

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 license⁷¹⁴ 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 1994⁷¹⁶ 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 respiratory 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 to 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.