TRIPS and the Primacy of Public Health

SHINZO KOBORI

The 1984 Uruguay round of trade negotiations was criticized by many as discriminating against developing countries. On the issue of intellectual property, the contentious issue was that of the patent protection given to the drugs manufacturers, mostly based in developed countries. In this article, Shinzo Kobori, distinguished research fellow at the Institute for International Policy Studies, explores the issues surrounding the dilemma: the drugs need to be provided for many people in the developing world but, on the other hand, adequate compensation needs to be given to pharmaceutical companies producing the medicine. Focusing on pharmaceutical patents of anti-AIDS/HIV drugs, he examines the barriers to access to essential drugs in developing countries. Kobori goes on to scrutinize the various policy options including compulsory licensing and parallel imports, and describes the potential hurdles facing global drug companies in light of the challenges from Brazil, South Africa and the US.

The scuffle at the 1999 Seattle World Trade Organization (WTO) Ministerial Conference was a misplaced expression of frustration by antiglobalization activists. Their protests did not stop there and the antiglobalization movement continued to other international gatherings in Washington, Prague, Québec City and Genoa. Even if one does not agree with their reasoning or their method of protest, one can at least sympathize with their frustration. The initial choice of the biennial WTO meeting for the venue of their protest against globalization may have been inappropriate, but given the outcome of the Uruguay round of the General Agreement on Trade and Tariffs (GATT), which also saw the creation of the WTO, there is a certain simple logic.

The Uruguay round was seen by many as favoring the rich countries and the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which was negotiated there, was one of the most contentious issues dividing the developing and developed countries. Thus, the 2001 Declaration on TRIPS and Public Health at Doha was hailed as a real coup for developing countries. In fact, the launch of the Doha Development Agenda, as the new round is called, is seen not only as the first step towards freer multilateral trade but, as the name would suggest, also in the interests of developing countries.
The launch of a new trade round had always been the priority of these WTO talks but the meeting at Doha may have unwittingly benefited from 11 September. For example, due to security concerns, many protesters stayed away. Furthermore, the public scares from the outbreak of anthrax incidents raised the profile of the question of a company’s patents rights over the interests of public health. Also, the prospect of a global recession and the US’ continuing struggle against terrorism meant that all countries had additional incentives to ensure that a new round was successfully launched.

Since the introduction of TRIPS, there have been a plethora of papers on the pros and cons, but mostly cons, of the agreement. This paper examines some of them focusing on the repercussions to the pharmaceutical patents and safeguards.

**Tripping at Doha**

On 14 November 2001, the Fourth WTO Ministerial Conference in Doha, Qatar, affirmed the primacy of public health concerns over pharmaceutical patent rights in the TRIPS agreement. The Declaration on the TRIPS Agreement and Public Health states that “the TRIPS agreement does not and should not prevent members from taking measures to protect public health” and furthermore, “the agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”

Thus, with this declaration, in theory at least, developing countries were no longer prevented from gaining access to cheap medicine. Nevertheless, as the declaration is a political but not legally binding document, it does not necessarily mean that pharmaceutical companies from the developed countries will comply. On the surface, the developing countries appear to have won the first round but the problem of countries who lack the domestic industrial capacity to produce the drugs they need has yet to be resolved, as mentioned in paragraph 6 of the declaration:

…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.

TRIPS became part of the new multilateral trading system as one of the most fundamental achievements under the Uruguay round of trade negotiations (1986–1994). Naturally, the proponents of TRIPS had been the developed countries who had the most to gain as they held the majority of intellectual property rights (IPR) including those for pharmaceuticals. The reason why developing countries had eventually agreed had been because they had hoped they would be able to benefit from greater access to advanced technologies and to win some trade concessions.
over the export of agricultural and textile products; a sort of quid pro quo. The usual path in which developing countries gain access to technologies is through import of goods and services, inward foreign direct investments (FDI) and contractual licensing of technologies.

Certain diseases are more prevalent in the third world than in the rich countries such as malaria, hepatitis, human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS). For example, as 95 percent of the world’s 60 million people with HIV or AIDS live in developing countries, there was growing concern and resentment that the TRIPS agreement was limiting access to antiretroviral medicine. Protection of pharmaceutical patents was considered to be the leading barrier to access to essential medicine as the cost of drugs was beyond the reach of most sufferers in the developing countries. Developing countries are not necessarily against patents per se, in and of themselves, but they are concerned about the potential adverse effects or the abuse of private patents on public access.

The agreement reached at Doha means that the interpretation of TRIPS has become flexible enough to allow developing countries to be able to make full use of the safeguards, including compulsory licensing and parallel imports for better access to medicines at reduced and affordable prices. As the legal text of the TRIPS agreement has not been amended, the objective of the Doha declaration is to clarify what governments can and cannot do under the TRIPS agreement. Before November 2001, there were cases of legal wrangling, for example between Brazil and the US, over whether or not a nation’s domestic patent laws contravened the TRIPS agreement.

**Patents and access to drugs**

On the whole, the benefits from IPR tend to go to the rich rather than to the poor countries, the latter being net importers of technology. The country with most to gain from TRIPS is the biggest (economy) of them all—the United States, as the net incomes earned from American patents in foreign markets is considerable. Since the 1980s, the US has become more and more enamoured with patents and have strengthened institutional frameworks by having the US Patent and Trademark Office aggressively extend patents to cover new technologies and services. This is not surprising considering the reason behind the growth of the US economy during the 1990s was, in large part, due to innovation in information technology. In addition, the US even threatened to close its domestic market to countries who did not comply with minimum intellectual property standards in accordance with the so-called “Special 301” provisions of the 1974 Trade Act, as amended.

The question is whether patent protection in accordance with the TRIPS agreement really influences the price of pharmaceuticals, and if so, to what extent. Certainly, to develop new drugs is costly, so patents are not only an insurance to drug companies that they will recoup their investment for the research and development (R&D) without being undercut by copycats, but also provide incentives
to develop even better medicine. It also naturally follows that the expenditure on R&D would be passed through the cost of the price of patented medicine. As some critics argue, the problem is that the huge prices commanded by branded drugs are because of the patents which give the company exclusive rights for 20 years. Nevertheless, to blame patent protection for the inaccessibility of essential drugs in developing countries is a feeble argument. Merely opposing patents and patent legislation is counterproductive as true innovation deserves to be recognized and protected.

A proposal on TRIPS from a group of developing countries in Africa and other regions submitted to the WTO Council for TRIPS before the Doha declaration had emphasized that “the patent protection should encourage the development of new medicines and the international transfer of and access to technology to promote the development and maintenance of sustainable domestic manufacturing capacities for medicines.”6 This is a clear acknowledgement that a flexible interpretation of the TRIPS agreement could be part of the solution and not part of the problem.

Some argue that the real barrier to procurement of medicine for poor countries has nothing to do with IPR or patent protection but is finance, or rather, lack of. It is self-evident that insufficient funding, both public and private, exacerbates the situation and poverty-reduction would be a primary objective of all developing countries. Lack of funds is certainly a contributory factor but should be part of a wider discussion on development economics rather than on this issue of access. Other barriers to access is the level of development of a developing country; such as the state of its infrastructure, health facilities, staff and equipment, education, access to information, distribution channels, and so on. In addition, certain drugs do not even have patents including those for infectious diseases such as malaria and tuberculosis, as well as 95 percent of the medicines considered by the World Health Organization (WHO) as “essential drugs.” Furthermore, people with an annual income which is often less than a month’s wages for a worker in a developed country, cannot possibly afford the prices charged by international drugs companies.

A survey of 53 African countries for 15 antiretroviral drugs used to treat AIDS, conducted by the Center for International Development’s Amir Attaran and Lee Gillespie-White (AGW),7 revealed that few African countries had patents of these drugs and of those that did, on average, only three types had been patented—the products of Agouron Pharmaceuticals (a Pfizer company), Boehringer Ingelheim and GlaxoWellcome (now GlaxoSmithKline).

This survey was the result of a suspicion that, despite the media attention given to patent protection, the number of patents per se was not the real problem. Thus, AGW point out, rather superfluously, that if the enforcement of patents were depriving Africans of access to AIDS drugs, countries with no patents should have better access: this is clearly not the situation in Africa. He concludes that the emphasis on patents may be taking energy and attention from more important barriers, such as lack of international aid to buy antiretroviral drugs and the prohibitive cost of AIDS treatments.
Another report which supports the AGW position and questions the appropriateness of painting patent protection as the villain preventing access to antiretroviral medicine is the “Facts and Figures on Patenting and Access in Africa” released in August 2001. Not surprisingly, released by the US Pharmaceutical Research and Manufacturers Association (PhRMA), this report asserts that patents are not the real problem and that poverty as well as limited public and donor spending on health care are more significant barriers.

The AGW report suggests that out of a potential 795 drugs, or combinations of drugs, in the 53 countries surveyed only 172 (21.6 percent) had patents whilst the PhRMA survey showed that 150 products had patents in 52 countries. According to both reports, these 150 to 172 products are not significant: Nongovernmental organizations (NGOs) contend otherwise. They point out that both surveys failed to include significant products that were blocked by patents and although poverty reduction was important, more immediate action could be taken if patents were lifted. In the relatively richer South Africa for example, patents completely block drug access and GlaxoSmithKline, one of the major pharmaceutical companies, has patented many of its popular combination AIDS drugs in most African countries.

Jean Lanjouw offers a proposal on how IPR for pharmaceuticals could be altered to ensure that poor countries have access to essential drugs, such as that for anti-AIDS, at a marginal cost of production. She distinguishes between diseases specific to poorer countries, such as malaria, and global diseases, such as cancer and AIDS. In her system, pharmaceutical companies can choose to have patents in either developed or developing country markets, but not in both. Thus, in the case of the antiretroviral drugs for HIV/AIDS, it would be in the interests of the pharmaceutical companies to have the patents protected in the developed countries. The developing countries would be able to produce the drugs but the producers should be prevented from exporting the cheaper drugs back to the developed countries. Lanjouw also makes the point that this system would be a very minor disincentive to innovation because most of the potential rents for global diseases are in developed countries.

It is inevitable that a certain amount of the cheaper drugs will flow out but developing countries would have access to cheap drugs and the incentives for innovation worldwide would remain strong. The advantages of this proposal is that pharmaceutical companies would not be discouraged from R&D: where demand in developed countries is low, as in the case of malaria treatments for example, the patents in developing countries will provide the incentive to develop new products. Lanjouw’s argument clearly demonstrates the role that patents play in innovation. She shows that developing countries should protect patents that will help produce better treatments for diseases prevalent in their own countries. On the other hand, they have no incentive to protect the patents on medicine for global diseases such as AIDS or cancer, because the multinational drug corporations will have already invested in R&D, based on returns in developed country markets. For diseases specific to developing countries, as the potential returns may be too limited, however,
international organizations such as the UN will need to provide financial assistance if pharmaceutical companies are to innovate new drugs.

**Compulsory licensing as safeguards**

By the provisions of the TRIPS agreement, governments can act to prevent patent owners from abusing their patents by unreasonably restraining trade, or the international transfer of technology. In such a case, a government allows someone other than the patent owner to produce the patented product or process, and this involuntary patent transfer is known as compulsory licensing. The TRIPS agreement allows compulsory licensing as a safeguard, to strike a balance between promoting access to existing drugs and innovation. Compulsory licensing is the tool that pharmaceutical companies dislike the most as it represents the loss of control of their patents.

The Paris Convention for the Protection of Industrial Property recognizes the right to grant compulsory licenses, as stated in Article 5, paragraph 4:

> A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of sub-license, except with that part of the enterprise of goodwill which exploits such license.\(^\text{10}\)

and was incorporated into the TRIPS agreement in the event of a national health emergency. On this basis, “failure to work or insufficient working” of a patent should be a legitimate ground to grant compulsory licenses. From a developing country’s perspective, it is clear that the local working of a patent is preferable as, apart from making products more affordable and readily available, the technology transfer opportunities and reduced foreign exchange expenditure from cutting imports would be considerable. Not surprisingly, the global drug companies have lobbied for a narrower interpretation, as can be seen by the US government’s complaint against Brazil and South Africa on their behalf.

For those developing countries with neither the domestic industrial capacity nor a sizable demand to justify local manufacturing, the compulsory license provision as it stands is pointless. Under these circumstances, a compulsory license for the importation of the patented medicines is the only feasible course of action, which has been suggested as a possible solution. Some have suggested that low-income sub-Saharan African countries be permitted to use a compulsory license to allow third countries to supply them with essential drugs from a manufacturer base, for example in South Africa or India, even if that producer is not the patent holder and is under patent restrictions in its own-home-country market.
Under present regulations, this is not possible as the export of products produced under a compulsory license is virtually prohibited. This is to prevent the cheaply manufactured goods from entering a third country where they compete against identical, but much more expensive, products produced by the patent holder. If the product in question is patent-protected in the third country market the cheap imports are legal, provided the importing WTO member country chooses the principle of international exhaustion of patent rights, as in the case of South Africa.

Parallel imports for developing countries

Clearly under compulsory licensing, the price of the same medicine will be very different in the developed and developing countries. Hence, some experts suggest using parallel imports for developing countries to diminish the negative impact of inflexible protection of IPR. In contrast, others argue for the exact opposite to ensure the incentive to innovate is not lost, and maintain that parallel trade in patented products should be banned, especially for pharmaceutical products. They attribute price differences to many factors outside the control of global drug companies and argue that prices do not necessarily fall even with parallel imports. Such a prohibition does not require an amendment to the TRIPS agreement, however, although each country is free to prevent or permit parallel imports by establishing its own regime for the exhaustion of patent rights.

The global drug industry’s concern over the possibility of a reverse flow of products needs to be addressed. Lanjouw points out that the first step is to help companies to separate markets by legislative confirmation that the country—for example, the US—does not have an international exhaustion of rights doctrine. This would be a clear sign that patent holders had the right to prevent identical goods from entering a country from abroad, even if those goods had been produced legitimately under patent legislation.11

How best to stop the reverse flow of essential drugs is also an issue being considered by the Accelerating Access to HIV Care, Support and Treatment program, organized by the Joint United Nations Program on HIV/AIDS (UNAIDS). This program came into fruition with the cooperation of the WHO, other UN agencies, and the major global pharmaceutical companies including Abbott Laboratories, Boehringer-Ingelheim, Bristol-Myers Squib, GlaxoSmithKline, F. Hoffmann La Roche, Merck and Pfizer. The participating pharmaceutical companies offer the same patented medicine under a differentiated pricing system to the poorest countries on similar lines to their system in developed countries.

Considering the costs involved, preventing the flow of drug traffic from the cheaply produced developing countries to the rich developed countries with the high prices will be near impossible. Therefore, enforcement will be a very complex and troublesome issue. “Smuggling drugs” and “drug mules” could take on a whole new meaning. Tablets of essential medicine are relatively easy to smuggle as they are small, compact, easier to disguise and, unlike illegal drugs, at least for the
moment, can bypass the sniffer dogs. In the future, this situation will worsen as this sort of trade will no doubt increase as a result of the opportunities offered by the internet. Effective enforcement will only be possible with the active participation of the developing countries.

**Brazil’s compulsory licensing**

Under Article 68 of Brazil’s intellectual property law, all patent holders are required to manufacture their products locally. Therefore, if products are supplied through imports, compulsory licensing of the patents will ensue, which is in direct violation of the TRIPS Article 27.1. In 2000, the Office of the US Trade Representative (USTR) filed a complaint with the WTO protesting the provisions of the Brazilian law. Although Article 68 covers all patents, the focus was on the break of patents on pharmaceutical drugs, in particular, antiretroviral drugs.

Brazil has one of the highest numbers of people—approximately 200,000—with AIDS in Latin America. As the local production of a patented drug would clearly benefit the AIDS program by the huge savings from the reduced price, the Brazilian government threatened to compulsory license Nelfinavir, the cocktail drug used by over 25 percent of AIDS patients in Brazil. After much wrangling, the Swiss company with the patent, La Roche, agreed to a 40 percent discount and the complaint was dropped.

**Another bend: the South African case**

South Africa has the largest economy in Africa with a per capita income of well above $3,170 (1999 figures), and accounts for 40 percent of the total gross domestic product (GDP) of sub-Saharan Africa. Nevertheless, how to treat the 4.7 million people who are HIV-positive, is a serious issue requiring urgent measures. Thus, in 1997, the government revised the South African Medicines and Related Substances Control Act to allow the abrogation of all patent rights for pharmaceutical products. Ministerial discretion was to decide on compulsory licensing and parallel imports of a generic version of antiretroviral drugs from India. The proposed revisions were challenged on the ground that it breached the Patents Act and the Constitution of South Africa by 39 pharmaceutical companies including the four multinational corporations, Merck, GlaxoSmithKline, Bristol-Myers Squib and Boehringer Ingelheim, backed by the US government.

In April 2001, however, the suit was withdrawn due to great political pressure from both domestic and international quarters. This reflects the growing concern that a rigid implementation of pharmaceutical patents has a detrimental impact on the public health policies of developing countries. For the many sufferers in the developing countries, this was a positive move. Immediately after the South African government’s victory, Kenya passed a patent act including a provision on compulsory licensing and parallel importation rights of antiretroviral medicine.
To bend or not to bend: compulsory licensing in the developed countries

The outbreak of anthrax scares in the US brought the drug companies at loggerheads with their former champion, the US government. Fearing a potential national emergency, the US government sought to revoke the patent of Bayer, the company with the patent for the anti-anthrax drug, ciprofloxacin, with the brand name Cipro. As it turned out, the anthrax scare was not substantiated and the US government did not have to use compulsory licensing but the threat had been enough. The damage had been psychological more than anything else but eventually Bayer agreed to discount Cipro for a large quantity procurement. Further up north in Canada, the health ministry had been even more impetuous, going as far as commissioning a generic version of Cipro. The plan was scrapped when Bayer donated the medicine.

In light of the above events, it is natural that there would be accusations of hypocrisy. To revoke a patent at the mere threat to North American lives on the grounds of a national emergency that was not even realized, but to object when to do so would save the lives of millions of non-Americans would seem to be a case of falling flat after tripping over the TRIPS agreement. The same rules should be applied to both rich and poor countries.

Conclusion

Although hailed as a victory for developing countries, the Doha Development Agenda was but the first step and the issue of IPR is but a small part of a wider issue of public health in developing countries. After all, the WTO’s mandate is multilateral trade, not public health. Nevertheless, the recognition that “a clearer understanding of the public health safeguard provided in the TRIPS Agreement, the global intellectual property rules must support, not undermine, the public health and development of poor nations, including the fight against AIDS,” is an indication of the greater political momentum.

In contrast to the developing countries’ approach of employing compulsory licensing and parallel imports, the major global drug manufacturers attempts to tackle the issue include:

- Company commitments to supply essential medicines at low cost or free to the developing countries, using a differentiated pricing system;
- The active implementation of the recommendations of the Accelerated Access to HIV Care, Support and Treatment program started in April 2000, in cooperation with the international organizations including the UN agencies, the WHO, and USAIDS; and
- Make better use of funds from various sources including governments, non profit organizations and corporations through international cooperation.
Safeguards can be effectively utilized by those developing countries with a reasonable standard of domestic manufacturing capacity to produce drugs but most developing countries lack this very capacity. Observation of the leading countries manipulating safeguards, such as Brazil, South Africa, and India, is necessary for the lessons proffered to other countries, for the insight into future policy options and also to ensure they are not abusing a hard luck story to promote domestic firms. At the same time, a close watch over the actions of the major pharmaceutical companies should also be kept as they are now at a cross roads and in particular, a close observation of how they proceed with their commitments to the Accelerating Access program will be revealing.

To emphasize, Doha was but the first step.

Notes
1. WTO Ministerial Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, Doha, WT/MIN(01)/DEC/2, 20 November 2001, para. 4
3. Declaration, para. 6.
5. Known as the “coercion story” to account for why the development countries went along in the TRIPS. Another story is the “contract story.” For more details, see Policy Discussion Paper [Preliminary Draft] (UNCTAD/ICTSD, 20 November 2001), p.18.