



# III

## INTELLECTUAL PROPERTY AND SOCIAL & DEVELOPMENT ISSUES: THE CHALLENGES

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*The paper has so far analysed the global architecture of IPRs and the broad, cross-cutting issues that deserve attention when designing IPR policies. Part Three focuses on specific areas of concern for developing countries in the implementation of new IPR standards: health; food, agriculture and biodiversity; traditional knowledge and folklore; and access to knowledge in general, including educational technical and scientific information.*



## 6 Health

*Chapter 6 discusses one of the most controversial aspects emerging from efforts at extending intellectual property protection to areas that were not fully covered in the pre-TRIPS era. In this context, this chapter considers the relevance of IPRs to the pharmaceutical sector, and provides an overview of international deliberations on this topic, particularly in the context of the Doha Declaration.*

### Introduction

In the past few years, attention has increasingly focused on the relationship between patents and the availability and price of essential drugs. In particular, a number of governments, as well as non-governmental organizations (NGOs) concerned with health and development, have condemned pharmaceutical companies for taking advantage of their exclusive rights accorded by patents. They allegedly do this first, by charging high prices for treatments,

including for diseases which affect a large number of poor people who cannot afford them; second, by putting pressure on developing-country governments to prevent the local manufacture or import of cheaper, copied versions of the drugs produced in countries where they cannot be patented. In addition, they are criticized for not undertaking R&D on diseases affecting poor people.

### Relevance of intellectual property to pharmaceuticals

Under the TRIPS Agreement all WTO member countries became bound to grant patents for pharmaceutical products. This obligation did not exist under previous international conventions. When the Uruguay Round negotiations began, more than 50 countries in the world did not grant such protection, thereby enabling the commercialisation of low-cost, non-patented products. In addition, the Agreement obliged Members to reinforce rights conferred under process patents, and to protect - against unfair commercial use - the information submitted for the marketing approval of drugs.<sup>1</sup> The new obligations also included granting patent protection for at least 20 years from the date of application, limiting the scope of exemptions from patent rights and obligations, and effectively enforcing patent rights through administrative and judicial mechanisms (see chapter 2 above).

These rules dramatically changed the legal framework for the production and commercialisations of and access to drugs in developing countries, despite the fact that, as examined elsewhere,<sup>2</sup> the TRIPS Agreement provided certain leeway for member States to adopt measures to mitigate the monopolistic rights conferred by patents and promote competition. Such measures, which may lower prices and increase access to drugs include, notably,

- *compulsory licences*, that is, authorization by the State to a third party to exploit a patented invention, generally against a remuneration to the patent holder;
- *parallel imports* of patented products when they are obtainable in a foreign country (where a patent also exists) at lower prices; and

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- the possibility of establishing *exceptions* to the exclusive rights, such as the *early working exception* (also known as “Bolar exception”), which allows generic firms to initiate and obtain marketing approval of a patented drug before the expiration of the patent.

Some governments and the pharmaceutical industry objected to the use of some of these flexibilities, although they are TRIPS-consistent and increase allocative efficiency. In South Africa, national legislation established provisions allowing for the parallel importation of medicines, in certain circumstances, and provided also for compulsory licensing. These and other aspects of the legislation were challenged by 39 pharmaceutical companies and the South African Pharmaceutical Manufacturers Association (PMA) before that country’s Supreme Court. Development aid to South Africa was also conditioned on the withdrawal of such provisions.<sup>3</sup> After a global NGO campaign, led by activists from the United

States, Africa and Asia, the legal action was withdrawn. A complaint was also initiated in WTO against Brazil, challenging legislation that authorizes the granting of compulsory licences and parallel imports in instances when patent holders have not worked (i.e. produced) locally. This complaint was also withdrawn, but the potential conflict between patents and public health became an important issue in several international fora. The World Health Assembly, for example, addressed the subject in a resolution on the Revised Drug Strategy in 1996.<sup>4</sup> Subsequent resolutions adopted by the World Health Assembly in 2001<sup>5</sup> required the World Health Organization (WHO) to evaluate the impact of the TRIPS Agreement on access to drugs, local manufacturing capacity and the development of new drugs.<sup>6</sup> WHO-sponsored studies over the past decade provide an indication of the potential effects of the TRIPS Agreement in the area of pharmaceuticals (see box 6.1).

*Box 6.1: Impact of the TRIPS Agreement on Pharmaceuticals: Studies in Thailand and Brazil*

A study undertaken in Thailand on the impact of that country’s 1992 revised patent law, which essentially applies the same standards as those required by the TRIPS Agreement, found that there had been no significant increase in transfer of technology or FDI, and that spending on pharmaceuticals had increased at a higher rate than overall health care spending.

Another study on the implications of the new Industrial Property Code (1996) on local production and access to medicines in Brazil revealed, *inter alia*, that:

- Of the 1,387 drug patent applications filed since 1996, when the new Brazilian Industrial Property Act was signed into law, only 36 (2.6 per cent) were filed by residents of Brazil compared with more than 500 by United States residents.
- While Brazil’s total imports roughly doubled during the period 1982-1998, pharmaceutical imports increased more than 47 times.<sup>7</sup>

The relationship of patents and public health is, indeed, complex. On the one hand, patents are not the only factor that plays an important role in determining access to drugs.<sup>8</sup> Other factors, such as infrastructure and professional support, are also significant. But, at least in principle, patent monopolies place the companies holding them in a strong position to set prices at high levels, and this can have a profound impact on the ability of poor people to acquire them. These issues have been brought to the fore by the current HIV/AIDS pandemic, which is now one of the most serious

public health crises the world is facing. Africa is the most severely affected continent. Millions of infected people there are doomed to die over the next few years unless they can be treated with anti-retroviral drugs. Yet in many developing countries, only a very small proportion of HIV/AIDS sufferers receive these treatments.<sup>9</sup> Poor people often live far away from clinics and hospitals. Also, many countries are short of medical practitioners trained to prescribe drugs for the treatment of HIV/AIDS in the appropriate combinations and dosages. And of course high prices, which the companies can set due to

*The relationship of patents and public health is complex*

their patent exclusive rights, obviously do affect the ability of poor people to acquire them.

On the other hand, drug companies rely heavily on patents to recoup their R&D costs and obtain profits. Several studies<sup>10</sup> have shown that patents are particularly important to the pharmaceutical industry, given the high costs of R&D, and the fact that once a new drug has been developed, knowledge of the molecular structure becomes public (because of regulations for marketing approval) and, hence, competitors may easily copy it. The “research-based” pharmaceutical industry claims that a globally strong patent system is essential for them to remain in the highly expensive business of discovering and developing new drugs. Its corporations are also concerned that if copying is allowed in developing countries, these drugs will be exported to developed-country markets, where these corporations make most of their profits. They also point out that 95 per cent of drugs on the WHO’s essential drugs list can be legally copied, either because the patents have expired or because they had never been patented (see box 6.2). However, the adverse

welfare implications of having even a small per cent of these drugs covered by patents (i.e. on-patent) is still extremely serious, since the WHO’s list does not include every drug that could reasonably be classed as “essential”. In fact, it is partly the relative cheapness of the drugs listed that makes them “essential”, and thus worthy of inclusion.

Though the role of patents in inducing R&D in pharmaceuticals is clear, the industry’s arguments about the need for a strong patent system in developing countries have been called into question. Doubts have been raised about the following: the actual costs of R&D involved in the development of new drugs (especially as compared to the marketing costs of pharmaceutical companies); the important role that public funding plays in the discovery of new drugs; the use of patents to protect a myriad of minor developments and prevent or delay the entry of generic products after patent expiry; and the justification for extending to developing countries the same model of patent protection applied in developed countries.<sup>11</sup>

*Drug companies rely heavily on patents to recoup their R&D costs and obtain profits*

*Box 6.2: Patents on HIV/AIDS drugs: do they affect access?*

Defenders of the position that patents do not hinder access to essential medicines in Africa point to a study in 2001 by Amir Attaran of Harvard University and Lee Gillespie-White of the International Intellectual Property Institute, a Washington-based organization.<sup>12</sup> It provides data on the extent of patent protection throughout Africa of 15 anti-AIDS drugs, which show that few of these have been patented widely anywhere on the continent, except in a few countries including South Africa. This finding suggested to the authors that “patents and patent law are not a major barrier to treatment access in and of themselves”.

But others have argued that while the study’s data are probably accurate as far they go, the study does not make a convincing case that patents do not obstruct access to treatment in Africa. Five organizations, Consumer Project on Technology, Essential Action, Oxfam, Treatment Access Campaign and Health Gap, distributed a joint statement rebutting the Attaran and Gillespie-White paper, and several other campaigners added criticisms of their own which were distributed on an e-mail news service called IP Health. Another response was circulated by the South African activist group, Treatment Action Campaign.

They had three main criticisms. First, anti-retroviral (ARV) drug patent coverage tends to be quite comprehensive in countries that have large populations and/or relatively high incomes *and* large numbers of HIV/AIDS sufferers. These include South Africa, Kenya and Zimbabwe. According to the rebuttal statement, “the 23 countries in Sub-Saharan Africa that have 4 or more ARV products on patent have 53 percent of the HIV+ patients and 68 percent of the Region GDP. The 20 Sub-Saharan countries that have patents on 6 or more ARV products have 46 percent of the patients and 56 percent of the region’s GDP.”<sup>13</sup> Second, effective treatment is based on the use of combinations of drugs. If only one ingredient in the “cocktail” is protected and sold at a monopoly price, the whole regime will be too expensive for most patients. Third, generic producers need to make profits like any other business. If they cannot sell in the major national markets or are only allowed to make one or two components of a combination therapy regime, they cannot easily achieve the economies of scale to make a profit.

In addition, the pharmaceutical industry devotes very little R&D effort to diseases of the poor in developing countries, since such diseases are not high-income generators. Between 1975 and 1997, only 13 of 1,223 new chemical entities, or 1 per cent, were for the treatment of tropical diseases.<sup>14</sup> The World Health Organization has estimated that only 4.3 per cent of pharmaceutical R&D expenditure is targeted at those health problems, such as malaria and tuberculosis, which mainly concern low- and middle-income countries.<sup>15</sup> According to James Orbinski, former President of the International Council of Médecins Sans Frontières, while 95 per cent of active tuberculosis cases occur in developing

countries, no new drugs for the disease have been developed since 1967.<sup>16</sup> On the other hand, a great deal of pharmaceutical research is targeted at discovering and developing treatments for health concerns of affluent societies, whether they be diet-related such as obesity and high cholesterol, trivial concerns like baldness, or chronic problems such as high blood pressure that do not involve a cure but need to be taken continually for many years. It is unlikely that the provision of stronger and better patent rights will shift research investment, or money otherwise being spent on marketing, towards malaria and tuberculosis.

*What can developing countries do to reduce the costs of granting patents for pharmaceuticals?*

## Policy responses

What can developing countries do to reduce the costs of granting patents for pharmaceuticals? The use of a patent's subject matter under compulsory licensing is permitted under TRIPS even without prior negotiation "in the case of a national emergency or other circumstances of extreme urgency" or in cases of public non-commercial use. And TRIPS also specifies that this must be "predominantly for the supply of the domestic market". However, compulsory licensing in general is not necessarily a panacea.<sup>17</sup> Where prior authorization from the patent owner is required (as is normally the case, except for national emergencies), negotiations can be complicated and take a long time to conclude. Second, the patent specification may not provide sufficient information to copy the drug. In fact, in the case of some drugs, the most efficient manufacturing process is protected as a trade secret or by a separate patent, which may even be owned by a different company. Third, many countries may lack chemists who can do the copying, and licensees may not necessarily be able to profitably sell the drug at a much lower price than that of the patent-holding firm. However, the very possibility of compulsory licensing tends to strengthen the bargaining position of governments and potential licensees. Also compatible with TRIPS is the ability of purchasers of drugs sold abroad to import them into a country where they are patented. Compulsory licences and provisions for government use of patented inventions should therefore be an integral part of patent legislation that is sensitive to public health concerns.

Differential pricing (that is, the application of different price levels according to countries' income levels or other indicators) has been presented by some analysts and the industry as an alternative to the use of flexibilities allowed by the TRIPS Agreement. Moreover, some companies have offered voluntarily to sell their drugs at heavily reduced prices in some markets, especially to fight HIV/AIDS. Though this is a positive development, such revised price offers are often not lower than they would be if generic competition were permitted. In some cases, drugs at reduced prices are only available to a limited number of patients. In other cases, corporations have gone further by donating drugs. But helpful as price reductions and donations may be, they do not provide a long-term solution to the problem of lack of access. Price fixing remains in the hands of the patent owners, and governments cannot control shifts in commercial policies nor decide on which medicines discounts will be offered.

While relaxing the international patent rules that restrict the manufacture and sale of generic versions of patented drugs is arguably the best possible IPR-related measure to enhance their availability to the poor, this would require agreement by the international community, which may be difficult to obtain. In the meantime, other measures may be available to widen access to treatments for diseases that affect the poor. These certainly include compulsory licensing, parallel imports and the use of "Bolar" exceptions. They also encompass tax incentives to

encourage research on diseases that most seriously affect poor people, and a global fund to pay for such research or to purchase essential drugs and supply them free of charge or at heavily discounted prices. Of course, these depend on the willingness of companies and governments to adopt such measures. Developing-country governments cannot depend on such measures, but need to take full advantage of the opportunities that may be gleaned from a careful reading of the TRIPS Agreement, including the language dealing with objectives (Article 7, see box 2.3, above), principles (Article 8), exhaustion of rights (Article 6), exceptions to rights (Article 30) and unauthorized use (Article 31).<sup>18</sup>

Apart from the expected effects of patents on prices, it is important to be aware that pharmaceutical companies often use patents to unduly delay or restrict generic competition, in some cases for several years beyond the 20-year patent duration. “Evergreening” or “line extensions” are terms used to refer to the use of IPRs for extending the monopoly, or at least the market dominance, of a drug beyond the life of the original patent protecting it. Drug companies will often try to stretch out their exclusive rights over successful drugs for as long as possible, especially when they are heavily dependent on a small number of highly profitable products (or even just one). For example, firms often apply for, and obtain patents on, new formulations or delivery methods for the drug, on reduced dosage regimens, or on new versions (e.g. polymorphs) of the active compound or combinations. Another tactic that may be possible in the case of drugs that are metabolised by the body, and thereby transformed into another substance that directly causes the therapeutic effect, is to patent this latter chemical as well.<sup>19</sup> In addition, pharmaceutical companies, like those in other industries, use patents for a range of strategic purposes such as creating broad zones of exclusion

around their inventions, preventing other companies from exploiting their own patents, and enhancing bargaining positions in cross-licensing deals.

Companies also use trademark law to extend their market power beyond the patented drug’s expiry date.<sup>20</sup> Patented drugs are usually marketed under their brand name rather than the generic name. Since generic producers cannot use this name, it is often very difficult for them to promote their alternative product effectively. Therefore, physicians may continue to prescribe the branded product, even if it is more expensive than the generic version. In fact, in many countries physicians may not even know that alternatives exist.

It is important to point out in this context, that the global market for pharmaceuticals is increasingly competitive, albeit also highly concentrated at the level of therapeutic groups. The quantity of new chemical entities has declined in recent years,<sup>21</sup> and many of the drugs entering the market are similar to existing ones in terms of their chemical structures and therapeutic effects. These are often referred to disparagingly as “me-too drugs”. In order to make big profits from these drugs, companies must be prepared to spend large sums of money on marketing. To give an idea of how much is at stake, “drugs with annual sales of some \$45 billion are set to go off-patent between 2001 and 2005”.<sup>22</sup> Companies that are excessively dependent on one or two highly profitable drugs that are nearing the end of their patent lives, but lack the security of having a large portfolio of potential bestsellers in the pipeline, have become vulnerable to takeovers. This situation has resulted in a consolidation in the industry. Clearly, therefore, evergreening has its limits as a business strategy. It may be a panacea for a weak product pipeline, but it is certainly not a cure.

## The Doha Declaration on the TRIPS Agreement and Public Health

WTO Members meeting in Doha for the November 2001 Ministerial Conference adopted a declaration (see box 6.3) intended to address the public health problems faced by the developing and least developed countries.<sup>23</sup> Paragraph 4 of the Declaration states 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

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particular, to promote access to medicines for all." The fifth paragraph clarifies the freedoms all WTO Members have with respect to compulsory licensing, their determination of what constitutes a national emergency or other circumstances of extreme urgency, and exhaustion of rights. Thus the Declaration reaffirms the right to use to the full the provisions in TRIPS allowing each Member "to grant compulsory licences and the freedom to determine

the grounds upon which such licenses are granted." The Declaration explicitly mentions that public health crises "relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency." Moreover, WTO Members are free to establish their own regimes for "exhaustion of intellectual property rights". This is important, because it means that if national laws indicate that

*Box 6.3: "Declaration on the TRIPS Agreement and Public Health" (Adopted on 14 November 2001)*

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
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.
5. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles. (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.
6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.
7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement."

patent rights over drugs are “exhausted” by their first legitimate sale, countries can then import drugs legally purchased in countries where they are sold at a lower price.<sup>24</sup>

One matter that the Declaration has left unresolved is the situation where countries lacking the capacity to produce drugs will find it difficult to make effective use of compulsory licensing. Since TRIPS stipulates that unauthorized use of a patent shall be “predominantly for the supply of the domestic market”, it may not be possible to grant a compulsory licence mainly or exclusively to supply a patented

medicine to a country in need. This is an important issue because many poor countries lack the capacity to manufacture different pharmaceutical products, and would therefore need to import them from countries such as India, an important supplier of cheap generic drugs. To make the situation even more difficult, India is required by the terms of TRIPS to introduce product patents on drugs from 2005.<sup>25</sup> Paragraph 6 of the Declaration instructs the TRIPS Council “to find an expeditious solution to this problem and to report to the General Council before the end of 2002.” As it turned out, no solution could be agreed within this deadline.<sup>26</sup>

*Countries lacking the capacity to produce drugs will find it difficult to make effective use of compulsory licensing*

## CHAPTER 6: END NOTES

- <sup>1</sup> See *Resource Book*, Part 2.7 on TRIPS Article 39.
- <sup>2</sup> See, for example, UNCTAD, "The TRIPS Agreement and developing countries", Geneva, 1996.
- <sup>3</sup> US Public Law 105-277 (105th Congress, 1999) established that "...none of the funds appropriated under this heading may be available for assistance for the central Government of the Republic of South Africa, until the Secretary of State reports in writing to the appropriate committees of the Congress on the steps being taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15 (c) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997."
- <sup>4</sup> WHO was mandated "to report on the impact of the work of the WTO with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO, as appropriate" (Resolution WHA49.14, 25 May 1996).
- <sup>5</sup> Resolutions WHA54.10 and WHA54.11.
- <sup>6</sup> The United Nations Sub-Commission for the Promotion and Protection of Human Rights also pointed out the "apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other", including human rights to food, health and self-determination (Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, Fifty-second session, Agenda item 4, The Realization of Economic, Social and Cultural Rights, Intellectual Property Rights and Human Rights).
- <sup>7</sup> Bermudez J, et al., "The WTO TRIPS Agreement and patent protection in Brazil: Recent changes and implications for local production and access to medicines", *WHO/PAHO Working Paper*, 2000, available at <http://www.neglecteddiseases.org/4-4.pdf>.
- <sup>8</sup> International Intellectual Property Institute, "Patent protection and access to HIV/AIDS pharmaceuticals in Sub-Saharan Africa", Washington, DC: 2001: 23.
- <sup>9</sup> Oxfam, "Cutting the cost of global health", *Oxfam Parliamentary Briefing* No. 16. February 2001.
- <sup>10</sup> For example, Levin et al., op cit; Mansfield, E, "Patents and innovation: an empirical study", *Management Science* 32(2), 1986: 173-181; Taylor, CT, and Silberston ZA, *The Economic Impact of the Patent System: The British Experience*, Cambridge: Cambridge University Press, 1973.
- <sup>11</sup> See, for example, Correa C, "Public Health and intellectual property rights", *Global Social Policy* 2(3), 2002: 261-278.
- <sup>12</sup> Attaran, A and Gillespie-White L, "Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa?" *Journal of the American Medical Association* 286 (15), 2001: 1886-1892.
- <sup>13</sup> Oxfam, Consumer Project on Technology, Essential Action, Oxfam, Treatment Access Campaign and Health Gap, "Comment on the Attaran/Gillespie-White and PhRMA surveys of patents on Antiretroviral drugs in Africa", 2001, available at: <http://www.cptech.org/ip/health/africa/dopatentsmatterinafrica.html>.
- <sup>14</sup> Byström, M and Einarsson, P, TRIPS. "Consequences for Developing Countries: Implications for Swedish Development Cooperation", Report commissioned by the Swedish International Development Cooperation Agency, 2001: 35. According to the UNDP, of the annual health-related research and development worldwide, only 0.2 per cent goes for pneumonia, diarrhoeal diseases and tuberculosis; yet these account for 18 per cent of the global disease burden (UNDP, *Human Development Report*, New York, Oxford University Press, 1999: 69).
- <sup>15</sup> World Health Organization, "Investing in Health Research and Development". Report of the Ad Hoc Committee on Health Research Relating to Future Intervention Options, Geneva: WHO, 1996.
- <sup>16</sup> Orbinski, J, "Health, equity, and trade: a failure in global governance", in Sampson, GP (ed.), *The Role of the World Trade Organization in Global Governance*, Tokyo: United Nations University, 2001: 230-231.

- <sup>17</sup> Reichman and Hasenzahl caution that "policymakers should view non-voluntary licensing of patented inventions as but one item in an arsenal of tools that may be used to promote national systems of innovation. What matters is not so much the use made of any particular tool, but rather the overall coherence and effectiveness of any given system. Absent a coherent strategy for promoting national and regional systems of innovation, excessive reliance on compulsory licensing of patented inventions may simply mask deeper structural problems and make them harder to solve in the long run." (Reichman, J and Hasenzahl C, "Non-voluntary licensing of patented inventions: historical perspective, legal framework under TRIPS, and an overview of the practice in Canada and the United States of America". Case study for the UNCTAD/ICTSD Capacity Building Project on the TRIPS Agreement and Sustainable Development, 2002.
- <sup>18</sup> For a detailed examination of these provisions, see UNCTAD-ICSTD, *Resource Book*.
- <sup>19</sup> Patenting targets chosen by companies to extend their monopolies on drugs may include the following: polymorphs (crystalline forms of the active compound); pharmaceutical forms (i.e. new ways of administering the active compound); selective inventions (elements selected from a group that were not specifically named in earlier patents claiming the group); analogy processes; combinations of known products; optical isomers; active metabolites; prodrugs (inactive compounds that produce active metabolites when introduced into the body); new salts of known substances; variants of existing manufacturing processes; and new uses for old products (see Correa, CM, "Trends in Drug Patenting: Case Studies", Buenos Aires: Corregidor, 2001:11-12).
- <sup>20</sup> This is not a new practice. As early as 1919, the American Pharmaceutical Association complained about this form of monopolistic "abuse", and accused the German chemical firms. At that time the Association favoured either compulsory licensing provisions, or the abolition of product patents on medicinal chemicals that would cover any process to manufacture them (see American Pharmaceutical Association, Report of the Committee on Patents and Trademarks of the American Pharmaceutical Association, August 1919, Cited in Dutfield G, *Intellectual Property Rights and Life Science Industries: A 20<sup>th</sup> Century History*, London: Ashgate Publishing Company, July 2003.
- <sup>21</sup> From 1969 to 1989 the number of new chemical entities launched per year on the world market fell from over 90 to under 40 (Chartered Institute of Patent Agents (CIPA), Patenting in the Pharmaceutical Industry: Supplementary Protection Certificates, Briefing paper. London: CIPA, 1998).
- <sup>22</sup> Reuters, "AstraZeneca holds off rivals as U.S. patent on world's top drug dies", 6 October 2001 (<http://www.economictimes.com/today/06wor111.htm>). See also *Financial Times*, "Ancient cures in a global market", 30 April 2002.
- <sup>23</sup> For a detailed analysis of this Declaration, see Abbott, F. "Legal Options for Implementing Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health", 2002, available at <http://www.geneva.quano.info/pdf/Legal%20Options%20Abbott.pdf>; Abbott, F, "The TRIPS Agreement, access to medicines and the WTO Doha Ministerial Conference", Quaker United Nations Office Geneva, Occasional Paper 7, 2001; Kempf, R, "Patents versus Patients?", *Archiv des Völkerrechts*, vol. 40, 2002: 90-134.
- <sup>24</sup> That is, the first sale or marketing under a parallel patent, trademark or copyright abroad "exhausts" the holder's right within that country. If exhaustion occurs when a good or service is first sold or marketed outside a country, the patent holder within the country may not oppose importation on the basis of its IPR (see *Resource Book*, op cit.).
- <sup>25</sup> UNCTAD, "Transfer of Technology for Successful Integration into the Global Economy. A Study of the Pharmaceutical Industry in India", Geneva and New York, UNCTAD, 2002; Omer, Assad, "Access to medicines, transfer of technology and capacity building", in *Wisconsin International Law Journal*, Vol. 20, No. 3, Summer 2002, pp. 551-562.
- <sup>26</sup> The Commission on Intellectual Property Rights (see box 1.2) was of the view that a solution to this problem should be based on the following principles. First, it should be quickly and easily implementable with a view to a long-term solution. Second, the solution should ensure that the needs of poor people in developing countries without manufacturing capacity are given priority. Third, it should seek to ensure that conditions are established to provide potential suppliers the necessary incentives to export medicines that are needed. (See Commission Report: 48).

