

Patents and medicines: the relationship between TRIPS and the human right to health

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The link between medical patents and the human right to health has become a subject of central concern at the international level, as exemplified by the debates at the 2001 World Trade Organization (WTO) ministerial conference.¹ International attention to the issue has focused in large part on the HIV/AIDS crisis and the question of access to drugs for patients in developing countries, which are the most severely affected by the epidemic.² The issue of access to drugs is acute in the case of HIV/AIDS but is of general concern in most developing countries.

From a legal perspective, two main areas of law are relevant in current debates. First, the question of access to medicines is a central issue in any consideration of the human right to health. Human rights law, in particular through the Covenant on Economic, Social and Cultural Rights, has made a significant contribution to the codification of the human right to health and our understanding of its scope.³ Second, debates on access to drugs are now strongly linked to the questions of whether drugs can, and should, be patentable. The increasing scope of patentability in the health sector, codified in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), constitutes one of the most significant changes in law for developing countries that are WTO members.⁴

Intellectual property law and human rights law have largely evolved independently. However, with the broadening scope of patents in areas related to basic needs such as health, and recent developments in the health sector itself, the links between the two fields are becoming increasingly obvious and direct, necessitating further consideration of the relationship between the right to health and patents on medicines, in particular in the case of developing countries.

¹ See WTO, Declaration on the TRIPS Agreement and Public Health, Ministerial Conference, Fourth Session, WTO Doc. WT/MIN(01)/DEC/2 (2001) [hereafter Doha Health Declaration].

² Over 95% of people living with HIV/AIDS are in developing countries. See UNICEF-UNAIDS-WHO/HTP/MSF, *Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS* (May 2001) [hereafter Drug Price Report].

³ International Covenant on Economic, Social and Cultural Rights, New York, 16 Dec. 1966, repr. in *International Legal Materials* 6: 360, 1967 [hereafter ICESCR].

⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh, 15 Apr. 1994, repr. in *International Legal Materials* 33: 1197, 1994 [hereafter TRIPS Agreement].

While human rights documents have given some consideration to the position of intellectual property in relation to human rights, there has been no similar effort in the field of intellectual property.

This article starts by examining the conceptual framework in which the debate over access to drugs is taking place. The first section looks at the intellectual property perspective and examines in particular the situation as it is developing in the context of the TRIPS Agreement. The second section focuses on human rights and examines in particular the development of the links between human rights and intellectual property. Finally, the third section examines some of the possible solutions to the problem of access to drugs in developing countries, focusing on the contribution that human rights can make to the debate in the case of inconsistencies between intellectual property and human rights.

Access to drugs and the international intellectual property rights regime

General considerations

Intellectual property rights, in particular patents, are deemed to provide the necessary incentives for research and technological development. Patents are time-bound monopoly rights. They constitute a derogation from the principle of free trade by offering exclusive rights to an inventor to exploit the invention and stop others from using it without his/her consent. The rationale for granting patents is the need to reward an inventor. In practice, this translates mainly into a right to commercialize the invention and simultaneously to stop others from doing so. The exception to the free trade rule is balanced by limiting the duration of the right and by forcing the inventor to disclose the invention so that society at large benefits from scientific advancement.

Human rights protect the fundamental rights of individuals and groups. Fundamental rights can be defined as entitlements that belong to all human beings by virtue of their being humans.⁵ This is in direct contrast to property rights, which can always be ceded in voluntary transactions.⁶ As codified in the two UN covenants and other relevant instruments,⁷ human rights constitute the basic framework guiding state actions at the domestic and international levels.⁸ As a result, states must bear in mind their human rights obligations when they negotiate and implement international rules on intellectual property rights or trade liberalization.⁹

⁵ See e.g. Martha C. Nussbaum, 'Capabilities, human rights and the universal declaration', in Burn H. Weston and Stephen P. Marks, eds, *The future of international human rights* (Ardsley, NY: Transnational, 1999).

⁶ See e.g. Guido Calabresi and A. Douglas Melamed, 'Property rules, liability rules, and inalienability: one view of the cathedral', *Harvard Law Review* 85, 1972, p. 1089.

⁷ ICESCR; International Covenant on Civil and Political Rights, New York, 16 Dec. 1966, repr. in *ILM* 6, 1967, p. 368 [hereafter ICCPR].

⁸ Cf. preamble of the ICESCR.

⁹ See article 1 of the Vienna Declaration and Programme of Action, Vienna, 25 June 1993, UN Doc. A/CONF.157/24 (Part I), which states that '[h]uman rights and fundamental freedoms are the birthright of all human beings; their protection and promotion is the first responsibility of Governments.'

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Health concerns in the intellectual property rights system

Patents generally constitute an incentive for the development of the private sector in areas where they are granted. In the pharmaceutical sector, the private sector health industry finds them indispensable.¹⁰ Industry representatives argue that the pharmaceutical industry spends more than any other industry on R&D and that, while the development of new drugs is a costly process, it is relatively easy to copy an existing drug.¹¹ The patent system thus allows firms to charge prices that are higher than the marginal price of production and distribution for the first generations of patients, who are expected to absorb the cost of developing the drug. It is only after the patent protection for the product expires that competition among generic versions can bring the price closer to the marginal cost. Compared to products in other sectors, however, the marginal price of drugs tends to be higher due to the relative inelasticity of demand for medicines.¹²

Despite the pharmaceutical industry's plea for patent protection, a number of countries traditionally put restrictions on the patentability of drugs on public policy grounds.¹³ While patents on drugs are now the norm in developed countries, even those with significant interests in the pharmaceutical sector, such as Switzerland, introduced product patents on drugs relatively recently.¹⁴ As far as developing countries are concerned, a number of them provided either no patent protection or only partial protection in the pharmaceutical sector before the Uruguay Round of the world trade negotiations, in large part because they took the view that the health sector met a basic need and thus should be protected from full commercialization.¹⁵ India characteristically endorsed this position with its strict patent legislation which did not recognize product patents on pharmaceuticals.¹⁶

¹⁰ See e.g. Frédéric M. Scherer, 'Le système des brevets et l'innovation dans le domaine pharmaceutique', *Revue internationale de droit économique* 110: 1, 2000. Note also that intellectual property protection is also considered essential in influencing investment decisions, including in developing countries. See Ida Madiha Azmi and Rokiah Alavi, 'TRIPS, patents, technology transfer, foreign direct investment and the pharmaceutical industry in Malaysia', *Journal of World Intellectual Property* 4, 2001, p. 948, concerning Malaysia.

¹¹ See e.g. Harvey E. Bale, Jr, 'The conflicts between parallel trade and product access and innovation: the case of pharmaceuticals', *Journal of International Economic Law* 1, 1998, p. 637; Thomas B. Cueni, 'Industrial property protection: lifeline for the pharmaceutical industry', in Thomas Cottier and Peter Widmer, eds, *Strategic issues of industrial property management in a globalizing economy: abstracts and selected papers* 13 (Oxford: Hart, 1999).

¹² See e.g. John H. Barton, *Differentiated pricing of patented products*, Commission on Macroeconomics and Health Working Paper Series no. WG4: 2, 2001.

¹³ See e.g. Carlos Correa, *Integrating public health concerns into patent legislation in developing countries* (Geneva: South Centre, 2000).

¹⁴ For Switzerland, see Loi fédérale sur les brevets d'invention, 25 June 1954, *Recueil officiel des lois fédérales* 1955, p. 893 and amendment of 17 Dec. 1976, *Recueil officiel des lois fédérales* 1977, p. 1997. Note also that the trigger for this change in some European countries was the adoption of the European Patent Convention more than internal pressure to change the laws. See Friedrich-Karl Beir, 'The European patent system', *Vanderbilt Journal of Transnational Law* 14, 1981, p. 1.

¹⁵ World Health Organization, *Globalization, TRIPS and access to pharmaceuticals*, WHO Policy Perspectives on Medicines no. 3, 2001 [hereafter WHO Policy Perspectives].

¹⁶ See India Patents Act 1970. See also Justice N. Rajagopala Ayyangar, *Report on the Revision of the Patents Law*, Sept. 1959.

In recent years there have been wide-ranging debates concerning the potential contribution of the introduction of patents in developing countries to the development of drugs related to specific tropical diseases. One of the perceived advantages is that it should give incentives to the private sector pharmaceutical industry to undertake more R&D in finding cures for diseases common in developing countries.¹⁷ However, if patent protection has the capacity to raise incentives marginally, it may also support considerably higher prices.¹⁸ Further, it is uncertain whether the redistribution of resources to the private sector which accompanies the introduction of patents will trigger the development of more drugs specifically related to the needs of the poor.¹⁹ In fact, as noted by the World Health Organization (WHO), of the 1,223 new chemical entities developed between 1975 and 1996, only 11 were for the treatment of tropical diseases.²⁰

The issue of patent protection in the health sector has proved increasingly divisive. This is in part attributable to the fact that there is a significant tension between the pharmaceutical industry's aim to recoup its investments and governments' interest in containing the costs of health care. Further, from a theoretical point of view, it remains uncertain whether the intellectual property rights system does in fact provide an incentive to invent.²¹ Controversies at the theoretical and practical levels concerning patents on drugs have led to the search for alternatives. A number of proposals look at making the patent system more 'health friendly' by keeping the existing system in place and seeking new arrangements within it, focusing for example on some of the 'traditional' exceptions allowed in patent law such as compulsory licensing. In recent times, significant attention has also been given to differential pricing.

Access to drugs and medical patents

Access to drugs is one of the fundamental components of the human right to health.²² It is of specific importance in the context of the introduction of

¹⁷ Pradeep Agrawal and P. Saibaba, 'TRIPS and India's pharmaceuticals industry', *Economic and Political Weekly* 36, 2001, p. 3787.

¹⁸ See e.g. World Bank, *Global economic prospects 2002* (Washington DC: World Bank, 2001).

¹⁹ The Commission on Intellectual Property Rights, *Integrating intellectual property rights and development policy* (London: CIPR, 2002) [hereafter CIPR Report] notes at p. 33 that all the evidence examined concerning the role that intellectual property protection plays in stimulating R&D on diseases prevalent in developing countries 'suggests that it hardly plays any role at all, except for those diseases where there is a large market in the developed world'.

²⁰ WHO Policy Perspectives.

²¹ See e.g. John H. Barton, 'Intellectual property rights and innovation', in Nicholas Imparato, ed., *Capital for our time: the economic, legal, and management challenges of intellectual capital* (Stanford, CA: Hoover Institution Press, 1999), pp. 123 at p. 132, arguing that the intellectual property rights system generally favours large firms over small ones and in the final analysis stifles innovation rather than promotes it. As a result, the intellectual property system may contribute to an unnecessarily concentrated industrial structure.

²² See e.g. Commission on Human Rights, Resolution 2001/33, 'Access to medication in the context of pandemics such as HIV/AIDS', in *Report on the 57th Session*, 19 March–27 April 2001, UN Doc. E/2001/23-E/CN.4/2001/167.

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patents on drugs, because patents have the potential both to improve access, by providing incentives for the development of new drugs, and to restrict access, because of the comparatively higher prices of patented drugs. Accessibility generally refers to the idea that health policies should foster the availability of drugs, at affordable prices, to all those who need them.²³ This implies a strong link between lack of access to drugs and poverty. About one-third of the world's population does not have access to basic drugs, a proportion which rises above one-half in the most affected regions of Africa and Asia.²⁴ Furthermore, a large proportion of people in developing countries do not have access to medical insurance and more often than not pay for drugs themselves.²⁵ Since price is a major issue in access, it is significant that patented drugs are more expensive than generics.²⁶ However, patents are not the only factor influencing access,²⁷ since even cheap generic drugs may not be affordable for people below the poverty line. In these situations access can be ensured only through further measures such as public subsidies or price control measures. The sheer scale of the problem of access to drugs is only too clear in the context of HIV/AIDS. A consortium of international organizations has estimated that fewer than 10 per cent of the people living with HIV/AIDS in developing countries have access to antiretroviral therapy. This proportion goes down to about 0.1 per cent in Africa.²⁸

The links among patents, the price of medicines and access to drugs have been taken into consideration by various countries in developing their legal and policy framework in the health sector. India is particularly noteworthy in this respect. As noted above, India adopted patent legislation which prohibited product patents for medicines, and this constituted one of the major incentives for the development of a relatively strong pharmaceutical industry.²⁹ In the first 25 years after independence, the domestic pharmaceutical industry remained relatively small, and by 1970 (the year in which the Patents Act was passed) accounted for only about 25 per cent of the domestic market; but thereafter the restrictions on product patents, prices and foreign investment contributed to the rapid development of the industry, which now accounts for 70 per cent of bulk

²³ See e.g. Germán Velásquez and Pascale Boulet, 'Globalization and access to drugs: implications of the WTO/TRIPS Agreement', in *Globalization and access to drugs – perspectives on the WTO/TRIPS Agreement* 2, WHO doc. WHO/DAP/98.9 (1998). See also United Nations Development Programme, *Human development report 2001* (Oxford: Oxford University Press, 2001), p. 3, estimating that about 2 billion people do not have access to low-cost essential drugs.

²⁴ See e.g. Germán Velásquez, 'Médicaments essentiels et mondialisation', *Revue internationale de droit économique* 37: 1, 2000.

²⁵ See e.g. World Health Organization and World Trade Organization Secretariats, *Report of the workshop on differential pricing and financing of essential drugs*, Høsbjør, Norway, 8–11 April 2001.

²⁶ See e.g. Jérôme Dumoulin, 'Les brevets et le prix des médicaments', *Revue internationale de droit économique* 45: 1, 2000. In the case of Malaysia, see Azmi and Alavi, 'TRIPS, patents'.

²⁷ See e.g. Drug Price Report, p. 5, indicating that factors related to affordability include patents, limited volume, limited competition, import duties and tariffs, local taxes and mark-ups for wholesaling, distribution and dispensing.

²⁸ Drug Price Report.

²⁹ See e.g. Jean O. Lanjouw, *The introduction of pharmaceutical product patents in India: 'Heartless exploitation of the poor and suffering'?*, NBER Working Paper no. 6366, 1999.

drugs and meets nearly all the demand for formulations.³⁰ One of the most important impacts of the Indian Patents Act, prior to its recent TRIPS-related amendments, and the resulting development of a generic pharmaceutical industry has been significantly lower prices for drugs compared to other countries. Indeed, while drug prices in India were among the highest in the world in the initial stages of development, they are now among the lowest.³¹ This is not to say that access to drugs is universal—millions still cannot afford basic generic medicines—but the trend since 1970 has definitely been in the right direction.³² Apart from the exclusion of product patents, the Indian Patents Act introduced further measures to foster access to drugs. With regard to the duration of patent protection, the Act provided specific restrictions in the health sector. While normal patents were granted for 14 years, process patents on drugs or food were granted for only seven years.³³ The Act also provided a strict compulsory licensing regime which included not only compulsory licences but also licences of right.³⁴

The TRIPS Agreement and access to drugs

The main vehicle for the introduction of medical patents in developing countries is the TRIPS Agreement. TRIPS generally seeks to provide minimum levels of intellectual property protection in all WTO member states. In other words, all WTO member states must accept standards of protection which are generally equivalent to a consensus position among developed countries. In the field of patents, the final agreement stipulates the patentability of inventions, whether products or processes, in all fields of technology.³⁵ The TRIPS Agreement is, as its name implies, concerned mainly with the interests of intellectual property rights holders. Further, intellectual property rights in the TRIPS Agreement are seen mainly as a vehicle to foster international trade and not as a moral recognition for scientific or technological prowess. Despite the very ‘technical’ nature of the agreement, TRIPS has significant impacts beyond the trade and intellectual property areas. However, the linkages among intellectual property, environmental management and human rights are not given much prominence in the WTO framework.

The TRIPS Agreement is by any account a treaty of major importance. For developing countries, TRIPS was part of the broader package deal of the GATT

³⁰ Government of India, Department of Chemicals and Petrochemicals, *Annual Report 1999–2000*.

³¹ Shekhar Chaudhri, ‘The evolution of the Indian pharmaceutical industry’, in Greg Felker et al., eds, *The pharmaceutical industry in India and Hungary: policies, institutions, and technological development* (Washington DC: World Bank, 1997), p. 6.

³² Note also that the Patents Act 1970 was not the only element in the Indian health policy aimed at containing health costs. It was supplemented by other important tools such as the Drug Prices Control Order. The latest version of the latter is the Drug (Price Control) Order, 1995.

³³ See section 53 of the Indian Patents Act 1970.

³⁴ See sections 86ff. of the Indian Patents Act 1970, which authorized the government to force patent holders to provide licences to any applicant who made an application. While licences of right were to be authorized only in specific cases for normal patents, the Act provided that process patents for inventions relating to medicines were automatically subjected to these provisions.

³⁵ Article 27.1 of the TRIPS Agreement.

agreements of 1994. Even though TRIPS was never understood by these countries as being a good bargain, the agreement includes at least some broad safeguard provisions. The objective clause of the TRIPS Agreement provides, for instance, that intellectual property rights should ‘contribute to the promotion of technological innovation *and* to the transfer and dissemination of technology’.³⁶ The implementation of this provision requires a certain level of flexibility in implementing the substantive clauses of the TRIPS Agreement—or, in other words, differential treatment for developing countries.³⁷ TRIPS will have significant impacts on the realization of fundamental human rights, such as the right to food and health in developing countries. As far as health is concerned, TRIPS will be an important agent of change in the health sector, especially in countries which previously rejected product and/or process patents on drugs. Indeed, the introduction of such patents in the pharmaceutical sector implies a fundamental change of orientation for countries like Brazil where no patents were available in this field prior to the Uruguay Round.³⁸ In particular, the new regime will have important implications in countries like India where, as noted above, the domestic pharmaceutical industry owes its current status largely to the existing legal framework.

The TRIPS Agreement introduces a strict legal regime for intellectual property protection, but provides some exceptions and qualifications which can be used to foster certain public policy goals, such as access to essential drugs. TRIPS first reminds signatory states that the intellectual property rights regime put in place should contribute to the promotion of technological innovation and to the transfer and dissemination of technology in a manner conducive to social and economic welfare.³⁹ It also recognizes that the rights and obligations of patent holders should be balanced, thus acknowledging that limitations on intellectual property rights are a fundamental component of the regime. The agreement specifically indicates that states can adopt measures necessary to protect public health and to promote the public interest in sectors of vital importance to their socioeconomic and technological development.⁴⁰ The potential of these provisions has not been lost on developing countries, as is clear from a statement by India to the WTO that articles 7 and 8.2 of the TRIPS Agreement are overarching provisions that should qualify other provisions of TRIPS meant to protect intellectual property rights.⁴¹

Apart from the general qualificatory clauses in articles 7 and 8, a number of important exceptions are found in the patents section itself. First, some exceptions

³⁶ Article 7 of the TRIPS Agreement (emphasis added).

³⁷ Cf. statement by the Committee on Economic, Social and Cultural Rights on Human Rights and Intellectual Property, in Committee on Economic, Social and Cultural Rights, *Report on the 25th, 26th and 27th Sessions*, UN Doc. E/2002/22-E/C.12/2001/17, Annex XIII [hereafter CESCR IP Statement].

³⁸ See Brazil, Industrial Property Code, Law 5772/71, 21 Dec. 1971.

³⁹ Article 7 of the TRIPS Agreement.

⁴⁰ Article 8 of the TRIPS Agreement. However, it would be difficult to justify an exception not foreseen in TRIPS under article 8 unless it were an exception to a right which is not protected under TRIPS.

⁴¹ World Trade Organization, *Communication from India*, WTO Doc. IP/C/W/195 (2000).

to the scope of patentability are allowed.⁴² Article 27.2 allows states to restrict the patentability of inventions, for instance, if they pose a threat to human life or health. However, the restriction on patentability is not acceptable if the law simply bans the exploitation of the invention. This would, for instance, prohibit a blanket restriction on product patents on pharmaceuticals. Additionally, article 30 permits states to limit the exclusive privilege granted through patent rights. The major difference between article 27.2 and article 30 is that the latter does not allow states to reject the patentability of a given drug or other invention but only to regulate its use. The exception provided at article 30 is also bound by several qualificatory provisions. First, there can be only ‘limited exceptions’ to monopoly rights. Second, the exceptions should not ‘unreasonably conflict’ with the exploitation of the patent; and third, the exceptions should not ‘unreasonably prejudice the legitimate interests’ of the patent owner. While the exceptions provided by article 30 are bound by these qualificatory statements, there is no definition of what the ‘limited exceptions’ can be. This provision can thus be used by countries to pursue public health goals. Indeed, that is exactly what the objectives clause of article 7 requires by calling for a balance between the promotion of innovation and the transfer and dissemination of innovation, and for a balance of rights and obligations on the part of the patent holder. This analysis is confirmed by a reading of the last part of article 30, which provides that states must both avoid ‘unreasonably’ prejudicing the interests of patent owners and at the same time take into account the legitimate interest of third parties. On this basis, it may even be possible to argue that article 30 permits states facing a severe HIV/AIDS crisis to make exceptions to patent rights to meet the ‘legitimate interests of third parties’—in other words, of HIV/AIDS patients who need access to existing life-saving drugs.

The general exceptions provided for in articles 27.2 and 30 are supplemented by article 31, which sets out a regulatory framework for compulsory licensing. Compulsory licensing is permissible under TRIPS but under strict conditions.⁴³ These include the following: states can allow compulsory licensing only on a case-by-case basis; they must first try to secure authorization on commercial terms unless it is a situation of national emergency or the state wants to make public non-commercial use of the invention; further, the term of the licence must be limited in time to the purpose for which it is authorized, must be non-exclusive, and must be mainly to supply the domestic market; the patent holder is entitled to ‘adequate’ remuneration and the decisions taken are subject to judicial review.

The compulsory licensing framework offers developing countries tools with which to control some of the impacts of the introduction of patents even where they are forced to extend patentability to new areas under article 27. The positive features from the perspective of public health include the fact that there

⁴² In principle, all inventions, whether product or processes, in all fields of technology are patentable. See article 27 of the TRIPS Agreement.

⁴³ See article 31 of the TRIPS Agreement.

is no limitation on the purposes for which compulsory licences can be granted, thus giving member states significant leeway in framing public health and other public policy goals.⁴⁴ This remains limited in so far as article 31 allows the licensing only of individual inventions. Clauses permitting the compulsory licensing of a whole class of products, such as drugs, would therefore be unacceptable.⁴⁵

Other important features of article 31 include the provisions concerning remuneration of the patent holder. While article 31(h) stipulates adequate remuneration, the context of article 31 implies that this remuneration is necessarily below the cost of a normal licence, since there would be no need for compulsion otherwise.⁴⁶ Article 31 also leaves states free to determine what constitutes a national emergency, as confirmed by the Doha declaration of 2001.⁴⁷ This is one of the clauses which may foster significant flexibility in TRIPS in the case of health emergencies. Indeed, African heads of state have proclaimed HIV/AIDS to represent a state of emergency across the whole continent.⁴⁸ They have also specifically stated their intention to use international trade regulations to ensure the availability of drugs at affordable prices.

Article 31(f) also addresses issues related to the exercise of patent rights and importation. As specified under article 28, the patent holder is not forced to produce the protected invention industrially in the country where it is registered. Commercial use through imports is also possible.⁴⁹ However, article 6 specifically indicates that the question of parallel imports is not dealt with under TRIPS.⁵⁰ This leaves countries free to decide whether to take advantage of existing price differences in countries around the world. In the case of compulsory licensing, countries can still take advantage of these provisions if they do not have the capacity to manufacture or can find cheaper alternatives elsewhere. However, article 31(f) restricts countries from compulsorily licensing an invention to manufacture it mainly for export. Articles 6 and 31(f) read together can thus be used by countries that have relatively high drug prices in their domestic market or no manufacturing capacity to buy elsewhere. In practice, the usefulness of compulsory licences for developing countries remains a matter of debate, partly

⁴⁴ As confirmed by the Doha Health Declaration.

⁴⁵ Cf. section 87 of the Indian Patents Act 1970 providing in derogation of the general regime that all food- and medicine-related inventions should be deemed to be endorsed with the rubric 'licence of right'.

⁴⁶ See e.g. Jayashree Watal, *Intellectual property rights in the WTO and developing countries* (New Delhi: Oxford University Press, 2001); Robert Weissman, 'A long, strange TRIPS: the pharmaceutical industry drive to harmonize global intellectual property rules, and the remaining WTO legal alternatives available to Third World countries', *University of Pennsylvania Journal of International Economic Law* 17, 1996, p. 1069. Cf. Daniel Gervais, *The TRIPS Agreement: drafting, history and analysis* (London: Sweet & Maxwell, 1998).

⁴⁷ See Section 5(c) of the Doha Health Declaration.

⁴⁸ Organization of African Unity, *Abuja Declaration on HIV/AIDS, tuberculosis and other related infectious diseases*, 27 April 2001, OAU Doc. OAU/SPS/ABUJA/3 (2001).

⁴⁹ The understanding of what amounts to 'working' the patent has changed over time and industrial use is not required any more. Cf. Carlos M. Correa, *Intellectual property rights and the use of compulsory licences: options for developing countries*, Working Paper no. 5 (Geneva: South Centre, 1999).

⁵⁰ On parallel imports, see generally Frederick M. Abbott, 'First report (final) to the Committee on International Trade Law of the International Law Association on the subject of parallel importation', *Journal of International Economic Law* 1, 1998, p. 607.

because they have not been applied, having at most been used as a bargaining chip in negotiations with pharmaceutical companies.⁵¹

The international human rights regime and access to drugs

Until recently, intellectual property law has been only very loosely linked to human rights law. This is because the intellectual property system has traditionally not been informed by socioeconomic concerns. The extension of patentability to sectors directly linked to the fulfilment of basic needs, such as health, requires renewed analysis of the linkages between intellectual property and human rights. This section focuses specifically on the human right to health and its relationship to the intellectual property rights system.

Health as a human right

The importance of a healthy life has generally been acknowledged at both national and international levels. Health as a human right has been included in a number of international instruments but, like other economic and social rights, it remains subject to frequent criticism for being vague in content and intersecting with too many other rights.⁵² One of the most detailed pronouncements of this right is found in the International Covenant on Economic, Social and Cultural Rights (ESCR Covenant) which recognizes everyone's right to the 'enjoyment of the highest attainable standard of physical and mental health'.⁵³ The right to health implies, like other economic and social rights, obligations to respect, protect and fulfil that right. States are to refrain from interfering directly or indirectly with the enjoyment of the right; they should take measures to prevent third parties from interfering with the guarantees provided; and they should adopt appropriate legislative, administrative and other measures towards the full realization of the right.⁵⁴

The covenant generally requires member states to take all feasible steps to the maximum of their available resources progressively to achieve the full realization of the protected rights. It also indicates that these measures should be taken both by individual states and through international assistance and cooperation.⁵⁵ The covenant thus recognizes that the full realization of the rights may require more than domestic measures. It is symptomatic that the Committee on Economic, Social and Cultural Rights (ESCR Committee) has indicated in its authoritative interpretation of the right to health that states have an obligation to facilitate

⁵¹ See e.g. Frederick M. Abbott, 'The TRIPS Agreement, access to medicines, and the WTO Doha ministerial conference', *Journal of World Intellectual Property* 5, 2002, p. 15.

⁵² Cf. David P. Fidler, *International law and infectious diseases* (Oxford: Oxford University Press, 1999).

⁵³ See article 12 of the ICESCR. On the right to health, see generally Brigit C. A. Toebes, *The right to health as a human right in international law* (Antwerp: Intersentia, 1999).

⁵⁴ See Committee on Economic, Social and Cultural Rights, General Comment no. 14, *The right to the highest attainable standard of health*, UN Doc. E/C.12/2000/4 (2000) [hereafter General Comment 14].

⁵⁵ ICESCR.

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access to essential health facilities, goods and services in other countries and to provide the necessary aid when required.⁵⁶ Further, states are to ensure that other international agreements to which they accede do not adversely impact on the right to health. These are indications that states must, for instance, cooperate in making drugs available at affordable prices.

As expounded by the ESCR Committee, the core obligations of the right to health include the imperative to ensure the right of access to health facilities, especially for vulnerable or marginalized groups.⁵⁷ In the case of primary health care, this includes the promotion of a safe and adequate food supply and proper nutrition; an adequate supply of safe water and basic sanitation; immunization against the major infectious diseases; appropriate treatment of common diseases and injuries; and provision of essential drugs.⁵⁸ In the case of HIV/AIDS more specific elaborations of these obligations have been given. The World Health Assembly has, for instance, called on its member states to increase access to treatment and prevention of HIV-related illnesses through measures such as ensuring provision and affordability of drugs.⁵⁹ The UN Human Rights Commission has taken the same direction with its resolution on HIV/AIDS stating that access to medication in this context is one fundamental element for achieving the full realization of the right to the enjoyment of the highest attainable standard of physical and mental health.⁶⁰

Apart from emphasizing the importance of accessibility and affordability, the ESCR Committee has also indicated some circumstances in which the right to health is said to be violated. This includes, for instance, the repeal of legislation which is necessary for the continued enjoyment of the right to health, or the adoption of legislation or policies manifestly incompatible with pre-existing domestic or international legal obligations in relation to the right to health.⁶¹ Similarly, the obligation to respect the right to health is violated if a state fails to take into account its legal obligations when entering into bilateral or multilateral agreements.⁶²

Links between intellectual property and human rights

From the point of view of human rights instruments, the relationship between the intellectual property rights system and the realization of human rights has

⁵⁶ General Comment 14.

⁵⁷ General Comment 14.

⁵⁸ See article VII of the Declaration of Alma-Ata, 12 Sept. 1978, repr. in *Report of the International Conference on Primary Health Care* (Geneva: World Health Organization, 1978).

⁵⁹ World Health Assembly, 'HIV/AIDS: confronting the epidemic', Resolution WHA53:14 (Genoa: World Health Organization, 2000).

⁶⁰ Commission on Human Rights, 'Access to medication in the context of pandemics such as HIV/AIDS', Resolution 2001/53 (23 April 2001).

⁶¹ General Comment 14.

⁶² See e.g. CESCR IP Statement, para. 12, which states specifically that 'any intellectual property regime that makes it more difficult for a State party to comply especially with its core obligations in relation to health, food, education or any other right set out in the Covenant, is inconsistent with the legally binding obligations of the State party.'

been given only limited consideration. References to the links between the two fields seem to have surfaced mainly in two distinct periods, namely at the time of the drafting of the ESCR Covenant and the Universal Declaration of Human Rights,⁶³ and more recently following the adoption of TRIPS and the growing importance of intellectual property rights in the realization of some human rights.

In treaty law, the core human rights provision dealing with intellectual property is found in the ESCR Covenant. Article 15.1(c) recognizes everyone's right 'to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author'.⁶⁴ The context within which intellectual property was included in human rights treaties is of direct relevance, given the lack of state practice. First, sub-paragraph (c) was not present in the original draft covenant of 1954. Article 15.1 included only two sub-paragraphs, which recognized everyone's right to take part in cultural life and the right 'to enjoy the benefits of scientific progress and its application'.⁶⁵ Article 15.1 was thus conceived mainly from the point of view of the 'end users' of scientific inventions or cultural development. The original article did not include even an indirect reference to the interests of inventors or authors. Article 15.1(c) must thus be read as an addition and should not be given precedence over the first two sub-paragraphs of the article.⁶⁶ Further, article 15.1(c) refers only to 'authors'. Indeed, the rationale for the introduction of the amendment, by Costa Rica and Uruguay, was to protect authors against improper action on the part of publishers.⁶⁷ Uruguay argued that the lack of international protection allowed the piracy of literary and scientific works by foreign countries which paid no royalties to authors.⁶⁸ The intention was not to qualify the first two sub-paragraphs but rather to highlight one specific problem.⁶⁹

Article 15.1(c) directly derives from article 27.2 of the Universal Declaration.⁷⁰ The drafting history of the declaration brings some more useful elements to the fore. First, the original article 27 did not include a second paragraph.⁷¹ This was added following an amendment proposed by Mexico on the basis of a similar

⁶³ Universal Declaration of Human Rights, 10 Dec. 1948, UN General Assembly Resolution 217 (III) A, *Official Records of the Third Session of the General Assembly*, Part 1, 21 Sept.–12 Dec. 1948, Resolutions.

⁶⁴ Article 15.1(c) of the ICESCR.

⁶⁵ Draft Covenant on Economic, Social and Cultural Rights, Commission on Human Rights, Report of the 10th Session, ECOSOC, 18th Session, Suppl. 7, Doc E/2573-E/CN.4/705 (1954). Note that article 15 was article 16 in the 1954 draft. References in this article are all to article 15.

⁶⁶ For the text of the proposed amendment, see UN Doc. A/C.3/L.636/Rev.1 (1957).

⁶⁷ Draft International Covenant on Human Rights, Report of the 3rd Committee, UN Doc. A/3764 (1957).

⁶⁸ United Nations, Third Committee Summary Record of Meetings, UN Doc. A/C.3/SR.797 (1957).

⁶⁹ Note that the amendment was accepted by 39 states, including most west European and Latin American countries, and rejected by nine countries from the communist bloc. Twenty-four countries abstained, including the United States. See Draft International Covenant on Human Rights, Report of the 3rd Committee, UN Doc. A/3764 (1957).

⁷⁰ United Nations, Third Committee Summary Record of Meetings, UN Doc. A/C.3/SR.796 (1957).

⁷¹ See United Nations, Report of the 3rd Session of the Commission on Human Rights, UN Doc. E/800 (1948). Note that article 27 of the final text was article 25 in the draft Declaration. References in this article are all to article 27.

provision included in the 1948 Bogota Declaration.⁷² In support of its submissions, Mexico argued that there was a need to add to the rights already protected in the draft declaration the rights of the intellectual worker, scientist or writer, so that all forms of work, manual and intellectual, would be protected on an equal basis.⁷³ Mexico and the other Latin American countries viewed the introduction of an intellectual property clause as a safeguard against predatory moves by foreign publishing houses. While some countries made reference to scientific development and patents in the course of the deliberations, statements show that state representatives usually analysed the clause from the perspective of copyright only.⁷⁴

Following the adoption of TRIPS, UN human rights bodies have progressively given more attention to the question of the impacts of intellectual property rights on the realization of human rights. Among the political organs, the Sub-Commission on Human Rights adopted, for instance, a resolution in 2001 which recognizes the existence of potential conflicts between the implementation of TRIPS and the implementation of economic, social and cultural rights.⁷⁵ Further, the ESCR Committee has embarked on the task of adopting a General Comment on the relationship between human rights and intellectual property. As an intermediary measure, a statement on the matter was adopted in 2001.⁷⁶ Though not binding on member states, this statement constitutes an important guide for an understanding of the human right to health in the TRIPS era. Specific elements of this statement are highlighted below.

The TRIPS Agreement and the human right to health

In most developing countries, the introduction of process and product patents on drugs is likely to influence access to drugs to a significant extent. There will be abrupt rises in price, impacts on local pharmaceutical industries and a greater emphasis on private sector research and development. Together, these are likely to create a situation where drugs become both less accessible and less affordable. There is therefore a direct link between the patentability of drugs on the one hand and, on the other, the availability of medicines, the realization of the right to health and ultimately of the right to life. In other words, it is necessary to analyse closely the relationship between intellectual property rights and the human right to health.⁷⁷

⁷² See article 13 of the American Declaration of the Rights and Duties of Man, repr. in *United Nations, human rights: a compilation of international instruments*, vol. II: *Regional instruments*, UN Doc. ST/HR/1/Rev. 5 (Vol. II), 1997; United Nations, *Draft International Declaration of Human Rights – Mexico: amendment to article 25 of the draft declaration*, UN Doc. A/C.3/266 (1948).

⁷³ United Nations, Third Committee Summary Record of Meetings, UN Doc. A/C.3/SR.150 (1948).

⁷⁴ See e.g. the statements of the Dominican Republic supporting the amendment, UN Doc. A/C.3/SR.799 (1957), and India, which abstained, UN Doc. A/C.3/SR.798 (1957).

⁷⁵ See Resolution 2001/21, 'Intellectual property and human rights', United Nations Sub-Commission on Human Rights, UN Doc. E/CN.4/Sub.2/RES/2001/21 (2001).

⁷⁶ CESCR IP Statement.

⁷⁷ Cf. United Nations Development Programme, *Human development report 2000* (Oxford: Oxford University Press, 2000), which mentions that TRIPS raises issues of compatibility with human rights and international environmental law.

Since human rights instruments mention intellectual property, it is germane to examine whether intellectual property rights qualify as human rights. The debates of 1948 and 1957 indicate that basic human rights treaties did not intend to recognize the interests of authors or inventors as fundamental human rights.⁷⁸ Both the Universal Declaration and the first covenant recognize as a basic claim everyone's right to enjoy the fruits of cultural life and scientific development; the right of the individual author is subsidiary in the balancing of priorities. The implication is that human rights put the emphasis on societal benefits.⁷⁹ This approach is opposed to that of intellectual property rights instruments, which focus mainly on the rights of authors, inventors and other legal entities to claim exclusive rights over an intellectual creation. The question of the balance of rights and obligations is addressed by the TRIPS Agreement, but here the interests of society at large figure more as an addition to—or even as an exclusion from—the rights provided than as an integral part of the treaty. Human rights treaties require the balance to be attempted from the perspective of society at large.

Overall, there appears to be a substantive difference between intellectual property rights, and the fundamental and universal entitlements called human rights. The former are temporary rights granted by the state that can be revoked and transferred, while the latter are inalienable and timeless.⁸⁰

Access to drugs after Doha

To date, only scant attention has been given to the relationship between TRIPS and the human right to health. This is due in part to the sectoral nature of international law but also to the unresolved issues raised by potential conflicts between different areas of international law. The general principle remains that developing countries should do their utmost to implement both the ESCR Covenant and TRIPS in such a way as to minimize conflicts. However, there are situations where conflicts may remain. This section starts by examining developing countries' options within the TRIPS framework as they are understood after the Doha meeting. It then goes on to examine ways in which conflicts between intellectual property rights and the human right to health could be resolved under international law.

Fostering access to drugs through the intellectual property system

Some of the avenues that developing countries can use within the TRIPS context to foster better access to drugs and the realization of the right to health in general have been outlined above. So far, the emphasis has been on finding acceptable interpretations of TRIPS from the point of view of access to drugs

⁷⁸ Sub-Commission on the Promotion and Protection of Human Rights, *The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights*, UN Doc. E/CN.4/Sub.2/2001/13 (2001).

⁷⁹ Cf. *ibid.*

⁸⁰ See CESCR IP Statement, section 6.

rather than examining the broader relationship between TRIPS and the right to health. This latter line of enquiry must, however, be pursued given that developing countries are obliged to implement TRIPS taking into account the existence of the ESCR Covenant and other relevant international treaties.

A number of recent developments at the international level indicate that developing countries can explore different possible interpretations of the TRIPS provisions or decide to act on the margin of TRIPS. This situation has been brought about largely by the scale of the HIV/AIDS crisis and the extremely high price of existing medicines used to alleviate the disease. In fact, the extent of the crisis has been sufficient to trigger the adoption of a US executive order which directs that measures taken by countries to promote access to HIV/AIDS medicines should not be challenged.⁸¹ The failed challenges to the South African and Brazilian Acts also indicate that even if the measures adopted are not strictly compliant with TRIPS, they are unlikely to be challenged again in the near future.⁸² This is likely to be the case with most laws seeking to foster better access to drugs for major epidemics but not necessarily for other diseases or in other sectors.⁸³

The question of the margin of manoeuvre that countries have in implementing TRIPS can be approached first from the perspective of the Doha Declaration. In effect, the Doha Declaration restates and increases the mechanisms that states can use within the TRIPS context to foster public health goals. The declaration confirms, for instance, that member states can interpret their TRIPS obligations in such a way that they contribute to and do not work against their health policies.⁸⁴ In other words, it reaffirms the importance of articles 7 and 8 in so far as they provide member states with a clear legal basis in TRIPS for taking measures that may diverge from generally accepted interpretations of the agreement.

The declaration is important for developing countries in that it strengthens the position of countries that want to take advantage of the existing flexibility within TRIPS.⁸⁵ The declaration does not open up new avenues within TRIPS,

⁸¹ US Executive Order no. 13,155, 'Access to HIV/AIDS pharmaceuticals and medical technologies', *Federal Register* 65, 2000, p. 30,521. Note, however, that under this executive order, beneficiary countries can benefit from its provisions only if they provide adequate and effective intellectual property protection.

⁸² In South Africa, the dispute concerned the Medicines and Related Substances Control Amendment Act, 1997 (Republic of South Africa, Government Gazette, 12 Dec. 1997). See *The Pharmaceutical Manufacturers' Association of South Africa et al. v. The President of the Republic of South Africa et al.*, Notice of Motion, High Court of South Africa (Transvaal Provincial Division), 18 Feb. 1998 and *The Pharmaceutical Manufacturers' Association of South Africa et al. v. The President of the Republic of South Africa et al.*, Joint Statement of Understanding (2001). In Brazil, the dispute concerned the Industrial Property Law, Law No 9.279 of 14 May 1996. See *Brazil: measures affecting patent protection—notification of mutually agreed solution*, WTO Doc. WT/DS199/4 (2001).

⁸³ The United States indicated as it was challenging Brazil in the WTO that it made a clear distinction between the health and other sectors. See United States Trade Representative, *2001 Special 301 Report* (Washington DC: USTR, 2001).

⁸⁴ Para. 4 of the Doha Health Declaration. See also Paul Vandoren, 'Médicaments sans frontières? Clarification of the relationship between TRIPS and public health resulting from the WTO Doha ministerial declaration', *Journal of World Intellectual Property* 5, 2002, p. 4.

⁸⁵ Cf. Abbott, 'The TRIPS Agreement', p. 38, suggesting more generally that measures adopted by developing and least developed countries to address public health should be presumed to be consistent with TRIPS and that any member challenging them should bear the burden of proof.

but confirms the legitimacy of measures seeking to use to the largest extent possible the flexibility already built into the agreement. In other words, it constitutes a confirmation of the position of countries like South Africa and Brazil which sought to go beyond a narrow interpretation of TRIPS in their search for ways to tackle health crises.

While the Doha Declaration has contributed to softening the tone of international debates concerning access to medicines in the context of TRIPS, it stops short of addressing the most significant issues in this field. Recent debates have focused mostly on the extent to which developing countries should be able to adapt the intellectual property rights system in situations where major problems have arisen. This does not address the question of whether the introduction of process and product patents in all WTO member states is generally reconcilable with the measures that states must take to foster the realization of the right to health.

The declaration also fails to provide answers to more practical questions, such as the prohibition on a country such as India compulsorily licensing a drug mainly to export it to other countries that do not have a manufacturing base of their own. If exports are not permitted in this context, most sub-Saharan African countries will not be able to take advantage of alternative sources of medicines.⁸⁶ This problem points to one of the major challenges that all developing countries will face in the future. If existing manufacturing capacity in countries like India were to be substantially reduced, this would have an impact not only on India but also on a number of other countries which do not have the capacity to manufacture drugs themselves and would therefore become totally dependent on supplies from developed country manufacturers.⁸⁷

Since the Doha meeting, there seems to be an international consensus that countries trying to deal with health emergencies will not be questioned in terms of their obligations under TRIPS. This, however, leaves completely open a number of other issues. As far as Brazil is concerned, while the United States halted the dispute settlement proceedings, it is not at all clear whether there is an international consensus that Brazil is free to grant compulsory licences for any 'reasons related to the public health, nutrition, protection of the environment or to the technological or social and economic development of the country'.⁸⁸ In the case of South Africa, article 15C(a) of the Medicines Act provides that patent rights can be overruled in some circumstances.⁸⁹ While the Act entered into force as adopted, it is unclear whether it will be fully implemented and, if so, whether implementation will go unchallenged. The theoretical acceptability

⁸⁶ See e.g. CIPR Report, p. 35.

⁸⁷ The Doha Health Declaration has not tackled this problem but required the TRIPS Council to provide a solution within a limited time frame (see para. 6 of the declaration).

⁸⁸ This constitutes the definition of 'public interest' under article 1 of the Brazilian Presidential Decree on Compulsory Licensing, Decree no. 3,201, 6 Oct. 1999. On this point, see also Paul Champ and Amir Ataran, 'Patent rights and local working under the WTO TRIPS Agreement: an analysis of the US–Brazil patent dispute', 27 *Yale Journal of International Law* 27, 2002, p. 365.

⁸⁹ See Medicines and Related Substances Control Amendment Act 1997, Republic of South Africa, *Government Gazette*, 12 Dec. 1997.

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of the Brazilian and South African laws thus does not indicate that all countries are entitled to deviate to such an extent from TRIPS.

From a broader perspective, even if deviation from TRIPS is allowed as an exception in the case of some health emergencies, this remains an unsatisfactory response from the perspective of human rights. It is not possible to distinguish the realization of the right to health from the eradication of poverty in general or the realization of the right to food and water. If exemptions are warranted in the case of health, they should be extended to all sectors related to the fulfilment of basic needs.

In other words, the fact that developing countries can use loopholes or unclear language in TRIPS to pursue the realization of the right to health is unsatisfactory in so far as the central concern of health is consistently framed as an exception to a property right. Thus the Doha Declaration on health is inadequate in so far as it merely extends the possibilities for granting compulsory licences and does not amend the TRIPS Agreement.

From the perspective of the right to health and access to drugs, the TRIPS Agreement needs to be revised to include principles in favour of access to drugs in the main provisions of the agreement rather than as exceptions.⁹⁰ However, an amendment to article 27 of TRIPS that would compulsorily reduce the scope of patentability is not very likely in the near future, while a strengthening of TRIPS in the context of forthcoming WTO negotiations is possible. There is, therefore, a need to analyse TRIPS in its present form and examine the extent to which states can fully implement their TRIPS obligations together with their human rights commitments.

Fostering access to drugs: linking human rights and patent rights

As noted, there are potential tensions between TRIPS and the ESCR Covenant. In trying to find a solution to the latent conflicts, it is of paramount importance to set the overall framework that should guide the more technical legal analysis. From the narrow perspective of access to medicines, the challenge is to find ways to make sure that existing drugs are available at little or no cost to people who need them. More generally, the central concern that should guide the implementation of all international treaties concerning health directly or indirectly is the promotion of better health care.

From the standpoint of TRIPS, the question of health can be tackled through some of the exceptions provided in section 5 of the agreement or through the two general qualificatory clauses of articles 7 and 8. This, however, falls short of an adequate resolution of the relationship between TRIPS and human rights. From the point of view of human rights, the link between the two fields was considered in the drafting of human rights treaties, when, as noted above, it was concluded that the interests of the community at large should generally prevail

⁹⁰ As argued by the World Bank; see *Global economic prospects 2002*, p. 148.

over those of individual authors. This does not imply a rejection of the interests of the author but rather their subordination to broader goals.⁹¹

A human rights perspective on health neither entails an *a priori* rejection of all intellectual property rights in the field of health nor provides another avenue for developing countries to claim preferential treatment. However, it does call into question some of the tenets of intellectual property law. As noted, patent protection does not ensure that the most common diseases will attract the most research even though it entails higher drug prices. This implies that even if patent protection can be justified in markets where all consumers can afford to pay (directly or indirectly) the price of patented drugs, this is not so in other situations. While there is a general divide between developed and developing countries with regard to the issues of drug prices and the development of medicines directly related to developing country diseases, a human rights approach to health is not strictly concerned with the level of economic development of countries. What is more fundamental from a human rights perspective is a focus on the most disadvantaged and marginalized individuals and communities. While human rights are universal entitlements, their effective realization is to be judged against the level of implementation among the most disadvantaged. The issue is therefore not whether developing countries can afford patent rights in general, but whether the majority of their poor population will benefit.⁹² One of the first steps in tackling the problems faced by the most disadvantaged sections of society would be to make sure that all essential medicines remain free from patent protection. This conceptual framework is what informed the 1970 Indian Patents Act, which rejected product patents on drugs, and, to a more limited degree, the Brazilian decree on compulsory licensing, which seeks to provide an extensive definition of the public interest.⁹³

From a practical point of view, patents on medicines in developing countries are fraught with other difficulties. In a number of countries, most people pay for their own health care. Since a large part of the population does not have access to existing drugs today, any price rise tends to limit access for more people. The Indian example is useful. Today, millions of Indian people cannot afford drugs under a regime which denies product patents on pharmaceuticals. If prices are allowed to go even higher under TRIPS-mandated product patents, even fewer people in India will have access to drugs. From this perspective, there is a need not for patent rights that lead to price rises but for even lower prices to facilitate broader access to drugs.

If compliance with TRIPS leads to reduced access to drugs, this might imply a substantive violation of the ESCR Covenant. Indeed, while article 2 of the covenant does not require immediate full implementation of the right to health,

⁹¹ See above, p. 136.

⁹² Similarly, the fact that developed countries in general can 'afford' the costs involved in patent-protected drug research does not imply that all individuals in those countries are in a position to benefit from the system.

⁹³ See Indian Patents Act 1970 and Brazilian Presidential Decree on Compulsory Licensing, Decree no. 3,201, 6 Oct. 1999.

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it requires states to take positive measures towards the fulfilment of that right.⁹⁴ The introduction of product patents could be construed as a ‘deliberately retrogressive’ step if no measures are taken to limit the impacts of TRIPS compliance on access to medicines.⁹⁵ From a health perspective, TRIPS is justified because, while it protects the interests of the private sector pharmaceutical industry, it also promotes increased R&D in the health sector. Going beyond controversies over the actual nature of the increases in R&D fostered by the patent system, it has become clear over time that, at the very least, the incentives provided by the patent system do not lead the private sector to invest preferentially in the most common diseases of the poor. As a result, one of the few possibilities open to developing countries to make sure that the introduction of medical patents does not constitute a retrogressive step in the implementation of the right to health is to provide significant public resources for R&D directed towards diseases of the poor and increased subsidies to facilitate access to drugs for the poorest.⁹⁶

Avoiding conflicts between human rights and intellectual property

The previous paragraphs highlight some of the problems that exist when trying to reconcile patents and the right to health but do not yet address the way in which international law would solve a conflict in practice if it occurred.⁹⁷ While most conflicts can be avoided with an interpretation that bridges the gaps between the different treaties, some further problems arise in the case of the relationship of WTO treaties and human rights treaties.

In case of conflict, states should first refer to treaty law, which provides broad rules of interpretation and reviews the question of conflicts between different treaties. At a general level, states must attempt to the maximum extent possible to reconcile all their international obligations, or at least to minimize conflicts, to comply with their duty to implement all their obligations.⁹⁸ International treaties are often sufficiently vaguely drafted to allow states significant room for manoeuvre in implementing them, and this provides an important tool enabling them simultaneously to implement fully all their international obligations.

Previous sections of this article show that patents on drugs and the right to health can be reconciled only to a certain extent. In other words, simultaneously meeting the different commitments under TRIPS and the ESCR Covenant

⁹⁴ Committee on Economic Social and Cultural Rights, General Comment no. 3, ‘The nature of states parties obligations (art. 2, para. 1 of the covenant)’, in *Compilation of general comments and general recommendations adopted by human rights treaty bodies*, UN Doc. HRI/GEN/1/Rev.4 (2000).

⁹⁵ *Ibid.*

⁹⁶ Cf. World Bank. The Bank would rather see public funds used to purchase drugs or licences than essential drugs removed from patentability; see *Global economic prospects 2002*, p. 148.

⁹⁷ Note that a conflict occurs if the fulfilment of one obligation leads to the violation of another commitment. A conflict can also arise where the only way to reconcile two treaties is to apply the one providing stricter obligations. On this point see Joost Pauwelyn, ‘The role of public international law in the WTO: How far can we go?’, *American Journal of International Law* 95, 2002, p. 535.

⁹⁸ See article 26 of the Convention on the Law of Treaties, Vienna, 23 May 1969, repr. in *International Legal Materials* 8, 1969, p. 679 [hereafter Vienna Convention 1969].

seems feasible only if states are allowed to adopt broad interpretations of TRIPS. Concerning the question of the relationship of the two treaties with each other, it is significant that neither specifically provides rules of interpretation.⁹⁹ However, it is not improbable that they may be on a collision course. TRIPS obligations tend to be precisely drafted and are backed by an effective dispute settlement mechanism.¹⁰⁰ The ESCR Covenant is drafted in much broader terms and there is no enforcement mechanism. The ESCR Committee has nevertheless indicated that a violation of the right to health can occur if states agree to international measures which are manifestly incompatible with their previous international legal obligations, an interpretation which clearly puts TRIPS in a lower position than the covenant in the hierarchy of obligations.¹⁰¹ The ESCR Covenant could also be seen as providing more specific norms in the field of the right to health, given that TRIPS addresses health concerns only peripherally.

While treaty law provides a number of rules to adjudicate conflicts between conventional norms,¹⁰² it is improbable that a conflict between human rights and other treaties can be satisfactorily addressed in this way. International law is to a large extent based on the principle that there is no hierarchy between sources of law and different areas of the law.¹⁰³ However, international law is not free from all forms of hierarchy. First, the UN Charter states that it prevails over any other treaty signed by its member states.¹⁰⁴ The charter does not, however, provide a clear answer to the question of conflicts between human rights and other treaty obligations.¹⁰⁵ Beyond the hierarchy recognized in the charter, the notion of *jus cogens* is noteworthy.¹⁰⁶ It is today largely agreed that there are some fundamental principles and norms that states are not free to modify or abrogate.¹⁰⁷ These include, for instance, the prohibition of slavery and crimes against humanity. The peremptory status of some other norms, such as the primacy of the respect for all human rights, remains controversial.¹⁰⁸ At the time of the drafting of the Vienna Convention on the Law of Treaties, a number of states mentioned human rights in their enumeration of peremptory norms. Further, human rights treaties recognize the peremptory status of some specific

⁹⁹ This makes reliance on the intention of the parties difficult. Cf. Pauwelyn, 'The role of public international law in the WTO', p. 543.

¹⁰⁰ See article 22 of the Understanding on Rules and Procedures Governing the Settlement of Disputes, Marrakesh, 15 April 1994, repr. in *International Legal Materials* 33, 1994, p. 1226.

¹⁰¹ See also Pauwelyn, 'The role of public international law in the WTO', p. 549, who concludes that the modification of human rights treaties by WTO treaties may have difficulties passing the test required by article 41.1(b) of the Vienna Convention 1969.

¹⁰² See Vienna Convention 1969.

¹⁰³ See e.g. Dominique Carreau, *Droit international*, 7th edn (Paris: Pédone, 2001).

¹⁰⁴ See article 103 of the UN Charter.

¹⁰⁵ Cf. Jean-Pierre Cot and Alain Pellet, eds, *La charte des Nations Unies: Commentaire article par article*, 2nd edn (Paris: Economica, 1991).

¹⁰⁶ See e.g. Lauri Hannikainen, *Peremptory norms (jus cogens) in international law: historical development, criteria, present status* (Helsinki: Finnish Lawyers' Publishing, 1989). See also Teraya Koji, 'Emerging hierarchy in international human rights and beyond: from the perspective of non-derogable rights', *European Journal of International Law* 12, 2001, p. 917.

¹⁰⁷ Article 53 of the Vienna Convention 1969.

¹⁰⁸ Carreau, *Droit international*.

rights.¹⁰⁹ However, while regional legal regimes such as the European Convention on Human Rights indicate an increasing recognition of the special nature of human rights, in general international law it is not yet possible to argue that all human rights are peremptory norms.¹¹⁰ The human right to health is clearly not a non-derogable right under present international law. However, if a hierarchy had to be established between human rights and intellectual property rights, it is likely that human rights would generally take precedence. This concurs with the conclusions of the UN Sub-Commission on Human Rights in its recent resolution on intellectual property and human rights, in which it noted ‘the primacy of human rights obligations under international law over economic policies and agreements’ and called on states to ensure that the implementation of TRIPS should not negatively impact on the enjoyment of human rights.¹¹¹

Overall, there seem to be a number of ways to resolve conflicts between the right to health and intellectual property rights without resorting to a prioritization between the two, for instance by guaranteeing the ‘social dimensions of intellectual property’.¹¹² Similarly, international judicial bodies have shown that they can go a long way towards resolving potential conflicts between different norms of international law. The concept of evolutionary approach – used, for instance, by the International Court of Justice – under which an old treaty can be interpreted in light of further developments in other fields of international law, is a case in point.¹¹³ However, in cases where prioritization is necessary, human rights should be given more weight than intellectual property rights. This is a situation that a number of countries may face. If the introduction of patents on medicines, which implies higher prices for drugs, is not counter-balanced with measures to offset price hikes and the shift in R&D away from diseases afflicting the poor, this is likely to lead to reduced access to drugs for most people in developing countries who have to pay for their own drugs. This situation is particularly in evidence in countries like India, which had formerly adopted specific restrictions on the patentability of drugs with a view to fostering better access to drugs. In this case, the dismantlement of a legal regime intended to foster better access to medicines is a step backwards in terms of the progressive realization of the human right to health. Unless these changes are offset by other measures such as subsidies to promote better access to drugs, this may amount to a violation of the ESCR Covenant which requires states at least to take positive measures towards implementation.¹¹⁴

¹⁰⁹ See e.g. article 4 of the ICCPR.

¹¹⁰ Some authors agree, however, that human rights are *jus cogens*. See e.g. Hannikainen, *Peremptory norms*, p. 429, noting that ‘[i]n my view there is no doubt that contemporary international law has reached a stage in which it has the prerequisites for the existence of peremptory obligations upon States to respect basic human rights.’

¹¹¹ Paras 3 and 5 of Resolution 2001/21, ‘Intellectual property and human rights’.

¹¹² Para. 18 of the CESCR IP Statement.

¹¹³ On this point, see e.g. Louise de la Fayette, ‘United States: import prohibition of certain shrimp and shrimp products; recourse to article 21.5 of the DSU by Malaysia’, *American Journal of International Law* 96, 2002, p. 685.

¹¹⁴ See text accompanying note 94 above, p. 140–41.

Conclusion

TRIPS is without doubt one of the most significant international treaties of the late twentieth century. In the field of health, it has had and will have sweeping impacts in most developing countries. One of the complications from an international law point of view is that TRIPS is being applied not in a vacuum but in a context where the right to health is a well-established human right codified in one of the two main international human rights treaties.

The introduction of patents on drugs has provoked a significant outcry in a number of developing countries where access to medicines is already abysmally low. The justifications offered for the existence of patents as incentives to innovation often do not appear convincing to patients in developing countries, who see that hardly any R&D is being invested in diseases specific to those countries. In other cases, such as HIV/AIDS, where drugs to alleviate the condition exist, the prices of these—for all practical purposes, life-saving—drugs have been so high as to render them unaffordable for all but the wealthiest in developing countries.

The legal arguments concerning the relationship between human rights and intellectual property rights, and the practical debates concerning access to drugs in developing countries, both point towards the existence of potential conflicts between the introduction of patents on drugs in developing countries and the realization of the right to health. While states must endeavour as far as possible to reconcile their different international obligations, there seem to be some cases where the implementation of TRIPS directly implies a reduction in access to drugs and thus a step back in the implementation of the right to health. This appears to be unacceptable under the ESCR Covenant and countries in this situation would be expected to give priority to their human rights obligations. This solution, which gives primacy to human rights, is unlikely to meet with the approval of all states and would probably not stand if it came for adjudication in a WTO context. It nevertheless seems adequate from a legal and ethical point of view.