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.

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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.

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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.

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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.

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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.

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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.

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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.

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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

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- 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-

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- 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.

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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.

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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.

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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.

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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.

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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).

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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.

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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).

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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.

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- 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'.

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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.

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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.

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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

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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).

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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.

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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.

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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.

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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

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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.

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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

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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.

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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.

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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.

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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.

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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.

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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

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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.

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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.

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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.

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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.

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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.

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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.

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- 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).

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- 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.

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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.

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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.

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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.

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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.

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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.

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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-

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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.

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