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Human Rights and the WTO: The Case of Patents and Access to Medicines

Holger Hestermeyer

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Subject: Human rights. **Other related subjects:** Health. Intellectual property

**Int. T.L.R. 122* Sources of international law have tended to characterise the interrelationship of intellectual property and human rights as one of conflict or coexistence.¹ Holger Hestermeyer, the author of *Human Rights and the WTO*, is of the former school. The subject of his book is the conflict between the international protection of patents and the right of **Int. T.L.R. 123* access to medicine.² Chapter 1 examines the legal implications of this conflict within the context of the HIV/AIDS pandemic that overwhelmed developing countries in Africa, Asia and South America with such devastating demographic impact.³ It describes how in 1997, South Africa, a country among the worst affected by the HIV/AIDS pandemic, sought to obtain anti-retroviral drugs at affordable prices, by amending the Medicines and Related Substances Control Act⁴ in order to permit the compulsory licensing of patented medicines for generic manufacture, and parallel importation from countries where medicines are available at a lower price. The following year, to the unanimous censure of civil society organisations, 42 applicants comprising a host of multinational and South African drug companies responded by taking legal action against the Republic of South Africa. The applicants claimed that the amendment was discriminatory with regard to the enjoyment of patent rights in the pharmaceutical field of technology, contrary to Art.27 of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs Agreement),⁵ and unconstitutional, insofar as it permitted the Minister of Health, contrary to s.25 of the Constitution, to deprive the owner of the prescribed medicine of its property, and to expropriate such property without compensation.⁶

Proposition: the global regulation of patents restricts access to medicine

Having identified patents as seminal to the debate on access to medicines, Ch.2 focuses upon the contentious entry into force of the TRIPs Agreement in 1995, an occasion that is said to have marked the beginning of a global era in patent regulation.⁷ The mandatory and enforceable standards of patent protection required by TRIPs give WTO members, the majority of which are developing countries, significantly less flexibility to adjust patent protection in keeping with their level of economic development.⁸ Article 27 of the Agreement obliges WTO members to provide a comprehensive definition of patentable subject-matter to include both pharmaceutical products and processes, while Art.28 requires that they confer upon patentees exclusive rights to prevent unauthorised third parties from making, selling, or importing the patented product.⁹

By weighing the international harmonisation of patent law against the incidence of epidemic disease in the developing world, the author seeks to correlate the global regulation of patents with the prima facie violation of human rights to life and health by governments and major pharmaceutical companies. This claim is primarily based on the capacity of patents to raise the price of medicines for the mandated 20-year term of protection¹⁰ and that of patentees, exploiting their exclusive right of sale, to keep less expensive, generic medicines off the market.¹¹ The intention is to invoke the norms of international human rights law to make governments and major pharmaceutical companies directly accountable for excessive drug-pricing and other non-competitive business practices that result in lack of access to medical treatment or the withdrawal of life-saving medicine.

Proposition: access to medicine is a universal human right against which governments and corporations may be held accountable

Chapters 3, 4 and 5 turn their attention to the relationship between access to medicine as an international human right and the TRIPs Agreement. The right of access to essential medicines, on a non-discriminatory basis, especially for vulnerable or marginalised groups, is protected as a core obligation under the right to health contained in Art.12 of the International Covenant on Economic,

Social and Cultural Rights (ICESCR).¹² Likewise, the International **Int. T.L.R. 124* Covenant on Civil and Political Rights (ICCPR) protects access to life-saving medicine as part of the right to life contained in Art.6.¹³ States may fulfil the right to access to medicine by establishing a comprehensive health care system and funding medical treatment for their citizens.¹⁴ Although corporations, as private parties, are not directly bound by international human rights law, a court might possibly attribute the human rights violation of a pharmaceutical company to its home state.¹⁵

For states that are not parties to the Covenants, there is a narrower principle of customary international law, limited to access to life-saving medicines in the face of national health emergencies. State practice shows that the United States, while persistently objecting to a right to health with a larger scope, does not object to this limited rule. States have an immediate duty to respect and ensure the right, which includes a duty to protect individuals against violations of the right by the state and by private pharmaceutical companies. However, there is no positive right of access to medicine because it is not a norm of customary international law *ius cogens*. A WTO member cannot therefore rely on the right to access to medicine as a defence against a claim of violation of WTO law absent a basis for the defence in the covered agreements. In short, the capacity of developing countries to invoke the right to health is severely curtailed by the fact that human rights are not enforceable via an independent system of international dispute settlement comparable to that of the WTO.

Proposition: human rights should be incorporated within the TRIPs Agreement

Against this incoherence within the international legal system's approach to the enforcement of human rights, the author advances his thesis that states' human rights obligations in providing access to medicines might better be attained by incorporating human rights within the law of the WTO. Hestermeyer's thesis contemplates the incorporation of human rights provisions within WTO law that might be invoked by developing countries in defence of measures taken to obtain cheaper medicines. The incorporation of human rights would serve to strengthen the TRIPs flexibilities that allow developing countries to adopt measures necessary to protect public health and to provide limited exceptions to the exclusive rights conferred by a patent.¹⁶

The thesis is formulated in both radical and moderate forms. The radical version of the thesis posits an express provision within the TRIPs Agreement, or provisions, perhaps in the form of a "WTO human rights treaty", that would be actionable by states. Alternatively, Hestermeyer posits the creation of a specific "human rights exception" within the TRIPs Agreement. The rationale for the incorporation of human rights law within WTO law rests on the view that developing country members who wish to rely on the right of access to medicine currently have no positive right or "sword" to use against the pressure applied by major pharmaceutical companies and their home states for the highest standards of patent protection. Nevertheless, such a proposition, particularly the offensive use of human rights, would entail a fundamental reform of the present system of international human rights system, which promotes adherence via monitoring, moral persuasion and public condemnation.¹⁷

Proposition: the Appellate Body should apply human rights to the interpretation of the TRIPs Agreement

In Ch.5 the author examines various approaches that scholars have advanced as to how the law of human rights might be applied to the settlement of WTO disputes. At one extreme, panellists would not admit human rights on the basis that the WTO constitutes a closed regime, outside the mainstream of international law.¹⁸ The author takes issue with this traditional view which, he considers, is based on a misperceived conception of self-contained regimes and at odds with the plain wording of the WTO Agreements.¹⁹ At the other extreme, human rights law, when formally incorporated in WTO Agreements, might be applied equally with WTO rules so that human rights law could be enforced by WTO dispute settlement proceedings.²⁰

**Int. T.L.R. 125* A third, moderate, approach would see adjudicators take account of human rights norms when interpreting the provisions of the TRIPs Agreement, at least to the extent there is no conflict with WTO rules. This approach capitalises on the law pertaining to the interpretation of treaties, whereby international human rights may be utilised as an aid for interpreting the TRIPs Agreement.²¹ Pursuant to the Vienna Convention on the Law of Treaties,²² the context for interpreting the TRIPs Agreement would necessarily include any relevant rules of international human rights law applicable in relations between the parties. To that end, the right of access to medicine under the ICESCR, ICCPR and customary international law may be taken into account in the interpretation of

the patent provisions of the TRIPs Agreement. Utilising the rules of interpretation, WTO panellists would “courageously step in” and actively bring human rights law to bear on the interpretation of the WTO Agreements, at least to the extent it constitutes customary international law.

The WTO case of *Canada --Patent Protection of Pharmaceutical Products*²³ is cited as an example of the current restrictive interpretation accorded Art.30 of the TRIPs Agreement, which allows limited exceptions to the patentee's rights provided they do not unreasonably conflict with the normal exercise of the patent. In that case the panel ruled that derogations for generic manufacture may allow regulatory review, but disallowed the preparatory manufacture of product prior to the expiration of the patent. In accordance with the author's proposed approach, taking account of the right to health, panellists should adopt a broad reading, one that would further the manufacture and export of medicines to developing countries, by taking account of human rights in determining whether the “legitimate interests of third parties”, in this case the manufacturers of generic pharmaceuticals, outweighs the patentee's interests in the full enjoyment of its legal rights, even if it means overriding the principle of non-discrimination in Art.27 of the TRIPs Agreement.²⁴

Nevertheless, a remaining drawback for Hestermeyer is that the middle way does not provide developing countries with an affirmative defence in respect of access to medicine. To this end the author argues that the security exception in Art.73 of TRIPs would offer the strongest endorsement of the right to access to medicine.²⁵ By such means, the law of human rights would serve as a vehicle for adopting a broader interpretation of the flexibilities within the TRIPs Agreement. The Appellate Body could base the import of human rights law on a broad, modern definition of “security”, holding large-scale threats to human rights to be a threat to security and allowing members facing public health crises to compulsorily license patents for medicines to treat pandemics. This proposal would accord with the World Health Organization's recognition of the concept of public health security which is defined as “the activities required, both proactive and reactive, to minimize vulnerability to acute public health events that endanger the collective health of national populations”.²⁶

Proposition: there is a conflict between patents and access to medicine

In Ch.4, the author examines the theoretical basis of his thesis insofar as it calls for the incorporation of human rights within TRIPs. In the case of high-income developed countries, he acknowledges the validity of the incentive theory of patent protection, in accordance with which a period of monopoly pricing is justified by the need to recoup investment in R & D. However, in the case of developing countries, the author does not find the incentive theory compelling, based on a combination of economic and legal grounds.²⁷ Indeed a conflict arises, on the one hand, owing to developing countries' inability to pay the monopoly rents caused by patent protection and, on the other hand, owing to the fact that the obligation to grant pharmaceutical patents interferes with their obligations under human rights law to provide their people with access to medicine.²⁸

It is the author's central contention that the very obligation to make patents available and patent rights enjoyable without discrimination gives rise to a “conflict” between the TRIPs Agreement and the human rights to health and medical treatment.²⁹ Such conflict is further deepened, he argues, by the fact that the flexibilities in the TRIPs Agreement that would ostensibly allow developing countries to obtain generic equivalents by means of limited derogations, compulsory licences and parallel imports have been narrowly interpreted by WTO dispute settlement panels. Moreover, the transitional period of the TRIPs Agreement, within which developing countries were exempt from having to provide patent protection for pharmaceutical products came to an end in 2005. As a result developing countries, such as India, with the capacity to manufacture new drugs for epidemic diseases, notably HIV, malaria and TB, are obliged to comply with the patent provisions of the TRIPs Agreement, including their attendant restrictions on compulsory licensing, generic production, export and pricing.

Hestermeyer contrasts the TRIPs Agreement with the earlier “international period” of patent regulation,³⁰ embodied in the Paris Convention for the Protection of Industrial Property of *Int. T.L.R.* 126 1883³¹ and characterised by a laissezfaire approach to the enforcement of intellectual property rights.³² He postulates that international patent protection prior to the conclusion of the TRIPs Agreement would not have prevented developing country governments from legislating to obtain cheaper medicines. He notes that the greater flexibility of policy-making India enjoyed for more than three decades, while it built its generic pharmaceutical industry, is no longer possible. A major contributor to the development of a local industry was the speed with which its scientists were able to develop cost-effective processes for manufacturing molecules already invented and patented in other countries, a practice supported by the comparatively thin patent protection provided by the former Indian Patents Act of 1970.³³

The author takes the conflict between patents and access to medicine beyond the utilitarian bounds of intellectual property law, as embodied in the TRIPs derogations and exceptions.³⁴ He argues that the TRIPs Agreement is in conflict with access to medicine regardless of the breadth of the “flexibilities” granted in the Agreement. Consequently, without affirmative rights on which developing countries can rely, such as the human rights to life, health and medical care, there will be a conflict between patents and access to medicines.

On reforming the relationship between patents and human rights

Presumably, the notion that the relationship between patents and human rights law needs reforming is premised on its inadequacy. If WTO law stipulates that panellists are bound to consider human rights law, sceptics might ask whether there is in fact a problem.³⁵ Article 8 expressly affirms that “[m]embers may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health”. The Doha Declaration on the TRIPs Agreement and Public Health affirms that the Agreement should be interpreted in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.³⁶ The decision of August 30, 2003³⁷ and the subsequent amendment to Art.31 of the TRIPs Agreement³⁸ sought to address the public health needs of LDCs by creating a procedural mechanism to facilitate the compulsory licensing and export of generic medicines to LDCs lacking a pharmaceutical manufacturing capacity.

While this might be seen as members co-operating in fulfilment of their human rights obligations, from the author's point of view these measures simply underline the need for the incorporation of human rights law within the WTO regime. Hestermeyer sees the Doha Declaration as evidence that the objective of the TRIPs Agreement as expressed in Art.7, to ensure a balance of rights and obligations, in this case between the rights of the patent holder and the public's right to health, is not capable of being fully realised without developing countries being able to withstand considerable economic and political duress. Despite the clear wording of the TRIPs flexibilities that would allow compulsory licensing in times of national emergency, it was necessary for WTO members to issue two declarations and to amend the compulsory licensing provisions of the TRIPs Agreement, an amendment that, owing to members' reluctance to ratify, for the substantial majority of countries remains a temporary waiver in status.³⁹ Hestermeyer considers that far from safeguarding access to medicine, the resulting procedure has effectively made compulsory licensing more difficult. The WTO's drug patent waiver is criticised as not only administratively complicated but also circumscribed by conditions designed to ensure that **Int. T.L.R. 127* cheaper generic drugs are not diverted to secondary markets. It was not until July 2007 that Rwanda became the first country to notify the WTO that it intended to import generic versions of the HIV/AIDS drug TriAvir, which is manufactured in Canada.⁴⁰

Hestermeyer submits that in weighing the property rights of the patent holder against those of patients to access medicines, the interests of the patentee should not jeopardise rights of access.⁴¹ In the abstract, who is to argue with patients having life-saving drugs? If we are going to weigh the needs of patients against the commercial interests of patentees then, as a matter of moral suasion, there is no argument. Legally speaking, however, there appears to be a conflict of discipline and doctrine. The essential elements of patentability testify to the utilitarian and functional character of patent law,⁴² insofar as it serves as a vehicle for securing a financial return. When the systems are opposed, it becomes difficult to reconcile the natural rights theories of the human rights system against the utilitarianism of the patent system.

Hestermeyer's thesis carries the risk that the utilitarian design of patent law, with its intent to encourage innovation, might well become blurred by association with the relatively undefined content of political, economic and social rights.⁴³ Arguably, in calling for an interdisciplinary weighing of interests between legal orders, the book's thesis tends to neglect the internal controls that government and judiciary may invoke to recalibrate the patent system.⁴⁴ Judicial oversight of novelty, non-obviousness and industrial utility helps to ensure that applications that do not satisfy the criteria are not granted patent protection, so that those inventions enter the market at a competitive price. Adjudicators are arguably better able to shape the rights of the patentee against those of the public interest by utilising such functional considerations as novelty or industrial utility. In *Novartis AG v Union of India*,⁴⁵ for example, the High Court of Madras invoked both the internal limits within patent law and the flexibilities of Art.7 of the TRIPs Agreement⁴⁶ to deny a second use patent on the leukaemia drug Glivec.⁴⁷ Intellectual property rights and human rights may find common accord in the balance between public and private interests but their spheres of activity are clearly distinct. Thus it may be a violation of human rights law for a state to deny medicines to its peoples, but that in itself

does not mean that there is also an infringement of patent law. Is patent law's domain necessarily a subset of human rights? Should we only ever allow patents on acts which are consistent with human rights?⁴⁸

Hestermeyer submits that an affirmative human right of access to medicines would help to remove the "legal insecurity" in the interpretation of the TRIPs flexibilities so dramatically evidenced by the fate of South Africa's Medicines Act of 1997. Against Hestermeyer's proposition, it might be argued that the insecurity of developing countries in making use of TRIPs flexibilities is not a legal but a political issue, a factor of the political economy of intellectual property rights.⁴⁹ The connection between intellectual property rights and human rights has risen to the fore because the political economy of intellectual property rights is one **Int. T.L.R. 128* in which the continued expansion of patent rights has generated a backlash in the form of a counter-movement to the demand for strengthened intellectual property rights in countries where the innovation system is weak and the intellectual property system, established predominantly for the registration of foreign patents, is costly to administer. In fact, the author concedes that in the teeth of current political opposition, the likelihood of incorporating human rights within WTO law is remote, at least in the radical form of a WTO human rights treaty or the creation of a human rights exception within the TRIPs Agreement. The task of WTO panellists, in accordance with Art.3.2 of the Dispute Settlement Understanding--"to clarify the existing provisions" of the TRIPs Agreement, subject to the proviso that adjudicators are not to increase or diminish its rights and obligations--might arguably favour a narrow interpretation of the right of access.⁵⁰ Arguably, elaborating the normative content of TRIPs flexibilities using the law of human rights might be said to diminish the rights conferred on the patentee by unreasonably conflicting with the normal exploitation of the patent.⁵¹

In any event, the question remains as to whether the express incorporation of human rights within WTO law would meet the desired aim of facilitating broad access. Or would it unintentionally result in further limiting access by the withdrawal of investment? On the one hand, human rights may facilitate access by helping to reframe the issue from one of patent enforcement to implementing public health programmes for the poor. On the other hand, by framing the issue as one of conflict between human rights and patents, rights discourse also risks lending an adversarial perspective to the provision of affordable medicines in developing countries. For example, shortly after the court's decision in *Novartis AG v Union of India*, the Swiss pharmaceutical company announced that it would abandon plans to locate an R & D centre in Hyderabad.⁵²

Arguably, a shift in focus from rights to process might better help WTO members to accept their interdependency, identify their common interests and work in partnership to address healthcare needs in developing countries. The regulatory models provided by the Doha Declaration on TRIPs and Public Health, the Doha Development Agenda and Work Programme, are instructive.⁵³ They recognise the importance of interpreting the TRIPs Agreement in a manner supportive of public health, by promoting both access to existing medicines through tiered pricing as well as research and development into new medicines.⁵⁴ They focus on support and technical co-operation for developing and least-developed countries, as well as co-ordination with other international organisations in the task. Although subject to conditions against trade diversion, the Paragraph 6 Programme for the supply of generic medicines,⁵⁵ and initiatives by IGOs and MNCs for accelerated access⁵⁶ nonetheless represent a significant development in members' co-operating in fulfilment of the right of access to medicine.

**Int. T.L.R. 129* Moreover, the emergence of India as an economic power and major manufacturer of generic drugs has begun to provide the regulatory leadership to enable other developing countries to exploit the TRIPs flexibilities with renewed confidence. The amendment of India's Patents Act in 2005,⁵⁷ introducing patent protection for pharmaceutical products that is also qualified by the use of TRIPs flexibilities, has paved the way for similar legislative initiatives in neighbouring countries. For example, in June 2008, the Philippines enacted the Universally Accessible Cheaper and Quality Medicines Act⁵⁸ with the aim of promoting the supply of generic medicine by disallowing the grant of patents based on newly discovered uses of a known substance; allowing regulatory exemptions for generic manufacturers to use patented drugs to obtain marketing approval; parallel importation; and compulsory licensing of patented drugs in the event of a public health emergency.

Amajor contribution to the scholarship on intellectual property and human rights

Although readers may differ as to the degree to which they are persuaded by the author's thesis, they cannot fail to value this book as much for its rich exploration of the relationship between patent protection and access to medicine as for its finely argued debate on the incorporation of human rights

within WTO law. All those readers with a stake in the implementation of the TRIPs Agreement will admire Hestermeyer's scholarship for the light it sheds on the way in which human rights can provide a foundation for building a global model of pharmaceutical innovation that also seeks to maximise public welfare.⁵⁹

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1. The resolutions of international organisations and the writings of scholars are considered a subsidiary source of law: Art.38 of the Statute of the International Court of Justice. See "Intellectual Property Rights and Human Rights", Sub-Comm'n on Human Rights Res. 2000/7, pmb., recital 11, UN Doc. E/CN.4/Sub.2/RES/2000/7 (August 17, 2000); and "Intellectual Property and Human Rights", Sub-Comm'n on the Promotion & Prot. of Human Rights, Res. 2001/21, UN Doc. E/CN.4/Sub.2/RES/2001/21 (August 16, 2001): suggesting "actual or potential conflict exists between the implementation of the TRIPs Agreement and the realization of economic, social and cultural rights, in particular the rights to ... health ... and in relation to transfers of technology to developing countries". See further L.R. Helfer, "Human Rights and Intellectual Property: Conflict or Coexistence?" (2003) 5 Minn. Intell. Prop. Rev. 47, 48-49.
2. Hestermeyer adopts a broad definition of conflict to the effect that "a norm containing a permission, i.e. an option to take a certain course of action or not, is in conflict with a norm that commands or prohibits said course of action." *Human Rights and the WTO: The Case of Patents and Access to Medicines* (OUP, 2007), p.175.
3. In the last 27 years HIV has caused an estimated 25 million deaths worldwide and has generated profound demographic changes in the most heavily affected countries. Sub-Saharan Africa remains the region most heavily affected by HIV, accounting for 67% of all people living with HIV and for 75% of AIDS deaths in 2007. Joint United Nations Programme on HIV/AIDS (UNAIDS), *Report on the Global AIDS Epidemic* (2008), pp.29-30.
4. Notwithstanding the exclusive rights of patentees, the Act gives the government the power to "prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public" by means of parallel importation (s.15C) and compulsory licensing for generic manufacture (s.22C): <http://www.doh.gov.za/docs/legislation/acts/1997/act90.pdf> [Accessed September 24, 2008].
5. Agreement on Trade-related Aspects of Intellectual Property Rights, reprinted in World Trade Organization, *The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts* 321 (1995) (TRIPs Agreement or TRIPs).
6. *The Pharmaceutical Manufacturers' Association of South Africa v The President of the Republic of South Africa*, Notice of Motion, High Court of South Africa (Transvaal Provincial Division) Case number: 4183/98 February 1998, <http://www.cptech.org/ip/health/sa/pharmasuit.html> [Accessed September 24, 2008].
7. See Hestermeyer, *Human Rights and the WTO* (2007), p.75. See also John Braithwaite and Peter Drahos, *Global Business Regulation* (Cambridge: Cambridge University Press, 2000), pp.373-374.
8. See Hestermeyer, *Human Rights and the WTO* (2007), pp.44-49 describing the concerns developing countries voiced over public health during the negotiation of the TRIPs Agreement; and at pp.70-75 describing the impact of the first WTO case involving TRIPs, a complaint by the United States against India for failure to implement transitional provisions for the protection of pharmaceutical patents: *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, 1997, Appellate Body Report, WT/DS50/AB/R.
9. TRIPs Agreement Art.27 provides an inclusive definition of patentable subject-matter. It stipulates that patents "shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". Article 28 confers on the patentee the negative right "to prevent third parties not having the owner's consent from acts of making, using, offering for sale, selling, or importing for these purposes that product".
10. TRIPs Art.33: Term of protection.
11. This claim on the potential power for monopoly pricing patentees was given following the entry into force of the TRIPs Agreement in 1995. Hestermeyer compares the price of AZT, the first anti-HIV drug produced by Burroughs Wellcome in 1987, at \$US10,000 per year per patient, with a yearly supply of an off-patent, generic version, produced in India in 2006, at \$US150 per person: *Human Rights and the WTO* (2007), p.5.
12. International Covenant on Economic, Social and Cultural Rights, adopted by the General Assembly on December 16, 1966 and entered into force January 3, 1976. On the right to health, see General Comment 14 of the UN Committee on Economic, Social and Cultural Rights, which analyses the normative content of Art.12 ICESCR: <http://www.unhcr.ch/tbs/doc.nsf/symbol/E.C.12.2000.4.En> [Accessed September 24, 2008]. Further concerning the content of Art.12 see Hestermeyer, *TRIPs and the Right to Health* (2007), pp.102-111.
13. Article 6(1) provides: "Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life." The ICCPR was adopted by the United Nations General Assembly on December 16, 1966 and entered into force on March 23, 1976: http://www.unhcr.ch/html/menu3/b/a_ccpr.htm [Accessed September 24, 2008]. Further concerning the content of Art.6 see Hestermeyer, *Human Rights and the WTO* (2007), pp.115-119.
14. Both the ICCPR and the ICESCR have been ratified by the majority of WTO Members: as of September 2004 the status of ratifications was 152 for the former and 149 for the latter: <http://www.unhcr.ch/pdf/report.pdf> [Accessed September 24, 2008]. Notably, the United States is among some 20 WTO Members that have yet to ratify the ICESCR: Hestermeyer, *Human Rights and the WTO* (2007), p.102.
15. Hestermeyer, *Human Rights and the WTO* (2007), p.98.
16. Chief among the TRIPs flexibilities, Art.8 expressly affirms that "[m]embers may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health"; Art.7 affirms that the transfer of technology should be made in a manner conducive to social and economic welfare; Art.30 provides additional flexibilities by way of "limited exceptions" to the exclusive rights conferred by a patent; and Art.31, as amended, allows governments to issue compulsory licences in order to permit the generic production of essential medicines without the consent of patent holders. Further on the TRIPs flexibilities and their interrelationship with human rights see Hestermeyer, *Human Rights and the WTO* (2007), pp.229-253.

17. While the UN Human Rights Committee (HRC) monitors implementation of the ICCPR and receives complaints, its findings are not enforceable (Art.28). The HRC may also entertain interstate claims whereby a state party may bring to the Committee's attention that another state party is not fulfilling its obligations under the Convention (Art.41). No comparable UN procedure exists with regard to economic, social and cultural rights. Further see International Commission of Jurists, "The Justiciability of Economic, Social and Cultural Rights: National, Regional and International Experiences", <http://www.icj.org/IMG/pdf/3.pdf> [Accessed September 24, 2008].
18. Discussing the status of the WTO in international law see D. McRae, "The Contribution of International Trade Law to the Development of International Law" (1996) 260 *Academy of International Law, Recueil des Cours* 114.
19. Hestermeyer, *Human Rights and the WTO* (2007), pp.211-112.
20. Concerning the characteristics of the WTO dispute settlement see G.E. Evans, *Lawmaking under the Trade Constitution: A Study in Legislating by the World Trade Organization, Studies in Transnational Economic Law*, (The Hague: Kluwer Law International, 2000), pp.44-50 and 164-167.
21. The provisions of the TRIPs Agreement are to be interpreted "in accordance with customary rules of interpretation of public international law" (Art.3.2 of the Dispute Settlement Understanding (DSU)) as embodied in the Vienna Convention (Note 16). In turn, Art.31(3)(c) of the Vienna Convention on the Law of Treaties stipulates that as part of the legal context, there shall be taken into account "any relevant rules of international law applicable in the relations between the parties".
22. Vienna Convention on the Law of Treaties 1969, entered into force on January 27, 1980, in accordance with Art.84(1): United Nations Treaty Series, Vol.1155, p.331, http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf [Accessed September 24, 2008].
23. See Panel Report, *Canada--Patent Protection of Pharmaceutical Products*, WT/DS114/R (March 17, 2000).
24. TRIPs Art.27 stipulates that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced".
25. On the potential application of TRIPs Art.73 Correa is of the view that a health crisis might justify invoking the security exception: *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (OUP, 2007), p.520.
26. World Health Organization, *A Safer Future: Global Public Health Security In The 21st Century* (2007), Ch.1, Ch.1 Box 1.1, http://www.who.int/whr/2007/07_chap1_en.pdf [Accessed September 24, 2008].
27. Concerning the inapplicability of the incentive theory to developing countries see Hestermeyer, *TRIPs and the Right to Health* (2007), pp.158-160.
28. Hestermeyer, *Human Rights and the WTO* (2007), pp.158-160.
29. Hestermeyer, *Human Rights and the WTO* (2007), pp.169-170.
30. Braithwaite and Drahos, *Global Business Regulation* (2000), pp.56-57.
31. Paris Convention for the Protection of Industrial Property of March 20, 1883, as last revised at Stockholm on July 14, 1967 (*United Nations Treaty Series*, Vol.828, No.11847, p.108).
32. Braithwaite and Drahos, *Global Business Regulation* (2000), p.61.
33. Patents (Amendment) Act 1970, No.39 of 1970, Acts of Parliament, 1970, www.wipo.int/clea/en/details.jsp?id=2393 [Accessed September 24, 2008].
34. Utilitarian theorists normally endorse the creation of intellectual property rights as a means of promoting innovation, subject to the proviso that such rights should be limited in duration so as to balance the welfare loss of monopoly exploitation: P. Menell, "Intellectual Property: General Theories" in B. Bouckaert, and G. de Geest (eds), *Encyclopedia of Law and Economics* (2000), p.129.
35. See for example, Doha Declaration on TRIPs and Public Health para.5(b), which recognises that the TRIPs Agreement allows Member States "the freedom to determine the grounds upon which such licences are granted"; and para.5(c), which recognises that each member has the right to determine what constitutes a national emergency or circumstance of extreme urgency, and that HIV/AIDS, malaria, tuberculosis, and other epidemics could constitute such emergencies. Finally, para.7 exempts least developed country members from having to implement patent and data protection rules (in ss.5 and 7 of Pt II of the TRIPs Agreement) with respect to "pharmaceutical products" (defined in an Annex to the TRIPs Agreement, http://www.wto.org/english/tratop_e/trips_e/wt1641_e.htm [Accessed September 24, 2008]) until January 1, 2016; nor does the text of the Declaration suggest that these provisions are restricted to medicines used to treat specific diseases.
36. See Doha Declaration on TRIPs and Public Health para.4: "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." WT/MIN(01)/DEC/2 November 20, 2001.
37. The decision of August 30, 2003 addressed the public health needs of developing countries with no capacity to manufacture pharmaceuticals. The so-called para.6 solution created a mechanism for the import of cheaper generics made under compulsory licensing abroad. The Decision had to be classified as a waiver under Art.IX(3) of the Agreement Establishing the WTO (AEWTO), even though it disregards several of the requirements imposed by that provision: http://www.wto.org/english/docs_e/legal_e/04-wto.pdf [Accessed September 24, 2008].
38. In December 2005 the entire Decision of August 30, 2003 was transformed into a permanent amendment. The derogations from Art.31(f) and (h) of the TRIPs Agreement are contained in new Art.31bis. Definitions and conditions (such as special labelling and colouring of the drugs) are contained in an Annex to the TRIPs Agreement: http://www.wto.org/english/tratop_e/trips_e/wt1641_e.htm [Accessed September 24, 2008].
39. Once two-thirds of WTO Members have ratified it the amendment will take effect, replacing the 2003 waiver: (Art.X (3) AEWTO). For the majority of countries (18 out of 153 members) it remains a temporary waiver. The deadline for ratification has been extended to December 31, 2009: http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm [Accessed September 24, 2008].
40. The notification (IP/N/9/RWA/1) filed on July 19, 2007 was the first of a number of steps that needed to be taken before the generic version of the drug, manufactured in Canada, reached patients in Rwanda: "Rwanda Becomes First Country to Try to Use WTO Procedure to Import Patented HIV/AIDS Drugs" (2007) 11 *Bridges Weekly Trade News Dig.*, <http://www.ictsd.org/weekly/07-07-25/story2.htm>.
41. Hestermeyer submits that Art.15(c) of the ICESCR which protects the "moral" and "material" interests of inventors does not justify the interference of patent laws with access to medicines: *Human Rights and the WTO* (2007), pp.157-158.
42. The exclusive rights of sale conferred on the patentee are the chief means by which the pharmaceutical industry recovers its expenses:

- J.H. Barton and E.J. Emanuel, "The Patents-Based Pharmaceutical Development Process: Rationale, Problems, and Potential Reforms" (2005) 294(16) J.A.M.A. 2075, 2076. The doctrine of functionality within patent law serves to ensure that its standards of novelty and utility are not eroded by effectively granting protection for the functional features of an invention through other, less exacting, forms of intellectual property protection": Menell, "Intellectual Property: General Theories" in *Encyclopedia of Law and Economics* (2000), p.153.
43. See Rochelle Dreyfuss, arguing that a utilitarian justification for patent rights is better suited to the task of furthering social welfare: "Patents and Human Rights: Where is the Paradox?" New York University, Law and Economics Research Paper No 06-38, pp.2, 7-9: available at SSRN: <http://ssrn.com/abstract=929498> [Accessed September 24, 2008].
 44. For example, in December 2005, the Chancellor of the Exchequer asked Andrew Gowers, a former editor of the *Financial Times*, to conduct an independent review into the UK intellectual property system. The resulting Gowers Report (http://www.hm-treasury.gov.uk/media/583/91/pbr06_gowers_report_755.pdf) prompted the Intellectual Property Office to review the inventive step requirement in United Kingdom patent law and practice: <http://www.ipo.gov.uk/responseinventive.pdf>.
 45. High Court of Judicature at Madras, August 2007. The case concerned a petition under Art.226 of the Constitution of India asking the court to declare that s.3(d) of the Patents Act, 1970 as substituted by the Patents (Amendment) Act 2005 (Act 15/2005) was unconstitutional: <http://judis.nic.in/chennai/chejudis.asp> [Accessed September 24, 2008].
 46. See Hestermeyer, *Human Rights and the WTO* (2007), pp.211-112.
 47. Section 3(d) as amended by the Patents (Amendment) Act 2005, excludes patents for new uses of known substances in the following terms: "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance ..." Novartis argued that, by inserting s.3(d), the government has violated its obligation under TRIPs which provides for liberal patent regime and hence Section 3(d) should be declared null and void as going against the spirit of binding international treaty.
 48. Hestermeyer argues in favour of a normative hierarchy in international law that would allow the "moral" to effectively transcend the "material": *Human Rights and the WTO* (2007), pp.185-192. See, however, *Anheuser-Busch Inc v Portugal* (73049/01) [2007] 45 E.H.R.R. 36, where the Grand Chamber of the European Court of Human Rights extended the protection of fundamental property rights under Art. 1 of Protocol No.1 of the European Convention on Human Rights both to intellectual property as well as applications for the grant or registration of intellectual property: at [75]-[78]: <http://www.echr.coe.int/ECHR/EN/Header/Case-Law/HUDOC/HUDOC+database/> [Accessed September 24, 2008].
 49. Susan Sell argues that the perceived inflexibility of TRIPs created new agents. In Ch.6, "Life after TRIPs--Aggression and Opposition", she highlights the rise of public interest groups as a countervailing force against private sector advocates for high protectionism: *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press, 2003).
 50. See Arts 3.2 and 19.2 of the DSU in respect of panel interpretations and findings "not adding to or diminishing the rights and obligations provided in the covered agreements". See also the Appellate Body: "[W]e do not consider that Article 3.2 of the DSU is meant to encourage either panels or the Appellate Body to 'make law' by clarifying existing provisions of the WTO Agreement outside the context of resolving a particular dispute." *Wool Shirts and Blouses*, WT/DS33/AB/R, Appellate Body, 1997 at p.19.
 51. See TRIPs Art.30 concerning "Exceptions to Rights Conferred" in accordance with which "Members may provide limited exceptions to the exclusive rights conferred by a patent, 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 owner, taking account of the legitimate interests of third parties".
 52. See "Novartis withdraws investment from India", *Chemistry World*, October 2007, <http://www.rsc.org/chemistryworld/Issues/2007/October/NovartisWithdrawsInvestmentFromIndia.asp> [Accessed September 24, 2008]. See further Hestermeyer on the human rights obligations of multinational corporations: *Human Rights and the WTO* (2007), pp.94-99.
 53. See comparable initiatives undertaken by Member States of the World Intellectual Property Organization (WIPO), notably the "45 Adopted Recommendations under the WIPO Development Agenda," para.14 of which states: "Within the framework of the agreement between WIPO and the WTO, WIPO shall make available advice to developing countries and LDCs, on the implementation and operation of the rights and obligations and the understanding and use of flexibilities contained in the TRIPs Agreement": <http://www.wipo.int/ip-development/en/agenda/recommendations.html> [Accessed September 24, 2008].
 54. DOHA Ministerial Declaration of November 20, 2001 para.17 states: "We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate declaration": http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm [Accessed September 24, 2008]. See also Gail E. Evans, "Strategic Patent Licensing for Public Research Organizations: Deploying Restriction and Reservation Clauses to Promote Medical R&D in Developing Countries" (2008) 34 *American Journal of Law & Medicine* 175.
 55. See "Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health" adopted by the General Council on August 30, 2003; and "Decision on the Amendment of the TRIPs Agreement, adopted by the General Council, 6 December 2005" and accompanying Annexures: http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm [Accessed September 24, 2008]. Further on provisions and programmes for technical assistance see TRIPs Art.67; Doha Declaration, para.2; Declaration on TRIPs and Public Health, para.7. Generally see "Technical Cooperation in the TRIPs Area": http://www.wto.org/english/tratop_e/trips_e/intel9_e.htm [Accessed September 24, 2008]. Similarly see Art.12 ICESCR: "The Committee wishes to emphasize that it is particularly incumbent on States parties and other actors in a position to assist, to provide 'international assistance and cooperation, especially economic and technical' (Covenant, Art.2.1.) which enable developing countries to fulfil their core and other obligations indicated in paragraphs 43 and 44 above." General Comment 14 of the UN Committee on Economic, Social and Cultural Rights, addressing the right to health in ICESCR Art.12, at para.45: [http://www.unhcr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En) [Accessed September 24, 2008].
 56. The Accelerating Access Initiative (AAI), begun in 2000, is a partnership between UNAIDS, the World Health Organization (WHO), the UN Children's Fund (UNICEF), the UN Population Fund (UNFPA), the World Bank and nine research-based pharmaceutical companies (Abbott, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Gilead Sciences, Merck & Co Inc, Pfizer, Roche and Tibotec) that work with governments and other stakeholders to broaden access to medicines for HIV/AIDS via preferential prices and supply of generic drugs: "Health Partnerships for the Developing World--2008, The R&D Pharmaceutical Industry's Contribution to the Health-Related UN Millennium Development Goals": <http://www.ifpma.org/index.php?id=672> [Accessed September 24, 2008].
 57. Patents Act 1970 as amended by the Patents (Amendment) Act 2005, No.15 of 2005, http://ipindia.nic.in/ipr/patent/patent_2005.pdf [Accessed September 24, 2008].
 58. Republic Act 9502, http://www.senate.gov.ph/republic_acts/ra_9502.pdf [Accessed September 24, 2008].
 59. The incorporation of human rights norms within the European Union's Economic Partnership Agreement with Caribbean states of July 2008 indicates their capacity to shift the analysis of healthcare to one of government accountability. The Cariforum-EU EPA affirms the parties' obligations to respect human rights and take full account of the health needs of their respective populations: See Recital 3 and Art.3 respectively, Acuerdo De Asociación Económica Entre Los Estados Del Cariforum, Por Una Parte, Y La Comunidad Europea Y Sus Estados Miembros, Por Otra 2008, http://ec.europa.eu/trade/issues/bilateral/regions/acp/pr220208_en.htm [Accessed September 24, 2008]. Further see L.R. Helfer, "Toward a Human Rights Framework for Intellectual Property" (2007) 40 U.C. Davis Law Review 977; and P.K. Yu, "Reconceptualizing Intellectual Property Interests in a Human Rights Framework" (2007) 40 U.C. Davis Law Review 1039.

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