02-4%
Indonesia	Certain HIV/AIDS drugs	0.5%
United States	AIDS test kit (infringement case)	1%
United States	Geostationary orbit technology for satellites	1%
Mozambique	Certain HIV/AIDS drugs	2%
Philippines	Cimetidine/Tagamet (ulcer drug)	2.5%
Philippines	Various medicines, licenses issued in 1980s	2.5%, with some variation; statute capped royalties on voluntary licences at 5% and compulsory licences at 3%
Zambia	Certain HIV/AIDS drugs	2.5%
Malaysia	Technology transfer agreements between Malaysian firms and foreign parties	Capped by statute at 3%
Japan	Cimetidine/Tagamet (ulcer drug) (infringement case)	3.5%
Canada	Medicines - more than 600 cases from 1969-1992	4% standard
Malaysia	Certain HIV/AIDS drugs	4%
United States	Eye-care related laser (infringement case)	5%
Singapore	Various medicines	5%
United States	Lathe	US$ 150 000 + 5% on each lathe
United States	Camouflage screens	17%
United States	Surface chemistry patent (infringement case)	40%
United Kingdom	Cimetidine/Tagamet (ulcer drug)	45%
United States	Aircraft patents (date: 1917)	US$ 200 per plane, total compensation capped at US$ 2 million

Table 1: Love, WHO Health Economics and Drugs TCM Series No. 18 (2005)