

PATENTS AND ACCESS TO DRUGS IN DEVELOPING COUNTRIES: AN ETHICAL ANALYSIS

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ABSTRACT

More than a third of the world's population has no access to essential drugs. More than half of this group of people live in the poorest regions of Africa and Asia. Several factors determine the accessibility of drugs in developing countries. Hardly any medicines for tropical diseases are being developed, but even existing drugs are often not available to the patients who need them.

One of the important determinants of access to drugs is the working of the patent system. This paper first maps out some facts about the global patent regime that has emerged as a consequence of the conclusion of the WTO-TRIPs Agreement in 1994. Attempts to construct a moral justification of the patent system have been based on three grounds: natural rights, distributive justice, and utilitarian arguments. This paper examines to what extent and on which grounds drug patents can be justified. The final section looks at the so-called 'Doha Declaration on the TRIPs Agreement and Public Health', which was adopted by the WTO Ministerial Conference two years ago, recognising the primacy of public health over the interests of patent proprietors.

I INTRODUCTION

The debate on the advisability of (certain aspects of) the patent system has a very long and turbulent history. The introduction of the WTO-TRIPs Agreement (1994) – which implies the quasi-worldwide implementation of high standards for the legal protection and enforcement of intellectual property rights, including patents – has by no means quieted down this debate, but rather,

has intensified it. At the WTO, as well as in various other forums, a remarkable debate is going on about the potential impact of patents on access to healthcare. In August 2000, the UN Commission on the Promotion and Protection of Human Rights adopted a resolution declaring that there are apparent conflicts between the TRIPs regime, on the one hand, and human rights (including the right to health) on the other. Other commentators consider the property right of patent holders as a human right and argue for a further strengthening of those rights. Yet others, who do not frame the problem in terms of rights, defend patents with economic arguments or by invoking fairness. The main question of concern in this paper is to what extent these different arguments can justify the practice of patenting drugs, particularly in developing countries.

II SOME FACTS ABOUT PATENTS IN THE TRIPS ERA

Patents form an example of intellectual property rights, next to, *inter alia*, copyrights and trade marks. A patent is a certificate delivered by or on behalf of the government, attesting that the object of the patent meets a number of requirements. The substantial requirements for patentability are novelty, inventiveness, utility and sufficient disclosure of the invention in the patent application.

The rights of patent holders are limited in two ways. Firstly, by time: in most countries a patent is valid for twenty years (counted from the date of application). Secondly, by space: its validity is limited to the jurisdiction of the Patent Office that granted the patent.

In the early 1980s, various industrial lobbies in the US reported enormous losses, which they attributed to infringements of their intellectual property rights (IPRs).¹ These infringements were said to be due to the 'inadequate' legal protection of IPRs in developing countries. Many developing countries note, however, that: (1) the evolution of IPR protection in industrialised countries has always been determined by what these countries regard as their national interest; and (2) in view of their economic development objectives, developing countries need lower protection standards.

In the traditional forum for intellectual property negotiations, the *World Intellectual Property Organisation* (WIPO), the developing

¹ See e.g.: US International Trade Commission. 1988. *Foreign Protection of Intellectual Property Rights and the Effects on the US Industry and Trade*. Publication No. 2065.

countries were considered too influential (in number) by some industrialised countries. Therefore, the US, later followed by others, pushed for the introduction of the intellectual property topic on the agenda of the General Agreement on Tariffs and Trade (GATT).² After seven years of hard talks in the so-called *Uruguay Round* of GATT negotiations came about the TRIPs agreement (*Agreement on Trade-Related Aspects of Intellectual Property Rights*).³ The TRIPs agreement significantly strengthens patent protection standards, and of course reduces the sovereign power of decision of national governments.

In the industrialised countries, TRIPs came into effect on January 1, 1996. In developing countries going through a transitional phase from a planned economy to a market economy, the Agreement entered into force on January 1, 2000. The so-called 'least-developed countries' were given respite until January 1, 2006. During the WTO's ministerial conference held in Doha in November 2001, the decision was made to extend this transitional period with respect to the introduction of patents on pharmaceutical products to January 1, 2016.

The WTO-TRIPs Agreement heralds a fundamentally new era for developing countries. In the pharmaceutical sector a product patent refers to the chemical structure of a drug.⁴ The final product (the actual drug) is protected, regardless of how it was manufactured and of the purpose it serves. Not surprisingly, a product patent is the most coveted form of protection. Process patents offer protection for the way in which the final product is made and for the way in which the product is used to reach certain goals (e.g. the treatment of specific diseases). A process patent offers a 'strong' form of protection only if there is no other (financially sound) way of producing the product in question, other than through the process covered by the patent. In the pharmaceutical sector, this is rarely the case.

² See e.g.: C.A.P. Braga. The Economics of Intellectual Property Rights and the GATT: A View from the South. *Vanderbilt Journal of Transnational Law* 1989; 22: 243–264.

³ GATT Secretariat, ed. 1994. Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights. In *The Results of the Uruguay Round of Multilateral Trade Negotiations. The Legal Texts*. Geneva. WTO: 365–403. Also available at: docsonline.wto.org/DDFDocuments/t/UR/FA/27-trips.doc

⁴ P. Grubb. 1999. *Patents for Chemicals, Pharmaceuticals and Biotechnology*. Oxford. Clarendon Press.

Developing countries generally offer less substantial protection for patents than industrialised countries. Many developing countries have traditionally excluded pharmaceutical products from patent protection; only processes for the production of pharmaceuticals could be patented. The rationale of such a policy is to guarantee that the local industry can play a significant role in the manufacturing of pharmaceuticals. With the same objective in mind, most developing countries have traditionally quasi-automatically imposed a regime of so-called compulsory licences on patented inventions in the pharmaceutical domain. In almost every country that has a patent system, mechanisms exist to remedy or prevent abuses of patent rights. A very important instrument used to that effect is the compulsory licence.⁵ The granting of compulsory licences implies that – after an administrative or judicial procedure – the government forces a patent holder to grant a licence to one or more third party/ies for the use of his patented product or process. The patent holder receives a royalty. In the context of the patent system, compulsory licences have a double aim: on the one hand to force the patent owner to allow society to benefit from his invention, and on the other hand to boost the industrialisation of the country in question. The basic principle of the system of compulsory licences is that they are only granted in the public interest. The rights ensuing from the possession of a compulsory licence are similar to those ensuing from the possession of a patent, except that compulsory licences have to be granted predominantly to supply the domestic market of the country that grants them.⁶

As a result of the implementation of the TRIPs Agreement, it becomes increasingly difficult – and probably even impossible – for developing countries to pursue a ‘selective’ patent granting policy, certainly as far as pharmaceuticals are concerned. Drugs cannot be excluded from patentability under TRIPs. For many developing countries the implementation of TRIPs in their national laws represents a major upheaval. This may have a profoundly negative impact on the access to drugs of people in these countries, while hundreds of millions of people already have no access to drugs.

What could possibly justify the quasi-worldwide introduction of such strong patent protection standards?

⁵ J-M. Salamolard. 1978. *La licence obligatoire en matière de brevets d'invention. Etude de droit comparé*. Genève. Librairie Droz.

⁶ See art. 31(f) TRIPs.

III ON WHICH GROUNDS CAN DRUG PATENTS BE MORALLY JUSTIFIED?

Attempts to construct a moral justification of the patent system have been based on three grounds: (1) natural rights; (2) distributive justice; and (3) utilitarian (economic) arguments. Each of these attempts involves many problems. After briefly discussing the general argument, we will, for each of the three, investigate its implications for the justifiability of drug patents.

Natural rights

Some people believe that man has a natural right to his ideas and consequently that society is obliged to enforce that right. Thus, the use of ideas without the authorisation of the owner must be considered as theft. Natural property rights take precedence over social institutions and should be respected whatever the consequences.

Discussions on the natural rights argument generally refer to John Locke's 'labour theory of property.'⁷ Although Locke seems to identify property with land, various commentators have applied his theory to other types of goods, including 'intangible' objects. According to Locke, the appropriation of a thing occurs by man applying his labour to it, by 'mixing' the thing with his labour. By adding something of his own to the thing, he excludes others from having a right to it.

If we look at the implications of this theory for the justification of drug patents, the main question seems to be: how much 'labour' is really involved in the research and development (R&D) of drugs? The greater part of pharmaceutical R&D budgets is spent on 'me-too' drugs – the slightly altered versions of successful products manufactured by the competition. The *American Food and Drug Administration* (FDA), for example, classifies the applications it receives either as 'priority drugs' (considered a significant improvement in relation to the existing drugs) and 'standard drugs' (considered similar to existing products). Of all drugs approved by the FDA over the past six years, almost 80% belong to the standard drug category. As a large-scale survey by the *National Institute for Health Care Management Foundation* (May 2002) shows, the ratio between priority-rated drugs and standard-rated

⁷ Which he formulated in his *Second Treatise on Government* (1690). See: P. Laslett, ed. 1988. *Locke, Two Treatises of Government*. Cambridge. Cambridge University Press: 285–302.

drugs within this group of approved drugs is constantly shifting towards less priority-rated drugs and more standard-rated drugs.⁸ The development of such drugs is not ‘labour-intensive’ (if ‘labour’ is understood as creative intellectual labour). Also, in view of the patentability requirement of inventiveness, the granting of patents for such drugs seems hard to justify.

Locke stipulated two conditions or ‘provisos’ which must be met in order for an appropriation (i.e. establishment of a property right) to be justifiable. Firstly, there must be ‘enough, and as good left in common for others.’⁹ Secondly, man is not allowed to appropriate more than he can use (even if he is the ‘maker’ of the things in question); there should be no waste.¹⁰

Robert Nozick has applied Locke’s first proviso to the rights granted by a patent. For him, ‘The crucial point is whether appropriation . . . worsens the situation of others.’¹¹ He thinks this is not necessarily so, and provides the following example:

If I appropriate a grain of sand from Coney Island, no one else may now do as they will with *that* grain of sand. But there are plenty of other grains of sand left for them to do the same with. Or if not grains of sand, then other things.¹²

In the case of patents, Nozick’s arguments may not be tenable, *inter alia* for the following two reasons. As to the statement that enough objects will remain for others to use, this is clearly not valid for any thing protected by a patent. Any product or process that fits what is described in the patent’s claims is also covered by the patent, including ‘equivalent’ (as opposed to identical) products or processes. With regard to Nozick’s proposition that, if not enough samples of an appropriated object remain for others to use plenty of other objects will be available to them, this is irrelevant if they need that specific object, as is often the case with drugs.

As to Locke’s second condition – the ‘non-waste’ condition – one aspect of the patent system which can induce waste is the fact that, in its present form, the system does not oblige patent holders to exploit their invention. If something is left unused by the one who appropriated it, while others need it – and drugs are examples of things that are often truly needed by a whole lot of people

⁸ Available at: <http://www.nihcm.org/innovations.pdf>.

⁹ Laslett, *op. cit.* note 7, § 27.

¹⁰ Laslett, *op. cit.* note 7, § 31.

¹¹ R. Nozick. 1974. *Anarchy, State, and Utopia*. Oxford. Basil Blackwell: 175.

¹² *Ibid.*

– the waste is all the greater. (Of course, in a system based on natural rights, the essence of the patent right exists in the patent proprietor determining what happens with the object of the patent. Thus, he cannot be forced to exploit his invention.) But even if a patent *is* exploited, waste is likely to occur. Indeed, the main consequence of issuing a patent is that the patent holder can limit the use of the invention. The extent of the waste depends on the utility of the invention for those who are excluded from using it. The utility of drugs, particularly essential drugs,¹³ is often very high.

Distributive justice

According to the distributive justice argument, fairness requires that inventors be rewarded because they render a service to society. It would be unfair to allow people a ‘free ride’ at the expense of others who apply themselves to the act of inventing. Free riders – people who did not invest time or money in the development of an invention – should not be allowed to compete with the inventor under normal market conditions. Therefore society should grant exclusive rights to inventors.

When examined in the context of the justification of drug patents, this argument, too, seems problematic. First, the question arises whether fairness does not also require an equal access to drugs, which is prevented by the working of the patent system.¹⁴

Another question at issue here is: does justice require that inventors be rewarded with patents, allowing them to decide who may legally use the invention? Put differently: does it follow from the proposition that justice requires the rewarding of inventors that inventors must be granted exclusive rights of ownership on their inventions? Hettinger rightly observes that it does not:

The mistake is to conflate the created object which makes a person deserving of a reward with what that reward should be. Property rights in the created object are not the only possible

¹³ I do not understand the concept of ‘essential drugs’ as ‘drugs that appear on the World Health Organization’s essential drug list.’ As some defenders of strong drug patents like to note, more than 95% of the drugs on that list are off-patent. However, the reason for this seems to be that a drug must be ‘affordable’ in order to get on the list, and patented drugs are usually expensive. But of course the fact that a drug is expensive does not necessarily prevent it from being ‘essential’ (in the sense of badly needed by a group of patients).

¹⁴ In a utilitarian framework, as discussed below, the unequal access is said to be justified by the incentive-to-invent it creates. However, in a framework of distributive justice such an argument cannot be decisive.

reward. Alternatives include fees, awards, acknowledgements, gratitude, praise, security, power, status, and public financial support.¹⁵

Thirdly: what about the fairness of granting private property rights to the results of R&D, which is, in great part, publicly funded? In the US, for example, the National Institutes of Health (NIH) (subsidised by the federal government) are great benefactors of the pharmaceutical industry. This year, the NIH will be spending \$23 billion on research, and of course there are other public institutes investing in health-related research. Much of this research is directly beneficial to the industry. According to the NIH, 55% of the research projects leading to the discovery and development of the 5 best-selling drugs in 1995 was performed by researchers whose work had been financed with taxpayers' money.¹⁶ As Bernadine Healy, former senior executive of the NIH, puts it:

There's no other industry in which you have so much public investment in the fundamental knowledge that enables . . . the development of the commercial industry itself.¹⁷

This seems to strengthen the case for allowing maximum access to the products of that knowledge – *inter alia* drugs.

Another problem with the justification of drug patents on fairness grounds is whether it is fair to grant inventors rewards that are excessive. Many manufacturers of brand-name pharmaceuticals relentlessly try to obtain extensions of the protection term of their patents, and they often succeed. This phenomenon, known as 'patent evergreening', hinders producers of generic drugs (products equivalent to brand drugs, which can be put on the market after the patent expires). Generic drugs are generally much cheaper than brand products. Even in the US, according to the *Kaiser Foundation*, the (retail) price of a prescription brand-name drug is 3.4 times higher than the price of a generic drug. In developing countries, the price difference is often even more

¹⁵ E. Hettinger. Justifying Intellectual Property. *Philosophy & Public Affairs* 1989; 18: 41.

¹⁶ National Institutes of Health. 2000. NIH Contributions to Pharmaceutical Development (administrative document). Cited in: Public Citizen. 2002. *America's Other Drug Problem: A Briefing Book on the Rx Drug Debate*. Washington, DC. Public Citizen: 51.

¹⁷ Cited in: ABC News. 30 May, 2002. *Peter Jennings Reporting – Bitter Medicine: Pills, Profit and the Public's Health*. Available at: http://abcnews.go.com/onair/ABCNEWSpecials/pharmaceuticals_020529_pjr_feature.html

striking. The public, of course, pays twice: people have to keep on paying artificially high prices for drugs, as well as the costs of a legal system used by the companies to delay competition.

Even supposing that the patent system, as we know it, could be justified on fairness grounds, the justification of the quasi-world-wide introduction of *drug* patents on such grounds would remain problematical. As Dan Brock justly remarks:

It can quite plausibly be argued that in not respecting patents developing countries are free riding on the research and development efforts of drug companies that are supported by the prices of drugs in countries in which patents are respected. But that free riding and resulting unfairness may not be enough to make it, all things considered, morally wrong for developing countries not to respect product patents . . . When developing countries choose not to respect product patents as their only effective means of making available pharmaceuticals necessary to save lives and protect the health of their citizens, doing so is arguably a step towards greater justice between the developed and developing world . . .¹⁸

Indeed, the health crisis in many developing countries has reached proportions beyond the imaginable. More than a third of the world's population has no access to essential drugs. In several countries life expectancy is dropping incredibly fast. And it is getting worse. The urgency of ensuring access to the necessary drugs cannot be ignored any longer. Rethinking the global patent regime is one of the keys to a solution.

A utilitarian justification

The utilitarian justification, which is considered by many as the most convincing, is essentially based on the following two arguments:

- (a) The so-called 'incentive-to-invent-and-innovate' argument: in the absence of patents, inventions can be copied by competitors. Consequently, the price must be reduced and the investor does not have the opportunity to regain his investments, let alone make a profit. Thus, the incentive to invent and innovate is eroded. A 'special' incentive is required so that enough people should be prepared to invest in R&D.

¹⁸ D.W. Brock. Some Questions about the Moral Responsibilities of Drug Companies in Developing Countries. *Developing World Bioethics* 2001; 1: 36–37.

According to this argument, the patent system provides the necessary encouragement.

- (b) The so-called ‘incentive-to-disclose’ argument: the patent system encourages inventors to disclose their inventions instead of keeping them secret. One of the patentability requirements is that the applicant must disclose the invention in sufficient detail in the application forms. Thanks to the patent system, it is said, technological information is spread – making technological progress possible, which in turn induces economic growth.

Several commentators claim that both these arguments are nowhere more valid than in the pharmaceutical sector, as this is the most research-intensive sector. However, both aforementioned arguments are problematic. We will only look at some of the problems with the first argument, as the second one is less relevant with regard to the topic that concerns us here.

Of course, the availability of patents does result in more inventions of drugs; we do not wish to question this fact – but this positive effect may well be cancelled out by the limitation of the use of patented drugs. The patent system allows the price of patented items to be kept artificially high. The introduction in developing countries – mandated by TRIPs – of product patents in the field of pharmaceuticals will almost certainly lead to a price increase of 200–300%.¹⁹ Moreover, as we noted earlier, pharmaceutical companies frequently take legal action to postpone the introduction of generic alternatives. This hinders the access to drugs even more.

The utilitarian (economic) arguments used to justify the patent system in industrialised countries do not necessarily apply to developing countries. Many commentators, nevertheless, automatically assume that they do. The advocates of strong drug patents claim that the implementation of the WTO-TRIPs Agreement will offer the following advantages: (1) the encouragement of local drug research, through which new drugs would become available catering to the country’s specific needs (e.g. drugs for tropical diseases); (2) industrialised countries making important new drugs available in developing countries; and (3) the attraction of foreign investments in the pharmaceutical sector. Each of these arguments is susceptible to criticism.

¹⁹ J. Watal. 2000. *Access to Essential Medicines in Developing Countries: Does the WTO TRIPs Agreement hinder it?* (Science, Technology and Innovation Discussion Paper No. 8). Cambridge, MA. Center for International Development, Harvard University: 5.

More Local R&D of Drugs?

Hardly any drugs for diseases occurring primarily or exclusively in developing countries are being developed. Of the 1223 molecules that were sold worldwide between 1975 and 1996, less than 1% was intended for tropical diseases.²⁰ R&D of drugs for these diseases is desperately needed. According to some commentators, if developing countries were to grant strong patents for drugs, this would stimulate local research. Not granting strong patent protection may well yield short-term advantages, but it would be harmful in the long run, they say, because such a situation can never bring about drugs that meet the specific needs of the country in question.

The introduction and the application of new technologies are indeed important instruments to help developing countries improve their standard of living. However, the fact that in developing countries few new technologies are being developed has more to do with fundamental economical problems (e.g. a lack of skilled workers and the absence of infrastructures capable of absorbing new technologies) than with patent protection standards.

Moreover, the economic purpose of patents is to enable patentees to recoup their investments and, if possible, make a profit. In the pharmaceutical sector, they are used to achieve high profits: the pharmaceutical industry is eight times more profitable than the average of all industries represented in the Fortune 500 list.²¹ It is highly unlikely that the recent strengthening of the patent system will incite pharmaceutical companies to invest in R&D of drugs for diseases occurring primarily or exclusively in developing countries, as the majority of the stricken patients have little or no purchasing power, which makes the market totally

²⁰ See: B. Pécoul, P. Chirac, P. Trouiller & J. Pinel. Access to Essential Drugs in Poor Countries – A Lost Battle? *JAMA* 1999; 281: 365 (Table 2). See also the recent survey by experts of the Harvard School of Public Health and an international group of experts, the *Drugs for Neglected Diseases Working Group*, available at: www.accessmed-msf.org. See also another recent survey which the umbrella organisation of the American pharmaceutical industry (*Pharmaceutical Research and Manufacturers of America*) held among its members, *New Medicines in Development*, available at: www.phrma.org.

²¹ See: Fortune 500. *Fortune Magazine* 2002; April. In 2001, the profits of America's 10 largest pharmaceutical companies went up by 33% – from 28 to 37,3 billion dollars! – despite the bad economic situation. Profits are also growing much faster than the volume of R&D investments. According to the 2001 Fortune 500 ranking, the pharmaceutical industry was the most profitable industry for the tenth time in a row.

uneconomical. Indeed, while health spending per capita in the developing countries amounts to 11 dollars (of which 6 are 'public' dollars), rich countries spend 1907 dollars per capita (of which 1356 are 'public' dollars).²² The pharmaceutical industry develops profitable drugs for the wealthy regions of the world, and makes its biggest profits from hair tonics, anti-impotency drugs, drugs for cholesterol, ulcers, depressions, allergies and high blood pressure. More money is invested in research of drugs against baldness than in research of all tropical diseases combined . . . strengthening drug patents in developing countries is not likely to change that. The diseases of patients with little or no purchasing power are simply neglected in the pharmaceutical market.

Increased Transfer of (Pharmaceutical) Technology and Increased Foreign Investment in the Pharmaceutical Domain?

The classical argument in this context is that those who possess technology are not too keen on transferring their technological knowledge to countries with a 'weak' patent system, for risks involving 'piracy.' If a developing country were to strengthen its patent system, so the argument goes, the industrialised countries will make new medicines available in that country. This prediction, however, does not sound very credible. Drugs that can be produced via conventional processes are already being brought onto the market by local production plants in numerous developing countries. Those drugs of which the production requires sophisticated technologies are generally not copied in developing countries, as the required manufacturing capacities are only available in industrialised countries. Moreover, such drugs are very expensive and therefore accessible only to the rich segment of the population in developing countries. It is therefore highly unlikely that the strengthening of patent protection in developing countries will bring in technology previously unavailable.

As far as the role of patents in the encouragement of foreign investments is concerned, various commentators claim that the absence or the availability of adequate protection of intellectual property rights constitutes a factor which plays an increasingly important part in the investment-related decisions of companies. An important element in this debate is, however, that under the

²² Keynote presentation on the occasion of the 'Forum 5' gathering organised by the *Global Forum for Health Research* (www.globalforumhealth.org), October 2001.

TRIPs regime patentees are no longer under the obligation to manufacture their inventions in the (developing) country that issued the patent. Art. 27(1) of TRIPs stipulates that:

... patents [can] be granted for any inventions, whether products or processes, in all fields of technology ... [and] patent rights are enjoyable *without discrimination* as to the place of invention, the field of technology and *whether products are imported or locally produced*.²³

Hence, lack of local exploitation of a patented invention can no longer be invoked as a ground for granting a compulsory licence. Patentees can freely choose to supply the market from their own country. This will lead to foreign companies investing in branches in developing countries only if the available human and/or infrastructural capacity offers them exceptional cost-reducing possibilities. As far as the pharmaceutical industry is concerned, such a situation is not very likely to occur.

Furthermore, research has shown that investment decisions are influenced by a whole series of diverse factors, one of which is the level of patent protection in the country in question – but this is by no means the most important one.²⁴

IV IN SEARCH OF A FAIRER BALANCE BETWEEN THE RIGHTS AND OBLIGATIONS OF PATENT HOLDERS AND BETWEEN PATIENTS' INTERESTS AND COMMERCIAL INTERESTS: THE DOHA DECLARATION ON THE TRIPs AGREEMENT AND PUBLIC HEALTH

The WTO Ministerial Conference in Doha (Qatar) in November 2001 produced, among other things, the landmark Doha Declaration on the TRIPs Agreement and Public Health.²⁵ The essence of the Declaration is worded in Paragraph 4. It stipulates that the TRIPs Agreement does not and should not prevent WTO member states from taking measures to protect public health, and that it can and should be interpreted and implemented in a manner supportive of member states' rights to protect public health and, in particular, to promote access to medicines for all. It declares the

²³ Emphasis added.

²⁴ See e.g.: C.A.P. Braga et al. 1999. *Intellectual Property Rights and Economic Development (Background paper for the World Development Report 1999)*. Washington, DC. World Bank.

²⁵ WTO Ministerial Conference. Fourth Session. Doha, 9–14 November 2001. WT/MIN(01)/DEC/2, 20 November 2001.

right of member states to use, to the full, the provisions in TRIPs that provide flexibility for this purpose. This is somewhat fleshed out in the fifth paragraph, which recognises that these flexibilities include *inter alia* that:

- (b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses 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.

Subparagraph (b) is important because developing countries that intend to grant compulsory licences are sometimes put under great pressure (e.g. via threats to redraw investments), primarily by the US, not to do so. However, the system of compulsory licences enables a country to factor national interests into its patent system and allows it to achieve a better balance between the rights and the obligations of patent holders. Therefore it should be used to the full, especially in 'vital' sectors such as drugs. Unfortunately the developing countries did not take advantage of the Doha negotiations to obtain a reversal of the burden of proof when it comes to decisions on whether to grant a compulsory license. It would seem fairer to place the burden of proof on the side of the patent holder – in other words, to force the patent holder to prove that granting a compulsory licence is not necessary, instead of forcing the applicant to demonstrate that the patent holder has abused his monopoly.

Subparagraph (c) is important in that it stresses that every member state has the sovereign power of decision to proclaim a (national) state of emergency.

The sixth paragraph of the Declaration runs:

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.

As foreseen, this provision has led to negotiations in the TRIPs Council. In 2002, the TRIPs Council convened on several occasions to reach a concrete proposal on this issue.

Pursuant to Article 31(f) of TRIPs, compulsory licences must be used predominantly for the supply of the domestic market of the member state that issued the compulsory licence and can, therefore, only be used to a limited extent for export. However, it would seem to be necessary that, if a country has insufficient or no manufacturing capacities and the drugs offered by foreign manufacturers are too expensive, the country should be allowed to look elsewhere for a suitable supplier. Until 2005, this will not really pose a serious problem because a number of developing countries – with India as the most prominent example – have a good production capacity and are still legally allowed to export their drugs, even when these are patented in other countries.

As noted earlier, the so-called ‘least developed countries’ have been granted a postponement until 2016 to conform their drug-related patent provisions to the WTO-TRIPs Agreement, but once the developing countries that can export drugs to them (e.g. India) must acknowledge drug patents – already in 2005 as foreseen in TRIPs – the least developed countries are sure to encounter even more serious problems in obtaining affordable drugs. In this context, compulsory licences will become increasingly vital.

The discussions in the TRIPs Council concerning export strategies went off the rails during a debate about the question for which diseases the export of drugs under compulsory licence should be allowed. When the president of the TRIPs Council proposed a draft in December 2002 stating that the Doha Declaration was not limited to HIV/AIDS, malaria and tuberculosis, the US (as the only among the then 145 WTO members) refused to accept this draft and negotiations were broken off.²⁶ In the meanwhile they have been reopened, but there is still no consensus.

Numerous countries are opposed to a limitation of diseases for which medicines can be exported under compulsory licences and feel that this cannot be the subject of negotiations. They justly observe that the Doha Declaration states that the TRIPs Agreement has to be implemented in such a way as to give *everyone* access to medicines.

²⁶ As noted by several NGOs, the position of poor countries would have been significantly worsened had this draft been adopted. MSF (Médecins Sans Frontières) rightly observes that: ‘[I]t would have made generic production almost economically unfeasible after 2005 . . . At the end of the day, the supply of affordable versions of new medicines would have slowed to a trickle, with developing countries left with very few alternatives to the high process and long-term monopolies of originator companies.’ See: MSF. 2003. *One Step Forward, Two Steps Back? Issues for the 5th WTO Ministerial Conference (Briefing Note)*. Cancun.

The US, however, fears that an interpretation of Doha that does not limit the diseases, for which drugs can be exported under compulsory licence, to HIV/AIDS, tuberculosis and malaria, will erode incentives for the development of new drugs. In a letter addressed to the trade ministers of all WTO members, US Trade Representative Robert Zoellick stated that:

[I]t became clear to us that some WTO members and advocacy organizations sought to expand the scope of disease beyond that intended at Doha to allow countries to override drug patents to treat a wide range of public health concerns, including obesity, asthma, cancer, diabetes, among others – even including the use of Viagra. We were seriously concerned that this approach would undermine the WTO rules on patents that provide incentives for the development of new pharmaceutical products.²⁷

Given the fact that North America, Europe and Japan together represent 80% of the global pharmaceutical market, and that of the remaining 20%, Africa represents only 1%,²⁸ Zoellick's concern about an 'undermining' of incentives for drug development is without foundation. The continuation of pharmaceutical R&D is not dependent on the markets of developing countries.

Another argument that the US has repeatedly referred to involves the risk of cheap medicines intended for the South being illegally diverted to the North. Brook Baker of the NGO Health GAP rightly remarks that this objection is untruthful:

there are billions of generic pills being produced each year around the globe that have not been diverted into the US and Europe. Not only do US and Europe outlaw such diversion, but they also guard their borders with remarkable efficiency. As a matter of law and of practicality, the US and Europe are in total control of the diversion risk. Rich consumers in London, Paris, and New York are not going to buy black market, smuggled heart medicines out of the trunk of a Chevy.²⁹

Indeed, the Doha Declaration should be implemented to the fullest extent without delay, in order to establish a fairer balance

²⁷ InsideHealthPolicy.com. Daily Updates. 17 January, 2003.

²⁸ See: IMS Health Market Report: Five Year Forecast of the Global Pharmaceutical Markets (available at <http://www.ims-global.com/insight/report/global/report.htm>), quoted in: MSF. 2001. *Fatal Imbalance*. Available at: www.msf.org.

²⁹ Ip-health mailing list. 23 December, 2002.

between the rights and obligations of patent holders and between the interests of patients and those of patent owners. Given the basic nature of health needs, patent rules should not prevent countries from adopting policies that protect public health and promote access to drugs.

However, after the adoption of the Doha Declaration, the US, the EU, Canada, Switzerland and Japan have constantly tried to undermine the Declaration through their attempts to limit its scope. In addition, the US has negotiated regional trade agreements such as the Free Trade Area of the Americas (FTAA) Agreement – and is continuously negotiating others – that threaten to erode or even abandon the Doha Declaration.

V CONCLUSION

Drug patents, particularly the strong kind of drug patents granted today, are hard to justify on natural rights, fairness or utilitarian grounds. Many drugs are of vital importance for very large groups of people. This vital importance should be reflected in the debate about the justification of drug patents.

The proposition that in the absence of strong patents no R&D of drugs can be expected is typically presented as universally valid – whereas it may well be that the advisable level of patent protection (or even the decision whether or not to grant protection) has to be determined in relation to the level of economic development of a country. Unfortunately, since the forum for decision making with regard to intellectual property shifted from WIPO to WTO, a ‘one size fits all’ view of patents has been firmly established.

As Jagdish Bhagwati rightly notes, the inclusion of intellectual property has turned WTO into a royalty collection agency.³⁰ The unwillingness of the major industrialised countries to accept a full implementation of the Doha Declaration seems to threaten the legitimacy of the WTO-TRIPs Agreement.

It seems that the reason why pharmaceutical lobbies are such zealous advocates of strong patents in developing countries is that it would allow them to hinder competition from local drug manufacturers. There is no credible evidence that the new global patent regime will promote the development of new medicines for diseases occurring primarily or exclusively in developing countries. Instead, this regime severely limits these countries’ possibil-

³⁰ J. Bhagwati. Patents and the Poor. *Financial Times* 16 September, 2002.

ities to implement a public health policy that addresses the health crises they are confronted with, and it is one of the main factors that hinders access to existing (patented) drugs – access which the lives of millions of people depend.

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