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.