THE OSTENSIBLE 'FLEXIBILITIES' IN *TRIPS*: CAN ESSENTIAL PHARMACEUTICALS BE EXCLUDED FROM PATENTABILITY IN PUBLIC HEALTH CRISES?

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The requirement that a country sign up to the complete package of WTO agreements in order to join the organization has been problematic for developing countries, entailing institutional reforms which are arguably ill-suited to their needs; particularly those of the least developed members. The WTO has emphasised that the 'flexibilities' provided by the compulsory licensing provisions in TRIPS *allow developing countries to determine their own national health policies and access essential pharmaceuticals. While political attention currently focuses on compulsory licensing under* TRIPS, *this article examines the art 27(2) of* TRIPS, *which allows members to exclude inventions from patentability if certain criteria are met. The article argues the approach of future dispute settlement panels and the Appellate Body will be shaped by jurisprudence on both* GATT*'s exception provision and the* European Patent Convention. *This jurisprudence shows that a very high threshold must be met in order to invoke unilateral trade restrictions or exclude an invention from patentability. This means it is likely that developing countries would have significant difficulty invoking art 27(2) of* TRIPS *to exclude certain pharmaceuticals from patentability in order to enable affordable access for those affected by diseases such as HIV-AIDS.*

I INTRODUCTION

The first substantive part of this article sets the *Agreement on Trade-Related Aspects of Intellectual Property Rights* ('*TRIPS*')[1] in context, describing the compromise that was made to include *TRIPS* in the agreement establishing the World Trade Organization ('WTO'). Part III outlines the jurisprudence on the *General Agreement on Tariffs and Trade* ('*GATT*')'s exception provision, art XX, and the parallel provision in the *General Agreement on Trade in Services*

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1 *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1869 UNTS 299, 33 ILM 1197 (entered into force 1 January 1995) ('*Marrakesh Agreement*'), *Annex 1C, Trade-Related Aspects of Intellectual Property Rights* ('*TRIPS*').

('*GATS*'), in order to set a benchmark for evaluating art 27(2) of *TRIPS*.[2] This part then analyses the concepts of 'morality' and '*ordre public*' using European patent law. Part IV applies this jurisprudence to *TRIPS*' art 27(2) in the context of pharmaceuticals, and considers whether developing countries will be able to successfully invoke this provision to exclude essential pharmaceuticals from patentability provided they adhere to the precepts distilled from prior jurisprudence. Part V sets this analysis alongside the WTO's focus on *TRIPS*' art 31, and discusses the impediments that developing countries continue to experience despite *TRIPS*' ostensible 'flexibilities.'

II BACKGROUND

A *The* TRIPS *Agreement in Context*

TRIPS introduced minimum international standards for intellectual property protection[3] and formed part of the 'single undertaking' required of members in the *Marrakesh Agreement* establishing the WTO. *TRIPS*' stringent patent protection requirements was a victory for a coalition of United States industries that united to lobby for enhanced intellectual property protection that could be enforced via trade sanctions.[4] Framing other members' lack of intellectual property protection as a central issue for the US' trade negotiations,[5] US pharmaceutical industries played an agenda-setting role in the negotiations, and achieved the desired effect of consolidating their economic power and monopoly through the extension of intellectual property rights, securing the industrialised states' advantage in the industry.[6] *TRIPS* represents developing countries' cession of sovereign autonomy in the area of domestic regulation of intellectual property – a greater degree of cession than what was required from developed members such as the US who effectively internationalised their domestic legislative framework. Given that developing countries members' obligation to protect intellectual property arose as a result of WTO membership rather than domestic political conditions, *TRIPS*' economic impact on these countries has been described as 'especially severe'[7]

2 Ibid *Marrakesh Agreement, Annex 1A, General Agreement on Tariffs and Trade* ('*GATT*'); *Annexure 1B, General Agreement on Trade in Services* ('*GATS*').

3 Prior to *TRIPS*, international protection of intellectual property was governed by the World Intellectual Property organization ('WIPO'), established under the *Paris Convention for Protection of Industrial Property*, amendment open for signature 14 July 1967 (entered into force 26 April 1970) ('Paris Convention'). The Paris Convention allowed for a number of exceptions to strict patent protection, including compulsory licensing, at the discretion of signatory countries.

4 Dreyfuss argues that 'the notion that [developing countries] consented to the current Agreement is specious…those in need of markets for raw and manufactured products had little choice but to sign on to TRIPS, no matter how antithetical intellectual property law was to their needs': Rochelle Dreyfuss, 'TRIPS Round II: Should Users Strike Back?' (2004) 71 *University of Chicago Law Review* 21, 25.

5 Brook Baker, 'Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Para 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (2004) 14 *Indiana International and Comparative Law Review* 613, 619.

6 Ibid 617.

7 Dreyfuss, above n 4, 25.

both in terms of the cost of implementation, and the interference with the provision of public health care.[8] Developing countries affected by the HIV-AIDS pandemic have increasingly sought to preserve domestic regulatory powers in an attempt to handle public health concerns within the confines of *TRIPS*.[9]

B *TRIPS and Patenting*

1 *Relevant Provisions*

Articles 27 and 31 of *TRIPS* (which allow for exclusions from patentability and exceptions to rights conferred by patents) were the result of a trade-off between industrialised members (who claimed that developing countries' poor standard of intellectual property protection unfairly disadvantaged their trading interests) and developing members, who sought concessions in other areas of the Uruguay Round, such as textiles and agriculture.[10]

Subject to limited exceptions, *TRIPS* requires that patents be available for any invention (whether a product or a process),[11] in all areas of technology, based on the criteria of novelty, non-obviousness and usefulness. Patents must also be available without discrimination as to the place of invention, the field of technology, and whether products are produced domestically or imported.[12] The rationale for the broad applicability of patent protection is *TRIPS*' objective, *inter alia*, to 'reduce distortions and impediments to international trade ... recognizing

8 Gregory Shaffer, 'Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of *TRIPS* and Pharmaceutical Patent Protection' (2004) 7 *Journal of International Economic Law* 459, 462.

9 Judy Rein, 'International Governance Through Trade Agreements: Patent Protection for Essential Medicines' (2001) 21 *Northwestern Journal of International Law and Business* 37, 39. There is a large body of scholarship on the impact of *TRIPS* on developing countries' access to pharmaceuticals: see, eg, Duncan Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?' (2004) 7 *Journal of International Economic Law* 73; Daniel Gervais, 'Intellectual Property, Trade & Development: the State of Play' (2005) 74 *Fordham Law Review* 505; Bradly Condon and Tapen Sinha, 'Global Diseases, Global Patents and Differential Treatment in WTO Law: Criteria for Suspending Patent Obligations in Developing Countries' (2005) 26 *Northwestern Journal of International Law and Business* 1; Valeska Marques and Caitlin Sternberg, 'Brazil's AIDS Controversy: Antiretroviral Drugs, Breaking Patents, and Compulsory Licensing' (2005) 60 *Food & Drug Law Journal* 471; Maxwell Morgan, Medicines for the Developing World: Promoting Access and Innovation in the Post-TRIPS Environment (2006) 64 *University of Toronto Faculty Law Review* 45; Obijiofor Aginam, 'Between Life and Profit: Global Governance and the Trilogy of Human Rights, Public Health and Pharmaceutical Patents' (2006) 31 *North Carolina Journal of International Law and Commercial Regulation* 901; Michael Santoro, 'Human Rights and Human Needs: Diverse Moral Principles Justifying Third World Access to Affordable HIV/AIDS Drugs' (2006) 31 *North Carolina Journal of International Law and Commercial Regulation* 923; Anthony Valach, TRIPS: Protecting the Rights of Patent Holders and Addressing Public Health Issues in Developing Countries (2005) 4 *Chicago-Kent Journal of Intellectual Property* 156. See, eg, Bryan Mercurio, 'TRIPS, Patents, and Access to Lifesaving Drugs in the Developing World' (2004) 8 *Marquette Intellectual Property Law Review* 211 (2004); Maxwell Morgan, 'Medicines for the Developing World: Promoting Access and Innovation in the Post-TRIPS Environment' 64 *University of Toronto Faculty of Law Review* 45.

10 Michael Trebilcock and Robert Howse, *The Regulation of International Trade* (1999) chp 12, 349.

11 Prior to *TRIPS*, Indian law provided patents for processes used to make inventions, but not the inventions themselves, allowing a large generic pharmaceutical industry to develop.

12 *TRIPS* art 27(1).

... the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights.'[13]

Article 27(2) was a condition of developing countries' support for *TRIPS*,[14] and provides an optional, limited exception to the general principle of patent protection:

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

While art 27(2) provides circumstances in which a country can derogate from the requirements of *TRIPS* and refuse to grant a patent, art 31 allows a member to use the subject matter of a patent without the right holder's authorisation (thereby preventing a patent holder from exploiting the monopoly rights provided by patent protection), which is referred to as compulsory licensing.

Article 27(2) has yet to be definitively interpreted, and its strength is unknown until tested by a WTO dispute settlement panel.[15] What the language of the provision does tell us, however, is that issues of public health are couched in terms of exceptions to a general theme of promotion of innovation through the provision of rights-based commercial incentives, and are arguably read down by the core provisions of the Agreement.[16] Notwithstanding developing countries' opposition to the invocation of *GATT*'s exception provision,[17] seen as a threat to their sovereign right to determine their domestic environmental and other process-based production standards, it is argued that the developing countries will be the primary *demandeurs* of exclusions from patentability using art 27 of *TRIPS*.

13 *TRIPS* Preamble.

14 *TRIPS* art 27(3) also allows countries to exclude from patentability 'diagnostic therapeutic and surgical methods for the treatment of humans or animals' and 'plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes' but does require members to provide for protection of plant varieties either by patents or a sui generis system. However, not all biotechnological 'inventions' come within the ambit art 27(3) – some can only be excluded under art 27(2). Article 27(3) is subject to a mandated review which has not yet been completed: WTO, *TRIPS: Reviews, Article 27.3(b) and Related Issues* <http://www.wto.org/english/tratop_e/TRIPS_e/art27_3b_background_e.htm> at 23 April 2006.

15 Disputes under TRIPS are subject to the WTO dispute settlement process, as set out in the provisions of the *Marrakesh Agreement, Annexure 2, Dispute Settlement Understanding* ('Dispute Settlement Understanding'). At the time of writing, no disputes had occurred in relation to art 27(2): WTO, *Dispute Settlement: The Disputes - Index of Disputes Issues* <http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm#patents> at 23 April 2006.

16 Amit Gupta, 'Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?' (2004) 2 *Buffalo Intellectual Property Law Journal* 127, 129.

17 See, eg, United States – *Restrictions on Imports of Tuna*, WTO Doc DS21/R-39S/155 (1991) (Report of the Panel) ('*Tuna-Dolphin I*'); *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58/R, (1998) (Report of the Panel) ('*Shrimp-Turtle I*').

While *GATT* and *GATS* jurisprudence will be used in order to predict likely jurisprudence under *TRIPS* art 27(2), it should be noted at the outset that *GATT* and *GATS* regulate different facets of international trade to that regulated by *TRIPS*. *GATT* and *GATS* regulate trade in goods and services respectively, with a view to eliminating barriers to trade. Both agreements allow members the right to determine their own domestic laws and policies, as long as these laws and policies do not conflict with the provisions of the core agreement. Exceptions to *GATT* and *GATS* (domestic laws that conflict with non-discrimination principles) are allowable, in theory, provided that they do not constitute an arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade. *TRIPS*, on the other hand, regulates intellectual property protection by requiring all members to harmonize their legislation with the Agreement, in order to afford a high degree of protection for right holders.[18]

III INTERPRETING THE PROVISIONS

A *Principles of Interpretation*

The WTO's Appellate Body has made it clear that principles of public international law apply to *GATT*;[19] particularly as embodied in the *Vienna Convention on the Law of Treaties*, which the Appellate Body has used as a guide to interpretation.[20] It has been a practice of WTO law to consider the evolution of a text as one of the elements to understand its meaning, where the meaning is not entirely clear, as permitted by art 32 of the Vienna Convention.

The WTO compact as a whole is relevant in interpreting art 27(2).[21] Although *TRIPS* constitutes *lex specialis* for examining patenting issues within the WTO compact, the interpretation of *GATT*'s art XX and *GATS*' art XIV is likely to play a role in the interpretation of art 27(2), given the similar purpose of the provisions, which provide for exceptions from the applicability of the core agreement.[22] Notwithstanding that the WTO dispute settlement process has no

18 It is notable that *TRIPS*' protection of intellectual property by monopoly rights is antithetical to general principles of competition and liberalized trade, because a patent gives the owner a monopoly right to exploit the invention.

19 *Dispute Settlement Understanding* art 3.2.

20 *United States - Standards for Reformulated and Conventional Gasoline*, WTO Doc WT/DS2/AB/R (1996) (Report of the Appellate Body) ('*Gasoline*'). The *Vienna Convention on the Law of Treaties* requires that 'a treaty should be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose': *Vienna Convention on the Law of Treaties*, open for signature 23 May 1969, 1155 UNTS 331, art 31(1) (entered into force on 27 January 1980) (the '*Vienna Convention*').

21 Article 31(2)(a) of the *Vienna Convention* further provides that the context for interpreting the treaty includes 'any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty.'

22 See *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc WT/DS50 (1997) [7.19] (Report of the Appellate Body) in which the panel noted that *TRIPS* is 'an integral part of the WTO system, which itself builds on the experience of over nearly half a century under *GATT* 1947', cited in ICTSD-UNCTAD, *Resource Book on TRIPS and Development* (2005) 378.

formal system of *stare decisis*, the Appellate Body has stated that previous decisions 'should' be taken into account, meaning Panels are required to follow previous decisions unless they can provide coherent reasons as to why this jurisprudence should not be followed.[23] In addition, the laborious process of amending WTO agreements through the ministerial process adds to the weight of WTO jurisprudence.[24] GATT jurisprudence shows that exceptions are to be interpreted as narrowly as possible, in order to preserve the sanctity of the core agreement.

B *The Application of* GATT *Article XX and* GATS *Article XIV*

1 *Necessary: where is the threshold?*

The inclusion of art XX in *GATT* 1947 anticipated that members might need to justify a domestic policy that constitutes a prima facie discriminatory barrier to trade. The article was carried over into *GATT* 1994, and can be divided into two subparts: the introductory paragraph or *chapeau*, and the enumerated exceptions. It provides a limited carve-out of *GATT*:

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:
>
> (a) necessary to protect public morals;
>
> (b) necessary to protect human, animal or plant life or health; ...[25]

GATS art XIV(a) mirrors *GATT* art XX(a), and additionally provides a further category of 'necessary to protect public order.' Public order is defined in a footnote to the Agreement: 'The public order exception may be invoked only where a genuine and sufficiently serious threat is posed to one of the fundamental interests of society.'[26]

The wording of *TRIPS*' art 27(2) correlates with art XX(b) of *GATT* and *GATS*' art XIV, notwithstanding the *chapeaux*.[27] Article 27(2) confers a discretion ('may

23 *Japan – Taxes on Alcoholic Beverages*, WTO Doc WT/DS8, 10-11/AB/R, (1996) [12] (Report of the Appellate Body).

24 Shaffer, above n 8. Shaffer also argues that because WTO laws are often drafted in a vague manner due to complex multi-party negotiations, the Dispute Settlement Body has a de facto power of lawmaking through judicial interpretation.

25 Some text omitted.

26 *GATS* art XIV(a), fn 5.

27 This provision also correlates with the *Marrakesh Agreement, Annexure 1A, Multilateral Agreements on Trade in Goods, Agreement on the Application of Sanitary and Phytosanitary Measures ('Sanitary and Phytosanitary Agreement')* art 2, which states that 'members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.' For a discussion on the effect of the exceptions provision in this Agreement, see Jan Neumann and Elisabeth Turk, 'Necessity Revisited: Proportionality in World Trade Organization Law After *Korea – Beef, EC – Asbestos and EC - Sardines*' (2003) 37 *Journal of World Trade* 199.

exclude') but requires that the exclusion be 'necessary'. Whether an exclusion is 'necessary' may not be solely based on a pre-existing domestic law that excludes patentability for a particular invention. Analysis of jurisprudence under *GATT* reveals that the exclusion conferred by art 27(2) is narrower than it first appears. To date, *GATT*-WTO dispute settlement panels and the Appellate Body have not allowed members to invoke art XX in support of unilateral trade restrictions that breach *GATT*'s non-discrimination provisions,[28] but the Appellate Body has recently found a member's invocation of *GATS* art XIV(a) to be justifiable.[29] Because the Appellate Body's analysis of *GATS* art XIV in this recent case was based on jurisprudence on *GATT* art XX, *GATT* jurisprudence forms the main part of the following analysis.[30]

The general rule under *GATT* art XX from *US - Patents*[31] to *Shrimp-Turtle*[32] was that a discriminatory trade measure is only 'necessary' - and therefore justifiable - if no other measure, less inconsistent with *GATT*, is available, and all other options reasonably available to a member are exhausted before the measure is invoked. This means that the least trade restrictive measure should be applied in order to fulfil the member's avowed policy objective.[33] However, in *Korea – Beef*[34] the Appellate Body refined this test to incorporate a balancing of interests, in order to determine whether an alternative, less *GATT*-inconsistent measure was 'reasonably available'.[35] In relaxing the necessity test, the Appellate Body seemed prepared, in theory, to show greater deference to members in designing trade restrictive measures designed to achieve policy objectives such as protecting human health. The Appellate Body emphasised three factors that should be taken into account in performing the balancing test: the importance of the value underlying the objective; the effectiveness in the measure in achieving the objective; and the extent to which that measure restricted liberalised trade.[36]

The Appellate Body, therefore, has indicated that when considering whether a member could use an alternative measure to achieve its avowed policy objective,

28 WTO, *Dispute Settlement: The Disputes – Chronological List of Dispute Cases* <http://www.wto.org/english/tratop_e/dispu_e/dispu_status_e.htm#yr2005> at 24 April 2006.

29 *United States - Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, WTO Doc WT/DS285/AB/R (2005) (Report of the Appellate Body) ('*United States – Gambling and Betting Services*').

30 Other 'necessity' tests in WTO law may also play a role in interpreting art 27(2), such as those contained in the *Sanitary and Phytosanitary Agreement, and the Marrakesh Agreement, Annexure 1A, Multilateral Agreements on Trade in Goods, Agreement on Technical Barriers to Trade* ('Agreement on Technical Barriers to Trade'). Analysis of GATT art XX / GATS art XIV is most likely to be used, however, because like art 27(2) of *TRIPS*, it is an exception to the general provisions of the core Agreement, whereas 'necessity' tests in other WTO agreements generally form part of positive obligations on members. See the discussion in Neumann and Turk, above n 27.

31 *United States - Section 337 of the Tariff Act of 1930*, WTO Doc L/6439 - 36S/345 (1989) (Report of the Panel).

32 *United States - Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58/AB/R (1998) (Report of the Appellate Body).

33 *Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes*, WTO Doc DS10/R - 37S/200 (1990) [223] (Report of the Panel) ('Thailand Cigarettes').

34 *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WTO Doc WT/DS161/AB/R (2000) [164] (Report of the Appellate Body) ('*Korea - Beef*').

35 Ibid.

36 See the discussion in Neumann and Turk, above n 27, 211.

it will weigh and balance several factors to ascertain whether a measure that is less inconsistent with *GATT* could be reasonably expected to be employed by that member. According to Neumann and Turk, if the value that the measure seeks to protect is important and the impact of the measure on trade is moderate, the Appellate Body is likely to give the member a margin of appreciation in this regard.[37] However, where the measure is highly restrictive of trade, the Appellate Body is likely to more closely scrutinise available measures that are less inconsistent with *GATT*. In *United States - Gambling and Betting Services*,[38] decided under *GATS*, the Appellate Body followed its previous analysis in *Korea – Beef*, upholding (in part) the US' invocation of measures prohibiting internet gambling as necessary to protect public morals and maintain public order.

2 *Article XX's* Chapeau*: A Further Balancing Test*

GATT case law on art XX's *chapeau* provides further application of a balancing test. The *chapeau* provides that trade measures applied by members must not be 'applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade' – in effect affirming the requirement of good faith as a principle of international law.[39] The Appellate Body's interpretation of the *chapeau* has involved a weighing up of the competing interests involved, in order to determine whether a discriminatory exception to liberalised trade can be justified.[40] The following elements are distilled from the Appellate Body's application of the *chapeau* balancing test:

- *Proportionality*: the relationship between the policy goal and the trade measure must have a proportional relationship to the effect on international trade[41] (a requirement akin to the Appellate Body's interpretation of the term 'necessary' in *Korea - Beef)*;[42]

- *Transparency*: the decision making by member states must satisfy due process and be capable of external scrutiny;[43]

37 Ibid, 214.

38 *United States - Gambling and Betting Services*, WTO Doc WT/DS285/AB/R (2005) (Report of the Appellate Body).

39 Neumann and Turk, above n 27, 230.

40 *Shrimp-Turtle I*, WTO Doc WT/DS58/R (1998) [156] (Report of the Panel); Korea Beef, WTO Doc WT/DS161/AB/R (2000) [164] (Report of the Appellate Body).

41 Sarah Cleveland, 'Human Rights Sanctions and International Trade: A Theory of Compatibility' (2002) 5 *Journal of International Economic Law* 133, 153.

42 However, Neumann and Turk reject the proposition that a proportionality test is read into the Appellate Body's construction of the *chapeau*: Neumann and Turk, above n 27, 231.

43 See Cleveland, above n 41, 155. It was this factor that caused the failure of the US' measures in See, eg, *Tuna-Dolphin I*, WTO Doc DS21/R-39S/155 (1991) (Report of the Panel), and *Gasoline*, WTO Doc WT/DS2/AB/R (1996) (Report of the Appellate Body).

- *A preference for multilateralism*: although the Appellate Body in *Shrimp-Turtle II*[44] noted that in order to avoid the charge of arbitrary or unjustifiable discrimination under the *chapeau* of art XX, a member would be required to make good faith efforts to negotiate a multilateral solution to the particular problem. However, the Appellate Body in *United States - Gambling and Betting Services* rejected the requirement to negotiate a bilateral solution.[45]

C *Defining Morality and* Ordre Public

Given that art 27(2) has not yet been considered at dispute settlement, it is necessary to look at the *travaux préparatoires* for interpretive guidance to determine the scope of the terms 'morality' and '*ordre public*'.[46] Earlier drafts of art 27(2) also provided public interest, national security, public health and nutrition as bases for allowable exclusions from patentability; as well as specific exceptions, including pharmaceuticals and food.[47] This suggests that the concepts of morality and particularly *ordre public* encompass a broad concept of human health. The phrase 'to protect human, animal or plant life or health' is used in art 27(2) to provide examples of which exclusion from patentability, and prohibition on commercial exploitation of an invention may be necessary to protect *ordre public* or morality.

Because art 27(2) provides that an invention cannot be excluded from patentability simply because it is prohibited by law, the exclusion for patentability must be justified with the terms of art 27(2) itself – on the grounds of *ordre public* or morality.[48] Neither concept is defined in *TRIPS*, but as *TRIPS* mirrors the language of European law with respect to patenting and trade in goods, European jurisprudence (as an example of harmonized law[49]) is relevant

44 *United States – Import Prohibition of Certain Shrimp and Shrimp Products, Resource to Article 21.5 of the DSU by Malaysia*, WTO Doc WT/DS58/AB/RW (2001) (Report of the Appellate Body) ('*Shrimp-Turtle II*').

45 *United States - Gambling and Betting Services*, WTO Doc WT/DS285/AB/R (2005) [302] (Report of the Appellate Body).

46 Article 32 of the *Vienna Convention* allows for the *travaux préparatoires* to be used as supplementary means of interpretation.

47 Daniel Gervais, The TRIPS Agreement: Drafting History and Analysis (2003) [2.253] – [2.255].

48 *Ordre public* and morality were also contained in the *Patent Co-operation Treaty*, open for signature 19 June 1970 28 UST 7645, 1160 UNTS 231 (entered into force 21 January 1978 in relation to international publication) ('PCT'), a treaty which provides a unified procedure for filing patent applications internationally. Article 21(6) of the *PCT* states that if an international application 'contains *expressions or drawings* which, in the opinion of the International Bureau, are contrary to morality or public order…it may omit such expressions, [and] drawings…from publications' (emphasis added). The *ordre public* and morality clauses do not seem to apply to the inventions themselves, but rather the description of their use or uses.

49 It is important to note that the European Community is a customs union and, as such, will demand fewer barriers to trade within the community than might be acceptable in the WTO; and has the power to harmonize members' domestic laws as a way of avoiding disputes. Although *TRIPS* provides for harmonization of intellectual property law, no such requirement exists in relation to moral or *ordre public* norms.

and appropriate in determining the scope of the interface between morality and *ordre public* and patentability.[50]

1 *The European Patent Convention*

The *European Patent Convention* ('*EPC*') governs patent applications in the European Union.[51] Like *TRIPS*, the *EPC* allows members to refuse to grant a patent in their territory where the patent would be contrary to the moral or *ordre public* norms of the particular member. The relevant provision, art 53(a), states:

> European patents shall not be granted in respect of:
>
> (a) inventions the publication or exploitation of which would be contrary to '*ordre public*' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.

The terms 'morality' and '*ordre public*' are not further defined in the Convention, but the *Guidelines for Examination in the European Patent Office* provide some clarification, stating that:

> The purpose of [the exception] is to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour ... [i]n general, this provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.[52]

The *EPC* requires a case-by-case analysis of moral, ethical and public policy

50 Trade in goods in the European Union is also subject to *ordre public* and morality exceptions. Article 36 of the *Treaty of Rome (Treaty Establishing the European Economic Community)*, open for signature 25 March 1957, 298 UNTS 3 (entered into force 1 January 1958), provides exceptions to the principle of free trade in goods The exception clause is similarly worded to *GATT* and provides an exception where the restriction is 'justified on grounds of public morality, public policy or public security...[or for] the protection of health of humans.' Like *GATT*, the treaty contains a chapeau that limits the use of exceptions: they must not 'constitute means of arbitrary discrimination or a disguised restriction on trade.' Two cases have focused on a member's invocation of 'morality' under art 36 as a means to restrict trade in goods: *R v Henn & Darby* (C-34/79) [1979] ECR 3795 ('*Henn & Darby*') and Conegate Ltd v Her Majesty's Customs and Excise (C-121/85) [1986] ECR 1007 ('Conegate'). In *Henn & Darby*, the ECJ stated that '[i]n principle, it is for each Member State to determine in accordance with its own scale of values and in the form selected by it the requirements of public morality in its territory': *Henn & Darby* (34/79) [1979] ECR 3795, 3813. The effect of members' broad powers, coupled with the burden of proof on the complainant, was that a member could invoke the provisions of Art 36 as a protectionist measure in the guise of a moral objection. In *Conegate*, however, domestic products were held to less stringent 'morality standards' than imported products – showing that discrimination (comparable to a breach of national treatment under *GATT*) had taken place. Following these cases, invoking the doctrine of morality requires a ban on domestic production and sale of products within the same class as the banned imported products.

51 *Convention on the Grant of European Patents*, open for signature 5 October 1973, 13 ILM 268 (entered into force 3 October 1977) ('*European Patent Convention*' / 'EPC').

52 *Guidelines for Examination in the European Patent Office* ('*EPO Guidelines*'), pt C, chp IV, [3.1] (Matter contrary to *ordre public* or morality), <www.european-patent-office.org/legal/gui_lines/e/c_iv_3_1.htm> at 23 April 2006.

considerations in each patent application. European Patent Office ('EPO') case law indicates that that any exceptions to patentability must be narrowly construed.[53] The Opposition Division of the EPO (which re-examines patent applications where the granting of a patent is opposed) has judicially commented that art 53(a) 'has very seldom been invoked', and the threshold under the section is whether the granting of a patent for a particular invention 'would be universally regarded as outrageous.'[54]

2 *Morality*

The EPO describes the concept of morality as

> a belief being founded on the totality of the accepted norms which [are] deeply rooted in ... the culture inherent in European society and civilisation. Accordingly, inventions the exploitation of which was not in conformity with the conventionally accepted standards of conduct pertaining to this culture [are] to be excluded from patentability.[55]

The EPO Board of Appeals has confirmed this approach, noting that an invention would violate the morality provision if the invention was 'not in conformity with the conventionally accepted standards [of] European society and civilization.'[56] To date, the EPO Board of Appeals has not declined to grant any patent on the basis that the invention contravenes morality.[57]

3 Ordre public

Ordre public is a different concept to morality, but overlaps in some areas.[58] The term is derived from French law and is a concept comparable to 'public policy'. It concerns the 'fundaments from which one cannot derogate without endangering the institutions of a given society'.[59] The concept takes account of the interests of society as a whole, represented by relevant state institutions; expressing concerns about matters that threaten the structure of civil society.[60] In addition, the EPO has stated that *ordre public* covers the protection of public security and the physical integrity of individuals as part of society.[61]

Evaluating an invention in terms of *ordre public* requires 'a careful weighing up of the ... possible risks ... on one hand, and the invention's usefulness to mankind

53 European Patent Office, 'Case Law of the Boards of Appeal of the European Patent Office' (4th ed, 2001) <http://db1.european-patent-office.org/dwl/legal/case_law/clr_all_en.pdf> at 23 April 2006.

54 *Greenpeace UK v Plant Genetic Systems NV* [1995] OJ EPO 557 ('*Greenpeace v Plant Genetic Systems*').

55 European Patent Office, above n 55.

56 Greenpeace v Plant Genetic Systems [1995] OJ EPO 557.

57 As at 23 April 2007. See also Benjamin Enerson, 'Protecting Society from Patently Offensive Inventions: the Risk of Reviving the Morality Doctrine' (2004) 89 *Cornell Law Review* 685, 688.

58 Timothy Ackermann, 'Disorderly Loopholes: TRIPS Patent Protection, GATT and the ECJ' (1997) 32 *Texas International Law Journal* 489, 493.

59 Gervais, above n 47, [2.261].

60 ICTSD-UNCTAD, *Resource Book on TRIPS and Development* (2005) 36.

61 European Patent Office, above n 55.

on the other'.[62] Applying this balancing test, the EPO has found that a transgenic mouse with an activated cancer-causing gene met the requirements for patentability, notwithstanding the potential for suffering of animals and the unknown environmental risks.[63] The EPO Board of Appeals has also noted, in relation to an application to patent a herbicide resistant transgenic plant, that the concept 'covers the protection of public security and the physical integrity of individuals as part of society [including] protection of the environment'.[64] Such inventions likely to breach these standards would be those 'likely to breach public peace or social order ... or to seriously prejudice the environment.' The European Court of Justice previously stated (in a civil liberties case) that *ordre public* 'must be ... interpreted strictly';[65] the threshold may be met where a 'fundamental interest ... of the state' is at issue.[65]

IV APPLYING ARTICLE 27(2) IN THE CONTEXT OF PHARMACEUTICALS

A *Morality and* Ordre Public

1 *Morality: The Requirements*

Morality is dependent on the societal context, depending to a certain degree on the particular culture of a country or region. If the concept of morality is assessed from a relativist perspective it seems that members should have a margin of appreciation in determining whether commercial exploitation of a patented invention is immoral. Although the EPO has proposed a universal standard of morality within the EU,[67] it is argued that the diversity of WTO members accords greater weight to the concept of relativism. Accordingly, there are no definitive statutory or judicial definitions on the bounds of morality, which means that it may be difficult for a WTO dispute settlement panel to adjudicate the morality doctrine.

Even if members exercise their right to determine what constitutes an incursion on morality, the threshold that must be exceeded in the relevant context appears

62 *Decision T* [1990] OJ EPO 476, 476-8.

63 The EPO initially rejected the mouse patent on grounds unrelated to morality, concluding that 'patent law is not the right legislative tool' for considering whether a particular invention was immoral.'

64 The Opposition Division of the EPO has also stated, in relation to a contested application for a herbicide resistant transgenic plant, that even if the patent application were denied, such a denial would not necessarily prevent commercial exploitation of the invention – and that a patent did not allow an invention to be exploited without regard to other laws and regulations in that regulatory approval must be obtained: *Greenpeace v Plant Genetic Systems* [1995] OJ EPO 557.

65 *Rutili v Minister for the Interior*, 1975 ECR 1219, 1231 cited in Ackermann, above n 58, 509.

66 *R v Thompson* (1978) ECR 2247, 2275, cited in Ackermann, above n 58, 509.

67 *Greenpeace v Plant Genetic Systems* [1995] OJ EPO 557. The Board of Appeals stated that morality is 'related' to certain beliefs about what behaviour is proper, such beliefs being founded on deeply rooted norms, noting that an invention would violate the morality provision if the invention was 'not in conformity with the conventionally accepted standards [of] European society and civilization.'

to be 'whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable'.[68] European jurisprudence further constrains the doctrine: only in 'rare and extreme' cases could issues of morality prevent patentability.

2 Ordre Public*: The Requirements*

In theory, WTO members have flexibility in defining their own public values, and which situations would give rise to invocation of the doctrine of *ordre public*. Rather than 'morality,' it appears that human, animal or plant life and health is better placed under the rubric of *ordre public*, where the requirements are arguably less esoteric. It may be a matter of *ordre public* to exclude some essential products from patentability in order to ensure their availability in developing countries. National health emergencies such as the HIV-AIDS crisis in sub-Saharan Africa are almost certainly an issue of *ordre public*. Assuming that the posited reason for exclusion from patentability is adjudged 'necessary', this exception would, in theory, provide a basis for members to deny patents to certain pharmaceutical products altogether on the grounds of protection of public health. However, the requirements for *ordre public* also appear to give rise to a high threshold: a fundamental interest of the state must be at issue, for example the protection of public security or the physical integrity of individuals. European jurisprudence also tells us that the exception must be interpreted strictly and can only be invoked in 'rare and extreme cases';[69] as for the requirements of morality, only where the granting of a patent would be universally be regarded [within the member's society] as 'outrageous'.[70]

B *'Commercial Exploitation'*

Article 27(2) requires the denial of patentability to be linked to a denial of *commercial exploitation* of invention, which further curtails the effect of the exception, as it is the commercial exploitation of the invention that must be prevented in order to protect morality or *ordre public*.[71] It does not allow for a patent-free system that allows corporations to market and sell generic pharmaceuticals, nor compulsory licensing schemes (which acknowledge the patent in order for it to be licensed, thereby commercially exploiting the invention). The risk of contravening morality or *ordre public*, therefore, must come not from the *invention* as such, but from its *commercial exploitation,* and the impact that of the risk can only be considered within the territory of the member concerned.[72]

68 *EPO Guidelines*, pt C, chp IV, [3.1]. The term 'universal' seems to import a uniform baseline of morality among members which may not be directly applicable to WTO members.
69 *EPO Guidelines*, pt C, chp IV, [3.1].
70 *Greenpeace v Plant Genetic Systems* [1995] OJ EPO 557.
71 Robert Weissman, 'A Long, Strange, TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Developing Countries' (1996) 17 *University of Pennsylvania Journal of International Economic Law* 1069, 1081.
72 Gervais, above n 47, [2.261].

It is argued that the current practice of many of the least developed countries (and countries such as India prior to implementing their *TRIPS* obligations) of denying patent protection to large areas of technology (and allowing domestic producers to profit from large scale manufacture using that technology) is inconsistent with art 27(2); however, a non-profit sale of the product would not amount to 'commercial exploitation'.[73] A member might require, for example, that *ordre public* dictates that an invention be available at the lowest possible cost, or be distributed to the public for free.[74] There is no justification in *TRIPS*' *travaux préparatoires* for limiting the term 'commercial exploitation' to simple 'sale or distribution.'[75] It appears highly unlikely that an exception would be invoked under *TRIPS* on a purely protectionist basis, because the exclusion from patentability must translate to an exclusion from commercial exploitation within the member's territory, thus denying the opportunity for domestic manufacturers to profit from the production of generic copies of the invention.

Following this logic, it seems that a member's invocation of art 27(2) must be accompanied by a ban on domestic 'commercial exploitation' of the invention of the production of an imitative or generic product. Because art 27(2) specifies *commercial* exploitation, the door is potentially left open for not-for-profit manufacture and distribution of a generic product. Such a construction of 'commercial exploitation' implies that where a particular invention is itself seen as immoral (such as a human-animal chimera), restricting its use *in toto* would best be done by domestic legislation.[76] But where an invention, although viewed as beneficial to society per se, raises pricing barriers to its access (an issue of *ordre public*) or raises issues of commercial gain from public health emergencies (possibly 'immoral'), the invention should be allowed to 'exist' in the member's territory, but be subject to controls ensuring its affordability and availability.

C *'Necessary' – Predicting the Outcome of a Balancing Test*

1 *The Necessity Test*

As noted in the preceding analysis of *GATT* art XX, the necessity test requires that all other options reasonably available to a member are exhausted before an exception is invoked, meaning that the least trade restrictive measure should be applied in order to fulfil the policy objective. In assessing a member's measure, panels and the Appellate Body are likely to balance a set of factors in order to determine whether another measure is reasonably available.[77]

If *GATT* art XX jurisprudence does set a precedent for the interpretation of art

73 Ackermann, above n 58, 498.

74 It is important to note that commercial exploitation of the invention might occur notwithstanding whether it is patented, subject to domestic regulation.

75 Ackermann, above n 58, 498.

76 Some commentators argue that patent attorneys and examiners are ill-equipped to assess questions of morality in relation to inventions: 'the patent system should not become a theatre for judging the morality of controversial inventions': Enerson, above n 57, 701. It is argued that other regulatory devices should regulate the use of abhorrent inventions, rather than a morality test in deciding whether the invention is patentable.

77 *Thailand – Cigarettes*, WTO Doc DS10/R - 37S/200 (1990) [223] (Report of the Panel).

27(2), a developing country member would have to show that there was no other measure it could reasonably take (including compulsory licensing under art 31) that was less inconsistent with *TRIPS*. While it is evident that protection of public health is an important objective, it is clear that excluding pharmaceuticals from patentability is antithetical to intellectual property protection and liberalised trade in patented products, particularly where other options (compulsory licensing) could be seen to be reasonably available to achieve the goal of access to essential pharmaceuticals and still compensate the right holder. Arguably, therefore, a compulsory licensing regime which recognises the patent holder's overriding proprietary right to commercially exploit their invention is the least *TRIPS*-inconsistent measure reasonably available, rather than a denial of patentability under art 27(2). Although the Appellate Body in *Korea - Beef* indicated that it would show a degree of deference to members in determining whether a measure was reasonably available, the availability of the compulsory licensing, an option specifically tailored to enabling access to pharmaceuticals in developing countries, tends to suggest that the necessary threshold would not be met in this case.

2 *The* Chapeau

Turning to an application of jurisprudence from *GATT*'s *chapeau*, art 30 of *TRIPS* is akin to a *chapeau*, stating that exceptions to the exclusive rights conferred by a patent are allowable 'provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent holder.' In addition, art 8 allows members to 'adopt measures necessary to protect public health ... provided that such measures are consistent with the provisions of this Agreement.'

TRIPS' *chapeau* is more general than the *chapeau* in *GATT*. It appears relate to both derogations from non-discrimination requirements and protection of patent holders' proprietary rights. This means that in adopting a measure necessary to protect public health, a member would need to ensure that the measure did not unreasonably conflict with the patent holder's rights.

It is therefore argued that a panel or the Appellate Body will apply a balancing test to art 27(2), either by way of the term 'necessary', or through by reading jurisprudence on *GATT* art XX's *chapeau* into *TRIPS*' *chapeau* when evaluating a measure under art 27(2).[78] In this analysis, it is likely that the 'rights' of the patent holder would be balanced against the right to health of the population of the member that attempts to invoke the exclusion. The Appellate Body has previously attempted to balance the competing objectives of public health and liberalised trade in the *EC – Hormones* dispute, where it opined that the relevant treaty provision reflected 'a delicate and carefully negotiated balance ... between [the] shared, but sometimes competing interests of promoting international trade

78 The EPO also utilizes a balancing test in determining patent applications, which takes into account the advantages and disadvantages of an invention.

and of protecting the life and health of human beings.'[79] In that case, the Appellate Body found that the perceived risk to human health was not scientifically justifiable, finding the EC ban on hormone-treated beef was inconsistent with the EC's WTO obligations..

3 *The Right to Health*

In reaching decisions under art XX, the Appellate Body has shown willingness to consider extra-textual materials such as multilateral agreements and conventions when weighting and balancing competing priorities. The right to health, enshrined in the *International Covenant on Economic, Social and Cultural Rights* ('*ICESCR*'), appears to directly conflict with the right to intellectual property protection with regard to the need to access essential pharmaceuticals.[80] However, the *GATT* art XX case law shows that, to date, the 'right' to liberalised trade trumps the right to environmental protection. Will a similar outcome occur in relation to public health?

The doctrine of state sovereignty precludes extra-territorial obligations concerning the right to health, as a state's obligation in this area applies only to individuals within its own territory or otherwise within its jurisdiction.[81] Just as there is no single document that is universally recognised as the international environmental law 'constitution',[82] the absence of a centralised international health law institution with adjudication and enforcement mechanisms renders many of these multilateral instruments merely hortatory, with variable enforceability at state level. In addition, prior *GATT*-WTO jurisprudence has indicated that positive rights cannot easily be recognised and acted upon through the dispute settlement process. Indeed, economic, social and cultural rights are less justiciable than, for example, civil and political rights because they require policy decisions on relative government funding appropriations for different sectors.[83] While it is a fundamental legal principle that private property rights can be curbed if doing so serves a greater public purpose, differences occur in determining what constitutes a 'greater public purpose.'[84] In relation to access to

79 EC — *Hormones*, WTO Docs WT/DS26/AB/R, WT/DS48/AB/R (1998) [193] (Report of the Appellate Body).

80 See, eg, *International Covenant on Economic, Social and Cultural Rights*, open for signature 16 December 1966, art 12 (entered into force 3 January 1976). The right to health is also contained in the *Universal Declaration of Human Rights*, GA Res 217A (III), UN Doc A/810 71 (1948) art 25; *Convention on the Elimination of All Forms of Discrimination Against Women*, opened for signature 18 December 1979, 1249 UNTS 13, art 11(1) (entered into force 2 September 1981); and other international agreements.

81 In any case, neither the US nor most sub-Saharan African countries have ratified the *International Covenant on Economic, Social and Cultural Rights*, opened for signature 16 December 1966 (entry into force 3 January 1976) ('ICESCR') <http://www.ohchr.org/english/countries/ratification/3.htm> at 26 July 2006.

82 Kevin Kennedy, 'The Illegality of Unilateral Trade Measures to Resolve Trade-Environment Disputes' (1998) 22 William and Mary Environmental Law and Policy Review 375, 381.

83 Article 2(1) of the ICESCR obligates each state party to take the necessary steps 'to the maximum of its available resources.' Interpretations of the universal right to health point to the right to access medical treatment for serious illnesses; meaning that, in theory, a developing country government who appropriates funds for intellectual property protection and enforces intellectual property rights violates the right to health for its citizens.

84 Dani Rodrik, 'Trade Policy Reform as Institutional Reform' in Bernard Hoekman, Aaditya Mattoo and Phillip English (eds) *Development, Trade and the WTO: A Handbook* (2002) 1, 5.

essential pharmaceuticals, a crude balancing test weighing up the relative value of the lives of HIV-AIDS sufferers in sub-Saharan Africa versus the economic interests of the corporation that invented the pharmaceutical seems repugnant to notions of justice, outside of the neo-liberal paradigm. Such an exercise will undoubtedly create a dilemma for panels and the Appellate Body.

D Is the Threshold Met?

The preceding analysis demonstrates that even a public health emergency giving rise to an urgent need for affordable pharmaceuticals is unlikely to meet the high thresholds indicated by WTO and European jurisprudence. The requirements of *ordre public*, coupled with the requirement of 'necessary' illustrate the difficulty in successfully invoking the exception.

Even if the threshold in art 27(2) was met, a member would require the capacity and infrastructure to manufacture the pharmaceuticals domestically and to distribute them through a state-owned entity or government funded organization. If the member did not have such capacity, it would be preferable to import a generic product through an art 31 waiver arrangement. It would be to a member's advantage to use art 27(2) and manufacture pharmaceuticals domestically, as it would avoid the requirement of compensation under art 31. However, art 27(2) does not provide any protection to members from patents already granted in respect of certain pharmaceuticals. Those rights can only be abrogated through compulsory license.

Following GATT jurisprudence, invoking art 27(2) as a unilateral measure would only be permissible after all other options had been employed, including an attempt to utilise art 31 (compulsory licensing). The WTO's contention that members can use the 'flexibilities'[85] in *TRIPS* to access essential pharmaceuticals is untenable: in order to exclude an invention from patentability, a member must first grant a patent for that invention. In addition, institutional and fiscal impediments to adopting provisions of the WTO compact are generally not considered in the dispute settlement process. This means it is likely that a WTO Panel will decline to consider these factors when deciding whether excluding a particular invention from patentability was 'necessary'. Exclusion of particular pharmaceuticals from patentability, therefore, appears not to be the most appropriate nor the most expeditious route that developing countries can take and then defend before the WTO, meaning that art 27(2) is likely to be effectively inutile in relation to access to pharmaceuticals.

85 WTO Secretariat, *TRIPS and Public Health: the situation in late 2005* (2005) <www.wto.org/english/tratop_e/TRIPS_e/health_background_e.htm> at 23 April 2006.

86 *Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)DEC/2 (2001) (Ministerial Conference) ('*Doha Declaration*').

85 Gupta, above n 16, 138.

V THE WTO'S POLITICAL FOCUS: ARTICLE 31 AND COMPULSORY LICENSING

As previously noted, subsequent legal and political developments since the creation of *TRIPS* have moved the political focus towards compulsory licensing of essential pharmaceuticals in times of national health emergencies. Article 31 of *TRIPS* provides that compulsory licensing of a patented invention for domestic use is allowable on public health grounds, but imposes a large number of conditions on both the exporting and importing country, including process requirements such as the general requirement to pay 'adequate compensation' to the patent holder and obtain authorisation from the right holder on reasonable terms (although this requirement can be waived in the case of a national emergency or 'extreme urgency'). The patent holder retains underlying proprietary rights in the patent, and the licence is revocable once the circumstances that justified its granting no longer exist.

The ambiguity of some aspects of art 31 was considered at the Doha Ministerial Conference, culminating in the 2001 Doha Ministerial *Declaration on the TRIPS Agreement and Public Health Ministerial Declaration* on *TRIPS* and Public Health (the '*Doha Declaration*').[86] The *Doha Declaration* acknowledged for the first time that stringent intellectual property protection under the *TRIPS* Agreement has had a negative effect on public health,[87] and, while 'reaffirming' the 'flexibility' of *TRIPS* for members to protect public health, also confirmed that 'intellectual property protection is important for the development of new medicines.'[88] While the *Doha Declaration* specifically recognises the power of member governments to issue compulsory licenses for pharmaceuticals 'where they believe public health concerns outweigh the urgency of international intellectual property protection,'[89] it provides no guidance as to the preferred way to utilize the provision. The *Doha Declaration* is silent on the issue of art 27(2). By inference, it is argued that the WTO has signalled that compulsory licensing is the more acceptable method for developing countries to gain access to essential pharmaceuticals.

Paragraph 6 of the *Doha Declaration* recognizes that some members lack the capacity for manufacture of pharmaceuticals, and directed the *TRIPS* Council to devise a *TRIPS*-legal solution to the issue. The subsequent decision of the *TRIPS* Council provides a waiver from the general requirements that a generic product manufactured under a compulsory license be manufactured domestically.[90] The decision provides that other members may export generic products to developing countries that lack manufacturing capacity, subject to a stringent list of

88 *Doha Declaration*, WTO Doc WT/MIN(01)DEC/2 (2001) [3] (Ministerial Conference).

89 Jessica Fayerman, 'The Spirit of *TRIPS* and the Importation of Medicines Made Under Compulsory License After the August 2003 *TRIPS* Council Agreement' 25 *North Western Journal of International & Business Law* 257, 260.

90 *Implementation of Para 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 (2003) (Decision of the TRIPS Council) ('Decision of the TRIPS Council').

conditions.[91] A General Council decision in December 2005 agreed to transform the art 31 waiver into an amendment to *TRIPS*.[92] This will become a permanent amendment to *TRIPS* if two thirds of members ratify the proposed change, and the waiver will remain in place pending any amendment. At the time of writing, while Thailand was reported to have utilized the provisions of art 31 to import HIV-AIDS drugs[93], this had not been formally notified to the WTO.[94] The lack of take-up of the waiver provisions are arguably a reflection of the scheme's excessively stringent requirements.

VI MOVING FORWARD?

A *Rule-Based 'Equality' in the WTO*

The *Doha Declaration* does not (except for a tacit acknowledgement of members with insufficient or no manufacturing capacities) acknowledge a fundamental problem for developing countries – the breadth of legislative and institutional reforms that these members must undergo in order to take advantage of the legal loopholes created by the exceptions provisions. Indeed, some WTO members are only newly familiar with a market economy and the rule of law. Although art 31(f) has been supplemented by paragraph 6 of the *Doha Declaration* and a move towards incorporating this decision into *TRIPS* itself, issues of extreme poverty in the least developed countries, lack of funding for healthcare and the related administrative issues including the storage, transport and distribution of drugs, mean this often-lauded political achievement of the Doha 'Development' Round will not be realised unless these underlying issues are addressed.[95]

The least developed countries have until 2016 to become *TRIPS*-compliant.[96] In order to implement *TRIPS* and codify the exceptions effectively, developing country members need experience with intellectual property law or assistance from legal counsel.[97] Without this, *TRIPS*' mandated requirements will simply be incorporated into municipal legislation. Although *TRIPS* itself exhorts developed countries to assist developing country members in developing a *TRIPS*-compliant

91 *Decision of the TRIPS Council*, WTO Doc WT/L/540 (2003) [2] (Decision of the TRIPS Council). It is unclear what 'insufficient capacity' will mean in practice: theoretical physical plant capacity, or the more pragmatic economic approach of insufficiency due to inability to produce with meaningful economies of scale: Baker, above n 5, 640.

92 WTO Secretariat, Members OK Amendment to Make Health Flexibility Permanent (Press Release, 6 December 2005) <www.wto.org/english/news_e/pres05_e/pr426_e.htm> at 26 July 2006.

93 International Centre for Trade and Sustainable Development, *Bridges Monthly Review*, (December 2006 - January 2007) available <http://www.ictsd.org/monthly> at 8 February 2007.

94 WTO, *Notifications by Importing WTO Members* <www.wto.org/english/tratop_e/TRIPS_e/public_health_notif_import_e.htm> at 8 February 2007.

95 Bryan Mercurio, 'TRIPS, Patents, and Access to Life-Saving drugs in the Developing World', (2004) 8 Marquette Intellectual Property Law Review 211, 213.

96 WTO, 'Poorest Countries Given More Time to Apply Intellectual Property Rules' (Press Release, 29 November 2005) <www.wto.org/english/news_e/pres05_e/pr424_e.htm> at 14 December 2005.

97 Dreyfuss, above n 4, 26.

domestic regulatory regime, evidence has shown that industrialised members who have furnished this assistance have done so in a way that favours their own interests.[98]

B *Horizon Scanning: the United States' Agenda*

Notwithstanding the *Doha Declaration* and *TRIPS* Council decision, the US has continued to block developing countries' access to generic pharmaceuticals, and has, in particular, attempted to block the production-for-export solution.[99] Meanwhile, the US has proposed further conditions to the *TRIPS* Council, seeking to severely curtail the range of diseases for which generic pharmaceuticals could be obtained,[100] and transnational corporations continue to lobby for the repeal of *TRIPS* art 27.[101]

There exists a real risk that the small gains made by the *Doha Declaration* and General Council decision to amend *TRIPS* will be undermined through bilateral and plurilateral free trade agreements being aggressively pursued and concluded by the US with individual developing countries.[102] Such agreements extend the realm of patent protection even further and negate *TRIPS*' ostensible public health exceptions: part of a phenomenon known as '*TRIPS*-plus'. Article 71 of *TRIPS* authorises the *TRIPS* Council to 'undertake reviews in the light of any relevant new developments which might warrant modifications or amendment of this Agreement,' which may be a way for the US to seek repeal or amendment of the exceptions provisions.

C *Dispute Settlement: Entrenching the Disadvantage?*

The *Doha Declaration* does not restrict industrialised members' ability to use the dispute settlement process in the event that a member objects to a developing country's invocation of either art 27 or 31. Despite the WTO declaring itself a 'rules-based institution' in comparison to *GATT* 1947, this focus on the letter of the law ignores the fact that the developing countries are entrenched in a position of significant disadvantage, described by Sell as 'a system of asymmetrical power relationships and global capitalism that constrain [their] abilities to exploit the flexibilities crafted into the law'.[103] While, in theory, the WTO treats all members as equals, most developing countries lack both institutional capacity and funds to defend a complaint before a Dispute Settlement Panel, and cannot absorb the high

98 Ibid.

99 Baker, above n 5, 620.

100 *Council for TRIPS - Paragraph 6 of the Doha Declaration - Communication from the United States*, WTO Doc IP/C/W/340 (2002); *Council for TRIPS - Paragraph 6 of the Doha Declaration - Second Communication from the United States*, WTO Doc IP/C/W/358 (2002).

101 Kevin McCabe, 'The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology' (1998) 6 *Journal of Intellectual Property Law* 41, 58.

102 Baker, above n 5, 616; See also Carlos Correa, 'Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses' (2004) 26 *Michigan Journal of International Law* 331.

103 Susan Sell, 'What Role for Humanitarian Intellectual Property? The Globalization of Intellectual Property Rights' (2004) 6 *Minnesota Journal of Law, Science and Technology* 191, 197.

litigation costs that are incurred through engaging in the Dispute Settlement process.[104] The flow-on effect of the situation is that developing countries are failing to develop experience in WTO law.[105] The potential for industrialised members to invoke cross-sectoral retaliation (in a different trade sector to the one in which the breach has taken place) means that there will be pressures on developing countries to bring their laws into to conformity with *TRIPS*' requirements before a dispute reaches the dispute settlement body.[106] Although art 24 of the *Dispute Settlement Understanding* provides for special procedures involving least developed country members (requiring other members to exercise due restraint in invoking dispute settlement procedures against these countries, and, in particular, asking for compensation or suspending concessions), developing countries may be unwilling to invoke art 27(2) on the basis that it might be prejudicial to their efforts at trying to attract foreign investment and technology transfer.[107] It can therefore be argued that like art XX of *GATT*, the exceptions provisions in *TRIPS* have had a chilling effect on members' willingness to invoke such measures.

VII CONCLUSION

This article has examined case law under *GATT* art XX and *GATS* art XIV as well as European patent law, attempting to demonstrate that the interpretation of art 27(2) of *TRIPS* will be significantly shaped by this prior jurisprudence.

At first glance, art 27(2) looks as though it will have benefits for developing countries. However, if the scope of the exception hinges on the interpretation of relevant terms from previous *GATT*-WTO and European patent law jurisprudence, developing countries' power to invoke art 27(2) is severely curtailed. European jurisprudence on the terms 'morality' and '*ordre public*' has set a high threshold for invoking an exception, and in any case the rubric seems to be more targeted towards dangerous or repugnant inventions than pharmaceuticals. The threshold of 'necessary' remains high, despite the WTO Appellate Body's softening of the requirements in *Korea-Beef*, requiring other 'reasonable' options to be exhausted before patentability is denied. This appears to lead to the absurd requirement that a member must first grant a patent in order to later escape it. The stringent requirements of art 27(2), coupled with a lack of institutional capacity in developing countries, is likely to render the provision inutile in practice.

The morass of complex legal hurdles required to overcome or sidestep stringent patent protection under *TRIPS* have served to entrench the patent rights of pharmaceutical corporations, with a resultant shortening of the lives of potential

104 Shaffer, above n 8, 469.
105 Ibid.
106 Weissman, above n 71, 1081.
107 Sell, above n 102, 198.

consumers who, without access to life-saving medicines, cannot participate in the globalised economy. The power of transnational corporations in agenda-setting at the WTO has resulted in a conflict between the right to health (as articulated in the *ICESCR*) and the 'right' of corporations to commercially exploit their intellectual property. Given this state of affairs, reform of this aspect of the WTO compact will require dedicated international intervention, recognising the perverse impacts that the present system has created, particularly in regard to the failure to achieve the WTO's putative objectives of social and economic welfare and protection of public health.[108] Without concerted action, these obstacles seem almost insurmountable given the current lack of will for reform.

108 *TRIPS* arts 7, 8.