Access to Medicines and Vaccines: Implications of Intellectual Property Protection and Trade Agreements
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1. INTRODUCTION

Patents for new drugs; variable impact

Patents for medicines grant patent holders a monopoly on an invention for the patent term, by preventing others from using their invention. This monopoly allows patent holders to charge high prices that recoup research and development costs, and make the profits that provide the incentive for further investments in the discovery and development of medicines. In developed countries, strict standards of patent protection and high drug prices may not produce an immediate health crisis, as the majority of the population can pay these prices, either privately or through insurance schemes or other public health services. However, in many developing countries, where payment for pharmaceuticals is out-of-pocket and health insurance is rare, high prices can deny patients access to medicines. That these prices are high is often highlighted by the fact that when the patent expires, generic medicines enter the market and are soon available at 10% of the patented medicines price.

There are other problems in depending on patents as the drivers for new medicines. Less than 1% of the new drugs developed in the past 30 years have been for tropical diseases; these are diseases afflicting a majority of the world’s population. However, this majority, in financial terms, is a small minority of the global medicines market. The global pharmaceutical companies that develop and patent new medicines have deemed this market too small and the profits insufficient to develop medicines for tropical diseases. Thus a fundamental right such as health for the majority of the global population has not been achieved due to “market forces”. This is an obvious defect of the patent system in serving society’s needs.

Patient and prices

The HIV/AIDS crisis and the consequent urgency to make antiretroviral (ARV) treatment available for the millions of people in need for treatment brought into focus medicines prices and public health need. Patent-protected ARVs were available at over US$ 10,000 per patient per year. The Indian manufacturer, Cipla, in supplying a generic version of triple ARV therapy at USD 350 per patient per year with no subsidy, introduced competition into the ARV market and the entry of other Indian generic manufacturers caused significant price reductions of patented ARVs. This further demonstrated that public health needs could be satisfied by pharmaceutical companies within commercial terms. Indian manufacturers were able to do this because India had made use of the flexibilities in TRIPS which allowed the manufacture as well as export of generic medicines.

How then do these issues tie into “Access to Medicines and Vaccines; Implications of Intellectual Property and Trade Agreements”? This paper discusses the changes brought about by the World Trade Agreement (which came into effect in 1995), and the Trade Related Intellectual Property Rights Agreement – TRIPS (which was a part of the WTO Agreement) and how subsequent trade agreements have affected the ability of developing countries to provide medicines and vaccines to their people. Specific issues in vaccines are addressed in Annex 1.
2. THE WTO AGREEMENT AND TRIPS OF 1995

Before the WTO Agreement in 1995, international trade was a patchwork of bilateral, multilateral and regional agreements. There were many anomalies and distortions (such as subsidies for favoured groups) that prevented the full effect of trade benefiting both the producer and the consumer. The WTO had as its objective, not trade for trade’s sake but trade as a tool for development, especially for the developing world. Thus, the WTO rules were intended to create a “level playing field” so that the full potential of trade could be realized; developing countries as low-cost producers (as for example in agriculture and labour intensive industries) could stand to benefit; the developed countries too had safeguards for their industries. Membership of the WTO meant subscribing to a package of agreements on trade; countries could not pick and choose what was relevant to them, but had to agree to all agreements of the WTO.

The TRIPS “flexibilities”

Patents, for the first time, were tacked onto trade in the WTO agreement resulting in the TRIPS Agreements. Patents which were previously National Decisions (including the right not to, or selectively grant them) were now regulated by TRIPS. Patents which are privileges granted to companies or individuals by governments (and still remain privileges, which can be withdrawn) also acquired the term, “Intellectual Property Rights”. TRIPS sought to impose global minimum standards on IPRs but developing countries, realizing the importance of appropriate patent and IPR systems adapted for their national needs, negotiated for flexibility in the implementation of the TRIPS standards. These flexibilities are an important means by which countries could achieve their national objectives while being a part of WTO.

Medicines in SEAR; Before and After WTO

The implications of the TRIPS provisions on affordability and access to pharmaceuticals (medicines and vaccines) were the most important component in TRIPS for the developing world. Prior to the WTO, developing countries were able to determine their national priorities vis-à-vis IPR protection, and had put patent protection second, their first priority being the provision of quality and affordable medicines and vaccines for its people. This was done where possible through a sustainable local pharmaceutical industry. India, in SEAR, was a very good example where the national industry developed was aided hugely by a patent system sensitive to national needs; Bangladesh and Thailand too developed their industries. Countries without a significant pharmaceutical industry, such as Sri Lanka, Myanmar, and Bhutan made full use of the advanced pharmaceutical industries in the Region to access the required medicines and vaccines. The TRIPS agreement with an imposition of “global standards” represented a dramatic change of the “playing field” in medicines in the South-East Asia Region.

The transition period for full compliance with TRIPS obligations has expired for four countries: India, Thailand, Indonesia and Sri Lanka. Thus they are obliged to fully implement the TRIPS obligations. Bangladesh, Maldives, Myanmar, Nepal have a further period. Ministries of Health in these countries should be involved to ensure that flexibilities are incorporated in their TRIPS obligations. Eventually, the WTO has the potential to affect the whole population of SEAR.

3. DOHA (2001) – A CLEAR STATEMENT FOR PUBLIC HEALTH

Challenges to resolving the conflicts between IPR and Public Health

The incorporation of intellectual property protection within WTO was promoted by the developed countries; the flexibility in implementing the standards of protection were
introduced and negotiated painstakingly by the developing countries. However, when these flexibilities were interpreted in favour of public health there was fierce opposition. The multinational pharmaceutical industry through its subsidiaries in South Africa challenged the countries’ legislation on parallel imports of medicines and the US-initiated a complaint against the Brazilian legislation on compulsory licences.

The Doha Declaration

The developing countries (including SEAR countries who are members of WTO) placed the question of Public Health and TRIPS on the biannual WTO Ministerial Meeting in 2001 in Doha and demanded a clarification. After a heated debate, the Doha Declaration was unanimously adopted by all countries. It said:

“We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”

Thus, for the first time, a global international agreement affirmed that health should take priority over trade when their objectives clash. There can be no international sanction if a country were to take measures to protect its public health, if this meant curbing trade.

4. USING THE DOHA DECLARATION IN FAVOUR OF PUBLIC HEALTH IN SEAR

The real test of the success of the Doha Declaration rests at the national level. Governments should implement the flexibilities confirmed by the Doha Declaration, including the use of Compulsory Licensing to import affordable generic medicines, or enable their domestic manufacturers to produce the medicines where they are not affordable or accessible. A compulsory licence in medicines is an authorization from the government permitting the import of generic medicines, or the local manufacture of the generic version of a patented medicine without the patent holder's consent. Patents are privileges; government can withdraw these privileges if they see fit.

However, many developing countries cannot effectively use compulsory licences to obtain affordable medicines (even though this right was affirmed in the Doha Declaration) because these countries often do not have domestic manufacturing capacity. To obtain affordable medicines, a government can grant compulsory licence to a local generic manufacturer to produce the medicines locally. However, a country without such manufacturing capacity would have to import from a foreign producer. But since TRIPS limits export under compulsory licences, this raises the issue of whether the exports under compulsory licence will be enough to meet the demand of importer countries. After much negotiations the WTO August 30 Decision in 2003 was finally adopted to allow the export of pharmaceutical products made under a compulsory licence, without restriction in terms of the amount. Thus, countries in SEAR that do not have manufacturing capabilities, can, under the Decision using Compulsory Licence, import generic versions of patented medicines.

Parallel importing can be used to tackle high prices, if that medicine is available at a cheaper price in another country. If patented medicine is expensive but is sold cheaper in another country, third parties can import that medicine without the consent of the
manufacturer to be sold at a cheaper price. Patenting of medicines should take public health safeguards into account. Ministries of health should interact with National Intellectual Property offices in matters concerned with health. Actions taken by some countries in SEAR are given below.

**Indonesia**

The Indonesian Government through a Presidential Decree in October 2004 issued a government use licence for two ARV medicines, nevirapine and lamivudine, "the urgent need of the community in the effort to control HIV/AIDS epidemic" being cited as the reason. Indonesia was the first country to do so in the Region. The decree authorizes the Minister to appoint a "pharmaceutical factory as the patent exploiter for and on behalf of the Government" taking into account the recommendations of the National Drug and Food Control Authority. A compensation rate of 0.5% of the net sales of the antiretrovirals will be paid to the patent holder.

The Indonesian patent legislation contained the provisions for the grant of the government use decree. It thus permitted the valid use of a TRIPS flexibility to address public health needs in a TRIPS-consistent manner.

**India**

The Patents (Amendment) Act 2005 was passed to comply with TRIPS and incorporated public health safeguards. For example, during the transition period of 1995-2004, patent applications were allowed and kept in a "mailbox"; however generic producers were allowed to manufacture the drug. When the mailbox is opened in 2005, and if the patent is granted, generic manufacturers will still be allowed to manufacture subject to certain conditions. Thus, the affordable generic medicines currently on the market should continue to be available. In another provision, by specifying that the time limit for dealing with a voluntary license, "shall not ordinarily exceed six months", it precluded delaying tactics and expeditious grant of compulsory licence if an application for voluntary license fails.

The Act also prevents unjustifiable extension of patent protection; for example, if an obscure, old, affordable, rarely used antibiotic is found to be effective in malaria, this new use of a known medicine cannot be further patented. Such patenting of new uses is permitted in some countries with different patent systems and may become a barrier to access as it prolongs the patent protection period. Another important provision permits the grant of a compulsory licence to manufacture and export generic versions of patented pharmaceutical products to any country with insufficient manufacturing capacity.

However, the complexities of Intellectual Property Law have resulted in a disruption of a lifesaving medicine. Imatinib is a drug for the treatment of Chronic Myeloid Leukaemia (CML) and extends life. It was patented in 1993, which was before the WTO agreement. Imatinib costs USD 120,000/year from the company that first developed it. Six Indian manufacturers produced the drug for USD 12,000 and made it accessible for the 25,000 patients with CML in India and others outside India too benefited. However, the company that developed the drugs filed a patent application in 2003 and the subsequent court cases in different states produced differing judgments and a final ruling by the Supreme Court is awaited. Meanwhile, supplies of imatinib are limited.

**Thailand**

Didanosine is an important medicine for the treatment of HIV. Although it was developed decades ago and should have been freely available, a broad patent was granted on the formulation of the medicine. Because of this patent the Thai Government Pharmaceutical Organization (GPO) was prevented from manufacturing the medicine in a tablet form. The
GPO had to manufacture the medicine in a powdered form, which caused problems of adherence and side effects. For these reasons, civil society organizations and people living with HIV/AIDS challenged the validity of the patent at the Thai intellectual property court, which found that the scope of the patent granted was too broad. The case is an important one, as it cites the Doha Declaration as part of its legal reasoning to allow individuals and civil society organizations the right to challenge a patent.

**Sri Lanka**

The new Intellectual Property Act was drafted without explicit provision for parallel imports. A Fundamental Rights application by a HIV/AIDS patient with the support of other health activists to the Supreme Court resulted in an order to revise the Act to incorporate parallel imports. As Sri Lanka seeks to incorporate this TRIPS flexibility in its intellectual property legislation, there are also other flexibilities that should be included, such as a clear and straightforward system for the grant of compulsory licences.

These activities by countries in the Region demonstrate that flexibilities for public health in intellectual property protection are being used. However, a consistent policy and strategy of placing the public health priorities in Intellectual Property and Trade is yet to emerge. The difficulties are not due to pressures from external sources only but sometimes from within the country itself. Often, ministries of trade focusing on increasing trade have ignored the health component in intellectual property legislation; the effect of the legislation may increase trade marginally in one particular area but the huge disadvantages to health in the country will result in a net loss to the country. Ministries of health are familiar with such situations; for example, ministries of trade may lobby for greater freedom in marketing tobacco to gain some minor trade advantage but the increased tobacco consumption in the country would result in greater ill-health and death.

Before discussing possible strategies, it is necessary to consider the recent challenges to public health that have come about from different type of trade agreements.

5. **BILATERAL AND FREE TRADE AGREEMENTS**

Despite the WTO Agreement providing clear “minimum” intellectual property criteria for being a member of the global trade community, there have been many attempts to enact criteria above this minimum. These have come from bilateral and regional free trade agreements; so far there have been no such agreements in SEAR. There have been some other regions. For example, the US-Australian Free Trade Agreement had a hotly debated section on pricing and patent protection of medicines which had strong implications for the prices of medicines in the Pharmaceutical Benefit Scheme of the Australian health care system.

A US House of Representatives report issued in June 2005 evaluated the effect of the recent US Trade Agreements on other countries including Singapore, Jordan and Chile with regard to their access to medicines. It found these agreements would delay approval of generic drugs, required patent extensions, linked drug approval to patent status, restricted compulsory licensing, prohibited parallel imports and expanded patent protection. These were in excess of the “minimum” that was laid down by TRIPS and were seen as TRIPS Plus. Clearly, each of these would hinder access to medicines and together would create a formidable barrier to the countries in providing access to medicines to their population. From SEAR, Thailand is in the process of negotiating a Free Trade Agreement with the US.
Thus, it is crucial that ministries of health be involved in these types of negotiations; increased trade would benefit a country but if it is at unacceptable expense in health care, then the “benefit” of increased trade would result in a net overall loss to the country.

6. WHO, ACCESS TO MEDICINES, INTELLECTUAL PROPERTY RIGHTS AND TRADE AGREEMENTS

The core of the WHO Medicines Strategy

The core of the WHO Medicines Strategy is access to medicines based on need rather than the ability to pay. Since 1999 there have been successive resolutions of the World Health Assembly which have requested WHO to cooperate with Member States and international organizations to monitor and analyse pharmaceutical and health implications of international trade agreements. This would enable WHO to assist Member States to assess and develop their pharmaceutical and health policies and regulatory measures that maximize the positive health aspects and mitigate the negative impact of those agreements. World Health Assembly resolution WHA57.14 urged Member States to take account of the implications of bilateral and regional FTAs on Public health safeguards. WHO is now developing a comprehensive policy on Intellectual Property Rights and Trade Agreements within the WHO Medicines Strategy.

Tools that have been developed

WHO publications in these areas have been the basis of many country actions in intellectual property legislation. Regional, sub-regional and national workshops held by WHO in the Region helped raise awareness on these issues in ministries of health. WHO has supported efforts by Thailand and Indonesia in the TRIPS Council to incorporate public health aspects in the decisions. A comparative study of Intellectual Property Legislation in India, Indonesia, Sri Lanka and Thailand enabled the advantages and disadvantages of the national legislation to be identified. WHO supported public health safeguards in the Patent Law, most recently in India.

The Challenge

Thus, the tools for these activities have been developed but more needs to be done; the differing aims of health and trade which, at times, are contradictory, will ensure that the issues will continue to be debated in future. Trade certainly will provide benefits to a country and enable it to provide a better living standard (including better health) to its people; however, the challenge is to keep a balance and ensure that health is not neglected.

7. POINTS FOR CONSIDERATION

1. Intellectual Property Protection and Trade Agreements have had an impact on access to medicines; however, the larger impact may be felt in the future when there could be limitations on access to new medicines required in a country. Hence, countries can and should make full use of the flexibilities permitted under the TRIPS agreement to ensure access to needed medicines. This means national legislation should be reviewed to ensure that the full range of TRIPS flexibilities are incorporated to ensure that public health needs and objectives can be adequately addressed.

2. Ministries of health should be “involved” in discussions on trade that have an impact on health. For this, ministries will have to develop capabilities outside their traditional spheres. Some of these could be WTO cells within the Ministry of Health and statutory requirements for National Intellectual Property offices and trade ministries to consult with these cells in issues related to medicines.
3. Ministries of health should be pro-active and initiate legislation to allow the country to deal with health emergencies such as impending pandemics, before such emergencies occur. Although compulsory licensing has been incorporated in the national legislation of some countries in the Region, it may be necessary to establish clear and straightforward decision-making processes to ensure speedy action. These would include establishing transparent administrative procedures and guidelines for compensation for the grant of compulsory licences. For those countries which have not yet included compulsory licensing provisions these should be incorporated in national legislation.

4. Regional cooperation will definitely help in resolving some of the issues. Drawing upon the existing intellectual property legislation of the countries, those developing their legislation will find useful pointers and well developed strategies. For example, the type and amount of data required for particular decisions is known and countries can therefore use these methods.

5. Sharing of information (as for example in medicines prices) will allow countries to take maximum advantage of regional experiences.

8. CONCLUSIONS

The Intellectual Property Protection provision in the WTO has had an impact on access to medicines; this impact will continue to expand. However, the intensity ultimately depends on how SEAR countries that are members of WTO incorporate the public health safeguards in their national legislation. Those countries in SEAR negotiating to join the WTO should be cognisant of these safeguards during the negotiations.

SEAR countries negotiating Free Trade Agreements should “ring fence” the public health safeguards of WTO to preserve access to medicines.

WHO has been mandated by Member States to provide assistance in these areas to preserve, protect and promote access to medicines. Countries should make full use of the tools developed by WHO and the technical assistance available to ensure public-health-sensitive approaches to intellectual property and trade agreements.
Annex 1

ACCESS TO MEDICINES AND VACCINES: REGIONAL IMPLICATIONS OF INTELLECTUAL PROPERTY PROTECTION AND TRADE AGREEMENTS

The vaccines context

Vaccines are pharmaceutical products. Though they have key differences with chemical medicines and products, as detailed below, they are covered by the WTO agreements:

- Vaccines are biological rather than chemical products. The production processes that ensure quality and potency are more complex and costly.
- Delivery systems, including cold storage, transportation, training and monitoring are more costly, labour-intensive and must be sustained over years for some vaccines.
- Clinical trials and regulatory approval, particularly for new vaccines, are often costly and time consuming and can have a different framework.
- "Copying" of vaccines may be more difficult or costly than in the case of medicines. The ability to reproduce a vaccine production process often depends on "know how" or "trade secrets" or "tacit knowledge" that is withheld from public documentation such as patent applications.
- The overall market for vaccines is smaller than for medicines. The total value from sale of vaccines is below 2% of total sales of pharmaceutical products. Of the global market for new vaccines, a small fraction is in developing countries. This acts as a commercial disincentive for undertaking research and development of new products.

Implications of international trade agreements on vaccines

The WTO agreement provides flexibility for developing countries to have access to pharmaceuticals, including vaccines, to protect the public’s health through national legal mechanisms.

In the case of vaccines, fewer vaccine products are patented compared to medicines. This limits the scope for producers to secure higher prices through exercising their intellectual property rights. However, the various steps in the development and manufacture of a vaccine are now patentable. Intellectual property (IP) plays an important role in the development and introduction of vaccines in developing countries because of its value for the private sector. Patents on each component of vaccines can present hurdles and could be a disincentive for research and development in new vaccines.

Although IP has not been an obstacle to accessing existing vaccines, it is likely to be more of an issue with referral to new and future IP protected vaccines. This will come about as manufacturers move out of basic vaccines to more profitable and combination vaccines that will be patent protected. Under the TRIPS agreement, all WTO members are required to implement patents for medicines and vaccines according to a time frame that has been provided. However, least developed countries have a longer time frame to implement this.
A key national legal mechanism permitted by the World Trade Agreement and affirmed by the DOHA Declaration on TRIPS allows access to vaccines through compulsory licensing. A government can issue a compulsory license and allow a third party to use a patent without the patent holder’s consent in a national emergency to protect the public’s health and if an attempt at securing a voluntary license on reasonable commercial terms from the patent holder has failed. It is up to the country to determine if a national emergency exists.

In vaccine-manufacturing countries in SEAR, the compulsory license would allow a local manufacturer to produce the vaccine in the country though there is an obligation to pay adequate compensation to the patent holder for use of the patent. In practice, some negotiation and agreement with the patent holder would still be necessary because the patent documentation may not contain the know-how for various steps in the production process. Therefore, reverse engineering may not be feasible for vaccines as in the case of medicines. The two basic issues that should be considered are (a) whether or not the vaccines of interest are under patent protection, and (b) whether or not the vaccines of interest can be produced by a generic or local manufacturer? If the answer is yes for both, then the use of compulsory licensing could be useful to facilitate the local production of the vaccine at more affordable prices, or at the least, as a bargaining tool in the price negotiations.

In vaccine-importing countries in SEAR, i.e. where there is no local manufacturing capacity, it may be possible to import the vaccine from a foreign producer, e.g., in India. In this situation, it would be possible to import the vaccine under compulsory license under the system adopted in the WTO August Decision if there are patents on the vaccine in India. If there are no patents, then only a single compulsory license in the importing country is required.

The role of WHO

WHO in 2004 convened a workshop to discuss and develop a clearer understanding of the implications of intellectual property rights and international trade agreements on the rights of developing countries to have access to vaccines that have significant impact on public health. Other WHO documents also deal with this issue. In the SEA Region, guidance for countries is provided in the document entitled “Regional Vaccine Policy”.

In collaboration with the Global Alliance for Vaccines and Immunization, UNICEF and manufacturers, WHO has a role to facilitate access to patented vaccines. The actual or potential mechanisms include:

- Tiered pricing (Actual)
- Bulk purchasing (Actual)
- Voluntary licensing (Potential)
- Compulsory licensing (Potential – this is a potential tool in an unclear situation).

WHO is also strengthening its role as an honest broker, knowledge manager and in facilitating the development of mechanisms for collaboration and cooperation between countries, manufacturers and between the public and private sectors.

WHO can also assist in mapping patent and know-how for vaccines. It can also play a role in encouraging the establishment of patent pools to facilitate R&D.

WHO can: 1) analyse, monitor and report on implications of globalization, intellectual property rights and trade agreements for public health; 2) assist Member States in strengthening pharmaceutical policies and practices; and 3) provide technical
assistance and support to Member States in the implementation of TRIPS flexibilities and public health safeguards.

**The role of Member States: points for consideration**

All Member States should develop their own national policy on immunization and vaccines. The policy should incorporate recommendations for basic immunization and provide broad guidance on vaccine procurement, production, availability, distribution and financing. It should outline areas for collaboration with other countries, including vaccine producing countries. It should also cover communicable disease surveillance, particularly vaccine preventable disease surveillance. Countries can use surveillance information to decide that a national emergency exists and use compulsory licensing as necessary.

Non-vaccine producing countries in the Region, especially those who do not have a strong national regulatory authority should strengthen this regulatory body or consider using assistance from the NRA of another country with a fully functioning NRA as accredited by WHO. These countries should also ensure that the Ministry of Health should be involved in discussions as part of the process of entry into world trade or bilateral free trade agreements.

While recognizing that there is global interdependence in the area of vaccines, all Member States should explore mechanisms of cooperation and collaboration to ensure vaccine security in the Region. They should amend existing patent laws or enact appropriate patent laws. Outcomes of such efforts could be:

(1) Development of an assured market for basic vaccines.
(2) Identification of priority vaccines for the Region.
(3) Stimulating research and development for priority vaccines. The IP rights for any product should be clarified from the beginning.
(4) In the vaccine manufacturing/exporting Member States, governments could foster public-private partnership through appropriate policy and financial resources that would link development of the vaccine with mass production, including sharing of clinical trial sites and data.
(5) Private sector manufacturers could pool and share resources in the areas of vaccine development and technology.
(6) Identification of regional centres of excellence in diseases of relevance to public health in the Region and utilizing these resource centres.