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The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries

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ABSTRACT. One of the major characteristics of the emerging international economic order is the treatment of intellectual property rights (IPRS). Developing country Members are very concerned about the impact that the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) will have on their economies. Of particular concern are those aspects of the Agreement that relate to the issue of access to new pharmaceutical inventions. TRIPS emphasizes a property rights approach whereby private "owners" of the inventions can restrict access on the basis of commercial considerations. As a consequence, higher prices for pharmaceuticals and other healthcare inventions can prevent low-income consumers in developing countries from obtaining life-saving medications and equipment. It is true, of course, that exploitative business practices are possible only to the extent that monopoly positions are tolerated. Many developing countries, however, lack the necessary financial resources and have not yet developed appropriate competition rules to deal effectively with the challenges presented by the TRIPS Agreement.

Keywords: Access to affordable medicines • Developing countries • TRIPS Agreement • WTO

Introduction

The compelling forces of technological change and economic globalization have taken intellectual property law from the library room to the front pages of policy journals. Intellectual property rights (IPRS) and their relation to international trade, investment, technology transfer, innovation and growth is a critically important issue that remains intensely controversial. Developing countries are

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particularly concerned about the impact that the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) will have on their economies.

Most developing countries resisted the profound transformation that came about with the WTO. Their negotiators had reservations about the capabilities of developing countries to introduce the necessary regulatory changes in order to comply with the demanding implementation requirements of the new WTO Agreements. The inclusion of an agreement on intellectual property within the WTO presents a particular challenge because many developing countries have to amend their existing IPRs regulations or draft completely new laws. Developing WTO Member-states and some transition economies were given 5 years, that is until January 2000, to comply fully with all TRIPS commitments,[1] while the least-developed countries must do so before January 2006.

The TRIPS Agreement established the minimum global standards of IPRs protection as well as rules on enforcement, and most importantly, brought the domestic IPRs regimes of WTO Members under the jurisdiction of the WTO dispute-settlement system. However, 7 years after the WTO came into existence, the problems with implementing its Agreements define the situation of developing countries as a group in the multilateral trading system.[2] The implementation of TRIPS has been particularly problematic. The TRIPS Agreement is said to be limited to the minimum standards of protection of intellectual property to be provided by each WTO Member. These standards, however, are modeled on western legal practice and are set at a level comparable to those in the developed countries.

The WTO rules on IPRs are controversial because of the persistence of the asymmetry in the level of development and research capacities between the North and the South. There is no doubt that a strong global regime for protecting IPRs increases the economic strength of the developed countries. The worldwide statistics on patents clearly demonstrate a dominance of these economies in intellectual property ownership. Most patents issued in the developing world, on the other hand, are filed by foreigners and are the property of a relatively few multinational interests domiciled in the USA, the EU, and Japan.[3] Consequently, in many developing countries, there is strong suspicion that the TRIPS Agreement is a component of a policy of *technological protectionism* intended at consolidating an international division of labor where the industrialized nations generate innovations and developing countries are the market for the resulting products (Correa, 2000: 5).

Yet the TRIPS Agreement has also proved to be problematic from a developed-country perspective. The developed countries have traditionally stood behind their prominent pharmaceutical companies and supported them in their quest for establishing a strong global IPRs regime. However, the recent anthrax scare in the USA and the AIDS crisis in Africa may have altered this relationship. The IPRs standards that TRIPS establishes severely limit the government's ability to introduce a radical policy initiative. This can emerge as an unwelcome constraint for any country in crisis.

The TRIPS Agreement helps to create powerful monopolies that control the market for often essential knowledge-based products such as life-saving medicines. Patents, by design, increase the price of medicines to consumers because they enable pharmaceutical firms to keep prices much higher than their marginal costs of production by discouraging the emergence of competitors (Abbott, 2002: 18). It is virtually impossible to compete with such dominant monopolies because of

the unprecedented financial resources at their disposal and their supreme research capabilities. In taking advantage of their dominant market position, the pharmaceutical companies have tried to maintain similar drug prices around the world despite the wide gap in the per capita income level between the developed and developing countries. This is because the pharmaceutical industry fears that if developing countries are allowed to buy low-priced medications, American and European consumers will demand the same. Indeed, many of the activists and lawmakers who support cheap generic drugs in developing countries are also lobbying to drive down prices in the USA and the EU.

Unexpectedly, the 2001 anthrax crisis has broadened the debate about the TRIPS-sanctioned inviolability of pharmaceutical patents. Having defended the sacredness of pharmaceutical patents in the developing world, the USA and Canada considered ignoring them at home when fear about bio-terrorism spread. As the impact of TRIPS comes under increased scrutiny, it may well be confirmed that public policy objectives in the industrialized countries and the developing world converge. The following article briefly explains the basic tenets of TRIPS, the problems with its implementation, and its impact on pharmaceutical drug policies in developing countries as illustrated by the South African case.

Brief Summary of the TRIPS Agreement

A milestone in the history of international trade was marked on 1 January 1995. On this date, the WTO was formally established. It was the final result of the Uruguay Round of multilateral negotiations that took over four years of preparations and seven more years of talks to complete (Croome, 1995). Unlike its predecessor, the General Agreement on Tariffs and Trade (GATT) of 1947, the WTO is a formal legal institution with its own strengthened dispute-settlement mechanism that operates on the principle of compulsory adjudication. This means that once a panel is being initiated, the dispute-settlement case cannot be blocked. Furthermore, and in contrast to GATT, the WTO's scope is vastly enlarged to include such new issues as investment, services and intellectual property.

One of the most significant new innovations created by the Uruguay Round was the principle of *the single undertaking*. It means that every WTO Member must now accept all the WTO Agreements, including TRIPS, as a single undertaking. The TRIPS Agreement is one of the three pillars of the WTO, the other two being trade in goods (13 agreements relating to industrial and agricultural goods, including the old GATT) and the new General Agreement on Trade in Services (GATS). One effect of the single undertaking is to entrench the tradition of consensus when it comes to decision-making. However, the number of countries with membership in the WTO has sharply increased, complicating the task of reaching consensus in future negotiations.[4]

The TRIPS Agreement is the most comprehensive legal regime ever concluded at the multilateral level in the area of intellectual property rights. The TRIPS Agreement supplements and modifies the previous conventions governing intellectual property rights. It also obligates Members to provide for the protection of plant varieties, either by patent or by an effective *sui generis* system such as the plant breeder's rights established in the International Union for the Protection of New Varieties of Plants (UPOV) convention.[5]

There are seven areas of intellectual property covered by TRIPS (Maskus, 2000: 17–23). *Copyrights* protect original works of authorship. *Trademarks* are words,

signs, or symbols that identify a certain product or company. *Geographical indications* identify a product with a certain city or region, with additional protection granted to wines and spirits. *Industrial designs* protect the ornamental features of consumer goods such as shoes or cars. *Patents* are legal titles granting the owner the exclusive right to make commercial use of inventions. *Layout designs for integrated circuits* protect producers of semiconductors. *Trade secrets* protect business from the unauthorized disclosure of confidential information.

In essence, TRIPS establishes minimum global standards of protection of IPRs and rules for their enforcement. However, these standards are set at a level comparable to those in the major industrial nations, making it very difficult and costly for developing countries to implement the Agreement. The implementation of TRIPS often requires substantial changes or even completely new legislation. It also means creating an additional administrative framework. A large number of developing countries were not signatories to the past IPRs conventions and they have in the past had very limited intellectual property laws. The depressed stage of market development and limited research facilities found in most developing countries had not been conducive to generating political pressure for such legislation.

From the developing countries' perspective the most demanding provisions of the TRIPS Agreement concern patents. The requirement of the minimum 20 years' patent protection from the filing date, as required by TRIPS, is a challenging novelty, especially for those developing countries that have never had any patent law. Among the 98 developing countries that were members of the WTO at the time of its establishment, 25 did not have patent laws covering pharmaceutical products. And among those that had such laws, the length of patent protection was much shorter in 56 of them (Braga, 1996: 356). Most importantly, however, the governments widely employed certain legal mechanisms, such as compulsory licensing, to limit the scope of the pharmaceutical patents and to advance new inventions and technologies.

A compulsory license is a license generally granted by a government, with or without the consent of the right owner, which permits a third party (a company, an organization, a government) other than the original owner of the rights to use a patent. TRIPS does not explicitly prohibit the granting of compulsory licenses. However, the leading developed countries threatened trade sanctions against those WTO members that proposed granting compulsory licenses (Abbott, 2002: 24). Moreover, the conditions under which compulsory licensing is allowed are sufficiently ambiguous to deter the governments from doing it. Article 31 of TRIPS sets out a long checklist of complicated procedures a government must follow before it can legally override a patent and issue a compulsory license.

For example, before a country can issue a compulsory license it must obtain permission to do so from the owner of the patent. The owner of the patent must be given a satisfactory compensation fee for overriding the patent. Overall, the whole procedure of granting a compulsory license under TRIPS is vague and costly, and it can be relatively easily challenged. In addition, the Agreement mandates that when it comes to the adjudicating process in patent-infringement cases, the burden of proof be reversed. In other words, the defendant country must now persuade the WTO panel that it is innocent. This approach only recently became a norm in the industrialized countries after it was acknowledged that proving process infringement was quite difficult. For example, the USA amended its law (section 337 of the Tariff Act of 1930) in 1988 (Ryan, 1998: 44).

The TRIPS Agreement also requires that civil judicial procedures must be

available to cover any activity infringing intellectual property rights covered by the Agreement (Articles 42–43). The enforcement provisions of TRIPS require that every WTO Member provide civil as well as criminal remedies for the infringement of intellectual property rights. Judicial systems and enforcement procedures must be developed or modernized in many countries to comply with this aspect of TRIPS. According to Article 61, provision must be made for criminal procedures to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. The enforcement provisions also obligate Members to provide means by which right-holders can obtain the cooperation of customs authorities to prevent imports of infringing goods.

Developing countries must now fully implement the TRIPS Agreement under the scrutiny of the WTO Council on TRIPS. Although the Council is allowed to review the domestic laws of WTO Members to ensure their compliance with the Agreement, the Council does not review the financial statements of the pharmaceutical companies, or the direction of their research. This is very unfortunate since there is growing evidence that the pharmaceutical industry pays very little attention to diseases of particular prevalence in the poorest countries, but spends a large portion of its resources on development and promotion of lifestyle drugs that appeal mainly to consumers in the leading industrialized nations (Abbott, 2002: 19).

The declared objective of the TRIPS Agreement, as stipulated in its Preamble, is "to reduce distortions and impediments to international trade, taking into account the need to promote effective and adequate protection of intellectual property rights." However, the Preamble also declares that intellectual property rights are *private rights*. Thus, IPRs as embodied in the TRIPS Agreement define the extent to which their owners may exclude others from using the new intellectual-property-based inventions. The critics of TRIPS observe that such emphasis on private rights favors a protectionist approach, which goes against a historical understanding of intellectual property.

The first intellectual property laws were designed to ensure a diffusion of knowledge and create a public domain for new inventions and knowledge. Patents began as instruments used by European nobility during the Renaissance to induce the transfer and disclosure of technologies. US patent institutions were derived from those of Britain. In 1641, the General Court of Massachusetts Bay adopted a number of provisions that created a statutory basis on which to grant future patents. However, the importation of inventions from the old continent was a natural enough proposition for the new world settlers. In fact, well into the 20th century the Americans continued to award patents freely as a way of providing incentives for technology transfers (MacLeod, 1991). In other words, the dissemination of technology, and not so much its protection, remained the principal rationale behind the early patent legislation in continental Europe and then in the USA.

In effect, the public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives, are explicitly recognized in TRIPS. In accordance with Article 7 (*Objectives*), "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to the balance of rights and obligations."

Most developing countries believe that the above provisions introduce flexibilities into TRIPS that permit countries to fashion their own IPRs laws, legitimize exemptions from patentability on necessary products, and allow the placing of certain conditions on foreign investors with respect to patent protection. As a result, the Brazilian legislation from 1997 establishes that, in order to enjoy exclusive patent rights in Brazil, the holder of a patent on an invention must satisfy a local-working requirement. In other words, the patent-holder *must work* the patent in Brazil to enjoy full patent protection. If it fails to do this, the law says it shall be subject to the possibility of the government issuing a compulsory license, allowing someone else to use the invention and pay a royalty fee to the patent-holder. And the Argentine patent law as approved by Parliament in April 1995 authorized the national patent office to establish "limited exceptions to the conferred rights" in sectors of "vital interest to the socio-economic and technological development of the country" (Article 44 of the Argentine Patent Law).

However, the first 6 years of implementing TRIPS have been characterized by attempts by industrialized nations to focus attention mainly on securing IPRs for their corporations while ignoring their obligations to disseminate technological knowledge to address the developmental objectives of the poorer countries (Mukerji, 2000: 53–57). Following this pattern, on 30 May 2000, the USA (later joined by the EU) filed a complaint against Brazil at the WTO, alleging that it was in violation of its obligations under the TRIPS Agreement. On the same day as the complaint against Brazil, the USA (again joined by the EU) filed a complaint against Argentina, alleging that its patent laws violated the TRIPS Agreement in a number of ways (see WTO, 2000b, 2000c).

(Mis)Interpretation of TRIPS by the Developed Countries

The TRIPS Agreement was conceived as a way of bringing intellectual property rights under a harmonized system of international rules. It was an attempt to establish a comprehensive set of intellectual property rights standards, legally enforceable around the world by the reformed dispute-settlement mechanism that the WTO Agreements had otherwise established. Its declared goal was to ensure global technological progress by securing the inventors' rights to benefit from their research and development efforts.

The developed countries insisted that high international standards of IPRs protection would vitally benefit the economies in developing countries. The argument has been put forward that foreign investors are more willing to transfer technology when it is protected by law (Mansfield, 1995). The TRIPS Agreement establishes standards that are applicable within national legal systems, and since foreign investors are protected by these rules, TRIPS is inherently investment related. It should be then expected that foreign direct investment (FDI) would increase as domestic conditions become more predictable and investment friendly. The implementation of the Agreement is thus expected to facilitate an investment-friendly environment in developing countries. However, more detailed research shows that there is no evidence that a strong IPRs regime is a significant determinant of foreign direct investment (Kondo, 1995). China, for example, has been one of the most consistent violators of foreign IPRs, and yet the flows of FDI into that country have grown significantly over the past 20 years.

While the anticipated benefits are uncertain, the harsh reality is that the

technologically disadvantaged countries already feel the adverse impact of the monopolistic nature of pharmaceutical patent rights. In addition, the pessimism over TRIPS also stems from the Agreement's requirement to enforce IPRs protection on a level that routinely exceeds these countries' financial and administrative capabilities. Most of these countries have not yet developed appropriate competition rules to deal effectively with the challenges presented by TRIPS.

In effect, TRIPS ushers into the system of global trading rules an extensive mechanism for policing the high IPRs standards in 144 countries. A question could be asked why intellectual property attained this status, when other major forms of business regulation such as competition policy, environmental regulations, and labor rights did not. To a considerable extent, the answer comes from research that analyzed the behavior of the three powerful industries—pharmaceuticals, entertainment, and high-tech/software—which recognized the opportunity afforded by the Uruguay Round to protect their interests, and made IPRs a core issue for the US Trade Representative (USTR). This approach was complemented by efforts to publicize the alleged damages they faced from weak global IPRs standards and to push for unilateral trade actions by the United States. As intellectual property became better recognized as a trade policy issue, more export-oriented industries signed on, making TRIPS a required condition for success of the multilateral trade negotiations (Ryan, 1998: 67–89).

The question of the protection of pharmaceutical patents was one of the key issues in the Uruguay Round and perhaps the crucial issue in the North–South dimension of the negotiations. It was the last issue to be resolved prior to the tabling of the draft Agreement at the end of 1991. At that time, it was clear that there would be no TRIPS Agreement without a commitment to make patent protection available for 20 years in virtually all areas of technology, including pharmaceuticals, and that without an intellectual property agreement it was doubtful that the Uruguay Round could be concluded. Some observers believe that the TRIPS Agreement was inserted into the WTO because it was backed by developed-country power, especially as reflected in "Special 301" retaliations by the United States (Raghavan, 1997: 24).

"Special 301" vested the USTR office with the obligation of monitoring the relevant laws in foreign countries and initiating actions for trade retaliation against countries viewed as not providing sufficient IPRs protection to potential US investors. The family of "Special 301" laws was advanced as part of the fast-track authority granted by Congress to the US administration in the Omnibus Trade and Competitiveness Act of 1988.[6]

Section 301 gives the USTR the authority to enforce the rights of the US under any trade agreement or to respond to any country's act that is "unjustifiable and burdens or restricts US commerce." The USTR may examine the policies of a foreign country that does not effectively protect US intellectual property interests for the purpose of imposing import restrictions or duties. Section 301 gives the executive branch the power to pressure foreign countries into adopting intellectual property laws to protect US intellectual property abroad. Even if the product never makes its way into the USA, the USTR can retaliate with restrictions or duties on other goods made in the infringing country and imported into the USA. The threat of trade restrictions by the USTR also gives a US company the leverage it needs to negotiate a license for the use of its intellectual property.

Throughout the Uruguay Round, the USA repeatedly put on its "Special 301 watch list" countries that supposedly did not provide the kind of IPRs protection

the USA wanted. The initiation of investigations or retaliatory actions, it was understood, would depend on the extent to which the negotiators of the countries concerned cooperated or obstructed the achievement of US objectives in this area in the Uruguay Round. And very frequently, the benefits of low duties under the Generalized System of Preferences (GSP) intended to facilitate trade with developing countries were withdrawn. Of course, since it was a preferential benefit that was being withdrawn, the countries affected could not raise it as a dispute in GATT.

It should be noted that the strengthening of "Special 301" in the Omnibus Act of 1988 was a culmination of a dangerous pattern of *contingent protection* that slowly grew in the American Congress following the 1974 Trade Bill (Grey, 1982).[7] When US industries felt competitive pressure, they went to Congress with complaints and suggestions regarding how the trade-remedy laws should be changed to work in their favor. The business coalition behind some of the most noteworthy provisions of the 1988 Omnibus Bill came from the pharmaceutical, computer software, telecommunication and entertainment industries. The coalition insisted on focusing on the issues of intellectual property to stop alleged piracy in developing countries. It was organized around the Intellectual Property Rights Committee (IPC) with the CEO of Pfizer playing an influential role as its chairman. In May 1988, this powerful coalition, which also included business groups from the EU and Japan, first presented a proposal for a multilateral agreement on IPRs (Ostry, 1990: 23–24).

In addition, both the EU and the USA had sought to restrict exceptions from patentability for non-commercial purposes (such as free distribution of pharmaceutical drugs), as evidenced by the draft TRIPS proposal from 29 March 1990, which contained a provision reading: "Limited exceptions to the exclusive rights conferred by a patent may be made for certain acts, such as rights based on prior use, acts done privately and for non-commercial purposes and acts done for experimental purposes, provided that they take account of the legitimate interests of the proprietor of the patent" (GATT, 1990a: 10). Such limited non-commercial exemptions, however, are essentially meaningless for many developing countries. Financially bankrupt governments in the developing world can hardly sponsor adequate domestic research facilities nor can they finance universal state-run drug plans or pay the often excessive license fees demanded by the patent-holders.

In response to the proposals submitted by the EU and USA, many developing countries made a case for a much broader approach to exemptions on patent protection, including measures which would permit the compulsory licensing of food and medicines. They suggested that the following provision be included in TRIPS: "Nothing in this Agreement shall be construed to prevent any Party from taking any action necessary: for the working or use of a patent for government purposes; or where a patent has been granted for an invention capable of being used for the preparation or production of food or medicine, for granting to any person applying for the same a license limited to the use of the invention for the purposes of the preparation or production and distribution of food and medicines" (GATT, 1990b: 9).

The USA, the EU and Switzerland rejected the above proposal. Instead, a limited compromise was reached, which now appeared as Article 30 (*Exceptions to Rights Conferred*): "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the

legitimate interests of the patent owner, taking account of the legitimate interests of third parties." Yet, in practice, given the actions initiated under the WTO dispute-settlement system against Brazil and Argentina, this compromise amounts to very little.

When initiating the WTO panels, the EU and USA pointed to Article 27.1 (*Patentable Subject Matter*) of the Agreement, which stipulates that: "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." The plaintiffs have argued that this provision should be interpreted as warning against, and ultimately prohibiting, the use of any domestic policy measures curbing the sacredness of the private rights of the title-owners. As a result, any national policy initiative that overrides an existing patent can be interpreted as discriminatory and trade restricting.

This interpretation of TRIPS has been contested by developing countries. Specifically, Brazil's 1996 industrial property law stipulates that a patent shall be subject to compulsory licensing if the patent is not worked in the territory of Brazil. Both the USA and the EU threatened Brazil with panel proceedings under the WTO. However, in July 2001, Brazil reached an out-of-court understanding with the USA. In response to the US demands, the Brazilian government agreed that in the event it would deem it necessary to grant a compulsory license on patents held by US companies, it would hold prior talks on the matter with the US government (WTO, 1996b, 2000d, 2000e, 2001c, 2001d). The US government subsequently withdrew its complaint in the WTO. However, the deal reached raises questions about Brazil's autonomy, since it obliges the government of Brazil to consult with the USA prior to making a decision on what amounts to domestic policy matters.

In 1999, India's inability to meet the WTO deadline of 19 April for amending its patent law to allow for exclusive marketing rights to drugs and agrochemicals had at its roots, among other things, disagreements over demands to abolish a provision on compulsory licensing. Under its old legislation, India could widely license marketing rights on pharmaceutical drugs and agrochemicals in the interest of public health and safety. Some Indian officials warned that under the New 1999 Patents Act, importation would be equivalent to the working of a patent locally, thus discouraging local production, increasing foreign exchange outflows, reducing employment and increasing prices. This argument is supported by evidence from Malaysia. Industrialized countries have asserted that importation of ready products (including pharmaceuticals) constitutes a sufficient requirement of "working" a patent. A survey of foreign-owned companies in Malaysia reveals that virtually all patents granted there have been used to cover imported products instead of producing them locally (Azmi and Alavi, 2001: 959).

India has argued within the WTO that compulsory licensing is perfectly justified with respect to pharmaceutical inventions because the public interest should prevail when it comes to assuring the supply of life-saving medicines. Compulsory licensing can create a strong domestic generic drug industry and is generally associated with greater competition and lower consumer prices. It can also lead to a necessary transfer of technology to less developed countries.

Prior to the global consolidation of the pharmaceutical industry in the past decade, compulsory licenses had been routinely used in North America and Europe to facilitate the distribution of new (generic or not) medications. The use of generic medicines, in turn, has resulted in important economies for the public healthcare system, thereby contributing to its viability and the protection of public

health. The World Health Organization (WHO) has endorsed the legitimacy of measures to promote the use of generic drugs as a means of protecting public health. In its resolution of the Revised Drug Strategy, the WHO (1999) encourages its members "to explore and review their options under relevant international agreements, including trade agreements, to safeguard access to essential drugs."

Canada routinely granted compulsory licenses for pharmaceutical drugs until it was pressured by the USA, as a condition of joining the North American Free Trade Agreement (NAFTA), to abandon its flexible approach to compulsory licensing. Between 1969 and 1992 such licenses were granted in 613 cases for importing or manufacturing generic medicines. It is believed that Canadian consumers saved millions of dollars in drug costs. In 1991–92 alone, such savings were estimated at more than US$170 million (UNDP, 2001). This is no longer the case since Canada accepted TRIPS after it agreed to adopt its early version, currently known as NAFTA Chapter Seventeen.

The Human Development Report 2001 reveals that under pressure from Europe and the USA developing countries fear that they may lose foreign investors if they legislate for or use compulsory licenses (UNDP, 2001). In addition, developing countries also face the threat of long, expensive litigation brought by pharmaceutical companies.

The Impact of TRIPS on Access to Affordable Medications

Since the TRIPS Agreement came into effect, many developing countries have been complaining about the growing monopolization of intellectual property in the hands of a few powerful titleholders. Developing countries have been concerned about the detrimental effect that such monopolization is having on their ability to gain access to affordable pharmaceutical products. The problems are complex. For example, by securing stronger (and longer) patent protection pharmaceutical firms could engage in abusive practices because of their protected market positions. Such abuses would translate into setting restrictive licensing conditions and establishing vertical controls through distribution outlets that prevent product competition. They could also mean price discrimination and predation against local firms.

The connection between IPRs and access to affordable medicines continues to attract widespread public attention, ignited by the dispute between the South African government and 39 leading pharmaceutical companies. Although there are almost 200,000 people suffering from HIV/AIDS in South Africa, existing treatments are too expensive for most patients there (Kongolo, 2001). In South Africa, the average annual income was less than US$3000 in 1995, while the HIV/AIDS regimens can cost US$12,000 a year. In 1997, the South African government took steps to introduce compulsory licensing of these medications to ensure the availability of generic substitutions, a move aimed at significantly reducing prices. This initiative, however, was stalled by a lawsuit filed in February 1998 by a group of the leading pharmaceutical companies claiming that the new legislation was inconsistent, among other things, with South African obligations under TRIPS.

For years, the drug industry had a sympathetic ally in the USTR office (Ryan, 1998: 69). Now, that may have changed. The lawsuit in South Africa initiated in the context of the global AIDS crisis has prompted a widening circle of activists, including nonprofit organizations such as Oxfam and the Nobel Prize winning

Médecins sans Frontières (MSF), to question the consequences of globally institutionalized pharmaceutical patents and consider them as a direct threat to the health of the world's poor. These groups are encouraging developing countries to make or import generics, even if it means violating "the rights" of patent owners. In a report released in February 2001, Oxfam said it would launch a new worldwide campaign to cut the cost of medicines for the poor, calling on the WTO to change patent rules, which it says result in restricted access to life-saving drugs.

The advocates of the WTO rules claim that the TRIPS Agreement strikes a reasonable balance between the interests of the private sector to ensure protection for their patented goods and the interest of governments to ensure their autonomy with respect to public policy initiatives (Otten, 1998). They also point out that the Agreement allows WTO Members to write provisions in their intellectual property legislation allowing them to adopt measures necessary to protect public health. However, in its 2001 Report, Oxfam argues that: "these TRIPS provisions are hedged in by onerous conditions and, in practice, efforts to apply these measures have been fiercely contested by pharmaceutical companies, often with the backing of western governments."

Oxfam also seeks changes to WTO dispute-settlement rules, under which disputes over TRIPS and other WTO Agreements are adjudicated. Oxfam argues that relevant experts such as health professionals should be appointed to dispute-settlement panels; that *amicus curiae*[8] briefs should be accepted; and that joint panels with other organizations such as the WHO should be set up when disputes have an important non-trade dimension.

Furthermore, the group proposes broadening and clarifying the criteria under which compulsory licensing and parallel imports can be invoked, and shortening patent terms protected under the TRIPS Agreement. The Oxfam Report argues that the WTO must change the rules that mandate the length of the patent (20 years) used by the industry to cripple cheap, local competition and to inflate the cost of new medicines. Oxfam also demands that developing countries should be allowed to make cheap copies of drugs to treat diseases such as AIDS, respiratory tract infections and childhood diarrhea. It has called on the US government and major pharmaceutical companies to drop legal actions against countries that are producing cheaper drugs. Oxfam maintains that this industry campaign has been led by the Pharmaceutical Research and Manufacturers of America (PhRMA), one of the world's most politically influential and well-financed industrial lobbies. The primary source of PhRMA's power is its influence over the office of the USTR, which has repeatedly backed its claims with the threat of trade sanctions (*Inside US Trade*, 2001).

For the USTR office, such debates are relatively new. In the past, the usual agenda of US trade practitioners in relation to intellectual property tended to revolve around the arcane details of TRIPS. Traditionally, the big issues at the trade office were about protecting compact discs, microprocessors and bio-technological formulas from piracy in developing countries. Everything started to change in 1998 after a group representing the pharmaceutical industry complained to the USTR office about the new South African law.

South Africa's 1997 Medicines Amendment Act authorizes two practices that are controversial (although not explicitly prohibited) under TRIPS. One is parallel importing, which allows importers to buy pharmaceutical drugs from the cheapest sources available abroad, regardless of whether the patent-holders give their

approval. The other practice, already explained in this article, is compulsory licensing, which would allow the South African government to license local companies to produce cheaper versions of drugs whose patents are held by foreign companies.

Several weeks after the South African law was passed members of the US pharmaceutical industry lobbying group asked the USTR office to take action against South Africa. According to an official in the trade office, the industry group framed the matter simply as a struggle over intellectual property rights. There was no mention of how this might affect the treatment of AIDS. For the next two years, the US officials took up the industry's arguments in a series of letters, phone calls and meetings with South African officials. According to US trade officials, their South African counterparts also did not address the subject of AIDS, perhaps because of the societal stigma. Rather, the two sides argued about whether the Amendment Act contradicted the TRIPS Agreement.

To pressure South Africa to withdraw its law, the USTR in 1998 denied Pretoria's request for additional benefits under the Generalized System of Preferences, a trade scheme which would allow South Africa to export products to the USA at reduced duties. Then, a year later, Congressman Rodney Frelinghuysen, a New Jersey Republican, speaking on behalf of pharmaceutical companies established in his state, suggested a revision to legislation providing the procedures for distributing aid for South Africa. He proposed holding up payments for a few months until the USA demonstrated it was pressuring South Africa on the Medicines Amendment Act.[9] In April 1999, the US trade office put South Africa on its annual 301-Watch List. It cited South Africa for the 1997 Medicines Act, which the USA said could potentially "abrogate patent rights." At this point it became clear that the next step could be an initiation of the WTO dispute-settlement panel that could translate to future trade sanctions.

The pharmaceutical industry was very pleased with the actions of the USTR, but decided to pursue the matter further. In February 1998, the consortium of 40 drug companies, led by the Pharmaceutical Manufacturers' Association of South Africa, filed a suit. Its key legal claim was that the statute, the Medicines Amendment Act of 1997, was in violation of South African obligations under TRIPS. It was also claimed that the statute was unconstitutional because it gave sweeping power to South Africa's health minister to override the country's patent laws (Kongolo, 2001). For its part, the South African government promised to defend the Medicines Act, which could not be implemented because of the lawsuit.

The decision by the pharmaceutical industry to pursue the legal proceedings, despite the devastation caused by South Africa's public health crisis, has provoked unprecedented international condemnation and an activist campaign that in its second year had spread to include hundreds of non-governmental organizations (NGOs) and different interest groups. In response to resounding global pressure, on 19 April 2001, the pharmaceutical companies dropped the case they had pursued for three years. The end of the lawsuit cleared the path for the 1997 Medicines Amendment Act to go into force, allowing importation of affordable medicines and increased use of generic drugs in South Africa.

The pressure has been especially intense in Washington. Before the AIDS crisis there was never any doubt that the USTR considered drug patents sacrosanct. Now a growing alarm about the spread of the disease, and a widening belief by consumers that pharmaceutical companies price their drugs too high, has forced the US government to reconsider its unyielding support for the industry's positions

overseas. Most recently, the anthrax scare has forced many policy-makers to take a close look at the TRIPS Agreement and its implications.

In October 2001, the Canadian government asked Apotex, a Canadian-based company, to make copies of Cipro, the drug under patent to Bayer of Germany considered to be the preferred treatment for anthrax. Some US trade negotiators immediately criticized Canada's decision, fearing that it could undermine its negotiating position on the TRIPS Agreement. Others, including the Health GAP Coalition and Charles Schumer of New York, a leading Democratic senator, called upon the US government to follow Canada's example, arguing that a decision not to supply cheap generic medicines would prevent poor Americans from obtaining Cipro.

Cipro retails for US$2.5 per pill commercially. In a measure of the wide variability in pharmaceutical prices among countries, Apotex offered to supply Canada with generic Cipro at US$0.99 a tablet. Consequently, the US Department of Health and Human Services demanded that Bayer drop the price on supplies being stockpiled by the federal government for emergencies. The US Health and Human Services Secretary Tommy G. Thompson announced that he would consider approaching generic manufacturers if Bayer did not significantly lower the drug's price for the government. Eventually, the threat of other firms being recruited to make generic versions of the drug induced Bayer to deliver the medicine more cheaply. The Canadian government also withdrew its decision to override Bayer's patent.[10] Still, the anthrax scare demonstrated how the inflexible approach to patents, as currently encouraged by the TRIPS Agreement, could dangerously exacerbate conflicts between private interests and public needs by leaving governments with too little room to maneuver.

Conclusion

It is not surprising that the protection, use and dissemination of intellectual property has moved to the central stage of international economic relations, given its growing importance for the conditions of international competition in the new knowledge-based economy. Yet keeping up with the shifting international economic environment has become a major challenge for domestic policy-making because global economic rules increasingly penetrate inside state borders while scrutinizing and constraining domestic laws and regulations. Since the TRIPS Agreement came into effect, many developing countries have been complaining about the growing monopolization of intellectual property in the hands of a few powerful titleholders and the resulting weakening of state autonomy to pursue their national policy objectives.

The progressive introduction of patents in the field of pharmaceuticals has been especially controversial because of the international context in which it is happening. TRIPS restricts the available policy options and it ignores the profound asymmetry in developmental and research capabilities between the developed and developing countries. Developing countries argue that a strong global patent regime as prescribed and monitored by TRIPS constitutes a likely obstacle to the development of a local pharmaceutical industry. Developing countries repeat that they lag behind the industrialized countries in their research and development capacities and thus must rely on imitation, often by means of compulsory licensing, to produce generic drugs affordable to their citizens. This, however, becomes increasingly difficult, as the leading industrialized nations tend to

interpret the TRIPS Agreement as practically prohibiting exemptions from patentability and flexibility to override patents by means of compulsory licensing of pharmaceutical drugs.

The global extension of intellectual property rights, especially with respect to patents, and the enhanced powers conferred on titleholders have raised concerns about the extent to which the fundamentally commercial interests protected by intellectual property rights may be given primacy over other of society's interests, such as those relating to public health and consumer protection. Since the TRIPS Agreement came into existence, western governments and their pharmaceutical companies have come under heavy attack from developing countries and NGOs. Most recently, the anthrax scare has brought the problem of access to affordable medicines to the doorsteps of the industrial nations.

The growing concerns over global patent rules and the unyielding plea by developing countries to modify TRIPS have finally produced some tangible results. During its Fourth Ministerial Meeting in Doha, Qatar, in November 2001, WTO Members adopted the Declaration on the TRIPS Agreement and Public Health, addressing, for the first time on a multilateral level, the problem of inaccessibility of medicines by the poor nations. The Declaration reads: "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health ... and to ensure access to medicines for all."

Some critics, however, are reserved in their embrace of the Declaration. In particular, it is disappointing that WTO Members missed the opportunity to resolve the question of imports of generic medicines for countries that do not themselves have the manufacturing capacity to produce such drugs. Whether the Declaration will actually improve access to medicines will depend on the extent to which developing countries are able to make use of the flexibilities in the TRIPS Agreement, and on the yet to be tested legal strength of the Declaration.

The leading industrialized countries must pay attention to the social and economic needs of developing countries. However, this would likely require a considerable departure from the existing attitude towards IPRs derived from western legal practice and now institutionalized in the TRIPS Agreement. The critics observe that there is no public justification for supporting the global standards of intellectual property rights as defined by industrial countries' laws (Templeman, 1998). Crudely interpreted, the implication of the TRIPS Agreement is that the global economy not only needs the IPRs standards to be harmonized, but needs to harmonize them up to the levels prevailing in the leading industrialized countries.

A change of attitude is necessary. A prominent economist suggests that we can begin with the idea of *fairness* as one of the principles that should govern the dialogue between the developed and developing countries (Stiglitz, 1999). Fairness entails *sensitivity* to the special needs of developing countries and one important dimension of this sensitivity is the recognition of the problems posed by human needs, such as health.

Notes

1. Those Members that did not provide patent protection for pharmaceutical products when the WTO was born were allowed until 1 January 2005 to implement it. However, under Article 70.8 of TRIPS, these countries still had to establish a "mailbox" for filing foreign patent applications that would preserve the priority dates of any pharmaceutical

(and agricultural chemical) patents during this interim period. India contested this provision, but it ultimately lost the case at the WTO dispute-settlement panel. See WTO (1996a, 1997).

2. The debate about implementation problems has been growing steadily within the WTO (see WTO, 2000a). As a result of the Fourth Ministerial Conference in Doha, Qatar in November 2001, WTO Members adopted the *Declaration on the TRIPS Agreement and Public Health* (WTO, 2001a) and *Implementation-Related Issues and Concerns* (WTO, 2001b).
3. Compare the worldwide statistics on patents collected by the World Intellectual Property Organization (WIPO) at http://www.wipo.int/ipstats/en. Also, see the United Nations Development Program's (UNDP) *Human Development Report 1999—Globalization with a Human Face* (UNDP, 1999: 69).
4. The General Agreement on Tariffs and Trade numbered 23 Members when it was formed in 1947. By the time the Uruguay Round concluded, and GATT was replaced by the WTO, it had 117 Members. As of May 2002, the WTO has 144 Members and 28 applicants are negotiating accession.
5. The most important of these IPRs conventions include: the Paris Convention for the Protection of Industrial Property (1967); the Berne Convention for the Protection of Literary and Artistic Works (1971); the Rome Convention (1961); and the Washington Treaty on IP in Respect of Integrated Circuits (1989). UPOV, initiated by a group of western European countries, is based on the International Convention for the Protection of New Varieties of Plants signed in Paris in 1961.
6. Fast-track gave the US administration the necessary power to negotiate the Uruguay Round. Incidentally, on 6 December 2001, the Bush administration secured a similar authority, presently named the Trade Promotion Authority (TPA). It permits negotiating in a new round of global trade talks set to begin in 2002.
7. Secondly, the interests of companies based on intellectual property were becoming increasingly global.
8. An *amicus curiae* (friend of the court) brief is intended to bring to the attention of the court relevant matters not already brought to its attention by the parties involved. Such a brief is usually filed by an interested group or institutions and constitutes a form of public pressure.
9. Personal interview, Washington DC, March 2001.
10. See the following articles: *Financial Times* (2001a, 2001b) and *Globe and Mail* (2001).

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