Intellectual Property Rights and Access to Medicines: A South-East Asia perspective on global issues
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Acknowledgements

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The report was revised and updated\(^1\) by Kathy Shapiro, based on input from the SEARO Trade and Health Working Group.

\(^1\) The text has been updated for major developments through Dec. 2007.
**Abbreviations and acronyms**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>FTA</td>
<td>free trade agreements</td>
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<tr>
<td>GATT</td>
<td>General Agreement on Tariffs and Trade</td>
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<td>IP</td>
<td>intellectual property</td>
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<tr>
<td>IPR</td>
<td>intellectual property rights</td>
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<tr>
<td>LDC</td>
<td>least-developed country</td>
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<tr>
<td>MFN</td>
<td>most favoured nation</td>
</tr>
<tr>
<td>NCE</td>
<td>new chemical entities</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>research and development</td>
</tr>
<tr>
<td>SPLT</td>
<td>Substantiative Patent Law Treaty</td>
</tr>
<tr>
<td>TBT</td>
<td>(Agreement on) Technical Barriers to Trade</td>
</tr>
<tr>
<td>TRIPS</td>
<td>(Agreement on) Trade-Related Aspects of Intellectual Property Rights</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WIPO</td>
<td>World Intellectual Property Organization</td>
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<tr>
<td>WTO</td>
<td>World Trade Organization</td>
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Introduction

This report starts by providing some background on the evolution of the multilateral trading system and on the relation between intellectual property rights/patents and access to essential medicines. It highlights key developments at the international level, as well as country experiences and actions in the Region and beyond. Further, it touches on concerns related to traditional medicines and questions regarding innovations. The report tries to put the various developments in a broad context, in order to facilitate understanding of the issues at stake and to inform action by countries.

1. Background and context

WHO estimates that one third of people in the world have no access to medicines; this includes a large number in South-East Asia. The Region is comprised of countries with diverse situations in terms of economic development, development of the pharmaceutical sector, intellectual property rights (IPR) legislation and health delivery infrastructure. Given this diversity, a single solution to intellectual property (IP) issues is not possible for the Region. There is a need to understand IP issues in their complexity, to share country experiences and to understand the impact of country-specific changes on access to medicines in the Region.

    Medicines should be available on the basis of need rather than the ability to pay. Where trade agreements affect health, priority must be assigned to health aspects. This is not always easy to accomplish given that apparently simple issues may hide enormous complexities. For example, a simple proposal that all drugs must be free of import tariffs can have entirely different consequences depending on the situation in a particular country. In a country dependent almost entirely on imports, such as Bhutan or Maldives, this measure would bring down prices and improve access. On the other hand, where there is a nascent or small domestic industry as for example in Nepal, this measure can harm domestic production of low-cost
generics and eventually lead to the import of more expensive medicines. Hence there is a need for countries to formulate, within the relevant international frameworks, their own policies based on a balanced evaluation of local conditions and needs.

<table>
<thead>
<tr>
<th>WHO perspective on access to medicines:</th>
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<tbody>
<tr>
<td>• Access to medicines is a human right</td>
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<tr>
<td>• The affordability of essential medicines is a public health priority</td>
</tr>
<tr>
<td>• Essential medicines are not simply another commodity</td>
</tr>
<tr>
<td>• Patent laws should be managed in an impartial way and strike a balance between the incentives provided to stimulate innovation and public health needs</td>
</tr>
<tr>
<td>• WHO supports the incorporation of TRIPS flexibilities in national legislation, in order to protect public health</td>
</tr>
</tbody>
</table>


WHO addresses its mandate by providing guidance on the revision of national pharmaceutical legislation, and by increasing awareness and information regarding the public health implications of the Agreement on Trade-Related Intellectual Property (TRIPS). This includes monitoring of the effects of globalization and TRIPS on access to medicines through different mechanisms. In the South-East Asia Region, several countries are taking active steps to safeguard access through legislative measures that involve IP laws.

**Issues for developing countries in relation to trade and IPR**

Patents are meant to encourage innovation and thus promote the development of new and useful products, including new medicines. Experience in this regard has been mixed, however; new drugs developed in recent years have been those that service a market that can pay, while too few drugs are being developed for major public health problems prevalent in developing countries. Thus, very few new medicines have been developed for diseases such as malaria, tuberculosis and helminthiasis. Even when drugs are developed for the latter, such development is often not a consequence of the patent system. For example, mebendazole, which
revolutionized anti-helminthic treatment, was first developed for the veterinary market in the developed world.

Similarly, there is little incentive to produce cheap and effective diagnostics and public health promotion technologies (e.g. impregnated mosquito nets) because the “market” for these is not lucrative enough. These gaps point to the necessity of developing alternate mechanisms for promoting innovations leading to development of useful products.

The HIV/AIDS epidemic and the high prices of antiretroviral drugs (ARVs), which were out of reach of the millions in developing countries needing AIDS treatment, led to significant concerns about the implications of TRIPS on access to medicines. These concerns ultimately culminated in the Doha Declaration (see Section 3), which represents an explicit recognition of the need to protect public health within international trade rules. However, implementation of the Doha Declaration remains problematic and access to expensive, patent-protected second-line ARVs remains uncertain in the developing world.

The threat of an avian-derived influenza pandemic has again highlighted the issue of strong IP protection and access. While public health measures remain the cornerstone of managing any possible pandemic, the principal drug that has been used in human infections of avian influenza is oseltamivir, which is under patent in many countries and hence relatively expensive. Countries should consider the health implications of this patent protection.

Challenges

Ongoing research raises the prospect of valuable vaccines and products soon becoming available to treat major diseases of public health concern. These include vaccines for HIV/AIDS, malaria and human papillomavirus, the cause of most cases of cervical cancer in women. The challenge for developing countries is to put in place legislation that allows access to such products, without dampening the incentives for innovation. Also to be examined are the ethical issues related to testing these interventions through clinical trials in developing countries, and ensuring that the countries where trials took place will also benefit whenever an effective intervention is identified.
Challenges to the efforts of countries to safeguard access to medicines and public health are posed by the increasing number of bilateral free trade agreements (FTAs) signed by countries over the past few years. Many of these agreements incorporate provisions that require higher levels of IP protection than what is required by the TRIPS Agreement (these provisions are sometimes referred to as “TRIPS-plus”). Addressing these challenges calls for:

- concrete steps to incorporate public health concerns in IP laws;
- concrete steps to incorporate all the TRIPS flexibilities into FTAs;
- improvements in transparency and efficiency of the present patent system;
- urgent attention to implementation of the Paragraph 6 solution to the Doha Declaration (see below); and
- exploration of new alternatives to promote research and development (R&D) for new, needed medicines that address diseases prevalent in the developing world.

2. **Evolution of the multilateral trading system**

The General Agreement on Tariffs and Trade (GATT), was established on a provisional basis after the Second World War in the wake of the creation of other multilateral institutions dedicated to international economic cooperation—notably the World Bank and the International Monetary Fund (IMF).

The GATT remained the only multilateral instrument governing international trade from 1948 until the establishment of the World Trade Organization (WTO) in 1995. During that period, eight GATT Rounds, or multilateral trade negotiations, were held. The final GATT round, the Uruguay Round, began in 1986 and for the first time included discussions on trade in services and intellectual property rights; it ended with the establishment of the WTO on 1 January 1995. The Agreement Establishing the World Trade Organization includes a comprehensive agreement on IPR, namely the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).
Principles of the multilateral trade regime

The main principle underlying the WTO system is nondiscrimination. The two main elements under this principle are a) most favored nation (MFN) principle, under which members extend the same treatment to imports from all the other members, and b) national treatment principle, under which imported goods, once they have met all the requirements of whatever border regime is in place and have entered into the internal (domestic) market in a member's economy, will be treated no less favorably than domestic goods are treated in the domestic market.

Two other underlying elements in the system are: a) elimination of quantitative restrictions and non-tariff barriers and reliance on tariffs as the sole instrument of border protection; b) transparency, which is achieved through publication of trade laws and regulations.

Recognizing the very large disparities in economic and technological development among Member countries, the WTO provides for exceptions to the application of WTO rules based on the principles of special and differential treatment for developing countries and least-developed countries, less than full reciprocity and protracted implementation periods.

Trade negotiations in the WTO context are based on the principle of a “single undertaking”, i.e. “nothing is agreed until everything is agreed.” Members do not have the flexibility to apply only a part of a decision. The WTO continues the GATT practice of taking decisions by consensus, but if a decision cannot be reached by consensus, it is to be arrived at through majority vote. In the Ministerial Conference and the General Council, each member has one vote.

WTO agreements and public health

The WTO agreements that are most important with regard to public health are the General Agreement on Trade in Services (GATS), the Agreement on Technical Barriers to Trade (TBT), the Agreement on Sanitary and Phyto-Sanitary Measures (SPS), and the Agreement on Trade-Related Intellectual Property Rights (TRIPS).

2 It is, however, uncommon for voting to take place in the WTO.
A national government’s pursuance of specific health policies may have implications for its positions on international trade and vice versa. It is therefore important that countries are aware of their rights and obligations under the various agreements in pursuing their health policies, which may impinge on international trade.

For countries in the Region, some of the important considerations that need to be kept in mind are:

- effective negotiating capacity and coalition building
- domestic preparedness of and consultation with all stakeholders
- reconciliation of domestic initiatives and priorities with international rights and obligations.

3. Patents

The basic idea behind patent protection is that the invention is made public, while the inventor for a limited time has the exclusive right to make, use or sell that invention. It can be argued that the notion of patent rights is built on a contradiction: in order to promote the development of ideas, it is necessary to reduce the freedom with which people can use them.

This contradiction is a running thread in all debates on patents, and patent laws attempt to create a balance between public interests and the rights of the inventor. These two contrasting interests, which often manifest as contrasting opinions, are reflected in the following statements:

“The relentless march of intellectual property rights needs to be stopped and questioned. Developments in the new technologies are running far ahead of the ethical, legal, regulatory and policy frameworks needed to govern their use. More understanding is needed—in every country—of the economic and social consequences of the TRIPs Agreement. Many people have started to question the relationship between knowledge ownership and innovation. Alternative approaches to innovation, based on sharing, open access and communal innovation, are flourishing, disproving the claim that innovation necessarily requires patents.”

UNDP Human Development Report 1999
“The commercial sector discovers and develops nearly all new drugs and vaccines, but this is expensive and risky; the patent system provides the incentive necessary to investigate thousands of new compounds and to invest an average of several hundred million dollars in R&D”.

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), ASEAN Workshop on TRIPS, Jakarta, May 2000

The central distinction between ideas/intellectual property and physical property is that information can be transferred without leaving the possession of the original owner. Unlike physical goods, there are no physical limits to sharing ideas widely.

Over time, the concept of intellectual property has changed in a fundamental manner. Starting from a “privilege” or “reward” granted by society to the inventor in return for full disclosure of the innovation, intellectual property is now seen as a “right”.

The principal arguments of the pharmaceutical industry in favour of patent rights are related to the fact that it invests huge amounts in the development of new drugs and hence deserves returns for such investments. However, even after those investments have been made on R&D, the pharmaceutical sector has consistently been more profitable than any other industrial sector.

High prices, driven by patent monopolies, limit access to medicines. In addition, the search for "blockbuster drugs" skews drug development in favor of new drugs for which there are buyers who are willing and able to pay high prices. Hence, more and more drugs being introduced are "me-too" drugs or drugs like sildenafil that are being used primarily for "lifestyle" needs and not predominantly medical needs. The fact that not all new medicines are therapeutically important is also illustrated by the data in table 1.
Table 1. Assessment of usefulness of new drugs introduced globally between 1981–2000

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of drugs</th>
<th>Percentage of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major therapeutic innovation in an area where previously no treatment was available</td>
<td>7</td>
<td>0.31%</td>
</tr>
<tr>
<td>Product represents an important therapeutic innovation but has certain limitations</td>
<td>67</td>
<td>2.96%</td>
</tr>
<tr>
<td>Product has value but does not fundamentally change the present therapeutic practice</td>
<td>192</td>
<td>8.51%</td>
</tr>
<tr>
<td>Product has minimal additional value, and should not change prescribing habits except in rare circumstances</td>
<td>397</td>
<td>17.59%</td>
</tr>
<tr>
<td>Product may be a new molecule but is superfluous; does not add to clinical possibilities offered by previous products available, in most cases a &quot;me-too&quot; product</td>
<td>1,427</td>
<td>63.23%</td>
</tr>
<tr>
<td>Product without evident benefit but with potential or real disadvantages</td>
<td>58</td>
<td>2.57%</td>
</tr>
<tr>
<td>Editors postpone their judgments until better data and more thorough evaluation available</td>
<td>109</td>
<td>4.83%</td>
</tr>
<tr>
<td>Total number of new drugs introduced between 1981-2000</td>
<td>2,257</td>
<td>100%</td>
</tr>
</tbody>
</table>


The functioning of a patent

A patent provides a proprietary title over an invention, which allows the patent holder the right to prevent others from using, making, selling or marketing the product for a specified period. There are no international patents; patent rights are limited to the country in which they have been granted. A patent gives the holder a temporary monopoly on using, making and selling the invention in exchange for publishing the full details of the
invention. As a result, the public pays a higher price during the patent term, but after expiry of patent, the invention can be used by others.

Given the significant benefits that may accrue to a patent holder, it has been questioned which inventions deserve a patent. Patents are a public policy tool, to be balanced against other public interests, and governments have the power to keep this balance. Ideally, health considerations should play a decisive role in defining which medical and pharmaceutical inventions deserve protection, but in practice health policymakers are rarely involved in decisions regarding patents.

Patents are granted for inventions, not for medicines per se. Thus, patents may be granted for: 1) a chemical compound or molecule; 2) a medical indication or therapeutic effect of the molecule; 3) the combination of products (e.g., a fixed dose combination of two or more molecules); or 4) the manufacturing process (known as a process patent). There could be more than one patent for a single medicine, e.g. the chemical compound and its production process can both be patented. It needs to be kept in mind, however, that national laws may restrict the kind of patents that may be granted for medicines; some laws can explicitly bar the grant of patents for drug combinations (see the case study on India below).

**Patents and prices**

The introduction of generic competition is often associated with a significant reduction in medicine prices (see figure 1), and this is to be expected given that patents confer a monopoly (albeit temporarily) on the patent holder. A reduction in prices of patented drugs normally occurs when this monopoly, usually enjoyed by multinational drug corporations who hold the overwhelming majority of drug patents, is curbed and market competition is introduced. Thus, for example, the cost of triple drug therapy to treat HIV/AIDS was in excess of U.S. $10 000 per patient per year, when an Indian generic manufacturer offered the same therapy in February 2001 at U.S. $350 per patient per year. As a result of further generic competition, prices for first-line triple ARV therapy fell to approximately U.S. $168 in January 2005 (see Figure 1).
Patents are granted with the understanding that they will be accompanied by “full disclosure” about the contents of the patent. Full disclosure usually means providing enough detail for a “person skilled in the same area of technology to construct and operate” the patented object. Some observers have, however, noted a tendency to disguise or omit important details in patent documents; this undermines the concept of full disclosure, and is a matter of concern for the scientific community.

Domestic industries outside the developed countries have been able to develop in places where strong protection for product patents did not exist. India is representative of such a situation; the Indian Patents Act of 1970 allowed Indian companies to develop and market generic versions of patented drugs. Similar strategies were used by developed countries when they were in the early stages of their industrial development\(^3\).

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4. TRIPS, the Doha Declaration and public health

A majority of members of the WTO already had some form of intellectual property protection in existence prior to the TRIPS Agreement. For example, as of January 1995, fewer than 20 of the current WTO developing country and least-developed country members excluded pharmaceutical products per se from the grant of patents. The key difference that came about after the adoption of the TRIPS Agreement in 1995 was that countries were bound to certain minimum universal standards of patent protection. Thus TRIPS prevents countries from changing their laws to suit national interests if such interests are at variance with the Agreement. Further, as TRIPS is part of the WTO system, there is now also the possibility of cross-sectoral retaliation in the event of noncompliance by any country of its provisions. This implies that any member country failing to bring its patent law into conformity with TRIPS, if challenged by another member country, is subject to the WTO dispute settlement system. If the dispute settlement system were to rule against it and the country still insists on not changing it law, other WTO countries can retaliate with trade sanctions.

The TRIPS Agreement covers two categories of intellectual property; 1) industrial property (trademarks, patents, geographical indications, industrial designs and trade secrets); and 2) literary and artistic works (copyright and neighboring rights). It establishes universal minimum standards, which WTO member countries are required to adopt in their national laws.

Thus, TRIPS requires countries to provide patents to protect inventions in all fields of technology, and for both products and processes. To be patented, inventions must meet three criteria: novelty, inventive step and industrial applicability (TRIPS Article 27). Before the TRIPS Agreement entered into force in 1995, countries did not have to grant patents for inventions in the pharmaceutical field if they did not wish to. This had allowed diversity in national approaches to patent protection in terms of what could be patented (scope), patent term, exceptions to patentability, etc. It must, however, be underlined that countries have some leeway in implementing TRIPS. For example, countries can choose whether or not to
allow parallel importation, and whether to apply strict or lenient standards for patentability.

**TRIPS flexibilities or safeguards**

Articles 7 and 8 of TRIPS set out the broad objectives of the Agreement. These include: promotion of technological innovation, transfer and dissemination of technology, measures to protect public health and nutrition and promotion of the public interest. Countries can include measures in their national legislation that limit exclusive patent rights, so that the objectives and principles of the TRIPS Agreement can be achieved. The Doha Declaration on the TRIPS Agreement and Public Health, made later during the WTO Ministerial Meeting in 2001, further affirmed the right of countries to use the flexibility in TRIPS to the fullest.

The flexibilities within TRIPS include the following, explained in detail below:

- government use
- compulsory licenses
- parallel importation
- exceptions to patent rights (e.g., “Bolar” exception)

*Government use* pertains to the government's right to use a patented invention, without consent of the patent holder, and is allowed under TRIPS (Article 31). It permits government agencies or a party authorized by the government to use an invention, for public, noncommercial purposes—e.g., public sector production of generic medicines, or import of generics for use in public hospitals. This provision can be considered as a "fast-track" compulsory license. Government use provisions are part of many national patent laws, and broad provisions on government use can be found in the laws of developed countries, such as the United States and the United Kingdom (where government use is known as “Crown use”).
Indonesia’s government use

In 2004, a presidential decree enabled “government use” of certain patented ARVs. The decree, “Exploitation of Patent on Anti Retroviral Drugs by the Government” states:

Considering:

- That in line with the urgent need in the effort to control HIV/AIDS epidemic in Indonesia, it is necessary to provide access to Anti Retroviral Drugs that are still protected under patent;
- That as exploitation of Article 5 of Government Regulation No 27 of 2004 regarding the Mechanism of Patent Exploitation by the Government, it is necessary to stipulate a Presidential Decree regarding patent Exploitation of Anti Retroviral Drugs by the Government;
- It has been decided that the Ministry of Health may appoint a Pharmaceutical Factory as the patent exploiter for and on behalf of the Government to exploit the patent by taking into account the recommendations from National Drug and Food Control Authority (NA-DFC);
- The Government shall give a 0.5 % compensation fee of net selling value of Anti Retroviral Drugs to the patent Holder;
- The Decree provides for the exploitation of patents on nevirapine and lamivudine.

Compulsory licenses are nonvoluntary licenses granted by the government to permit third parties to use a patented invention without the patent holder’s consent. Using such licenses, local pharmaceutical companies may produce generic versions of patented medicines or generic versions of medicines may be imported from foreign manufacturers. Governments have the right to determine grounds for issuance of a compulsory license, and such grounds are not limited to emergencies. The main conditions for grant of a compulsory license are prior negotiations with the patent holder and payment of compensation or royalties (see also section 5).

Parallel importation is the import and resale of a patented product in another country without consent of the patent holder. It involves the import of a patented medicine from country A to country B, when the patented product is sold at a higher price in country B than in country A. In this case, parallel importation from country A could reduce the prices in country B. TRIPS does not prohibit parallel imports. Many countries, (for examples
Argentina, India, Malaysia and South Africa) have provisions in their national laws allowing for parallel imports.

Exceptions to patent rights allow limited use of a patent in specific circumstances. TRIPS allows for exceptions to patent rights under Article 30. For example, the "Bolar" exception allows the production of generic medicine for testing and regulatory approval, to enable speedy introduction of a generic product once the patent expires\(^4\). Exceptions can also be made for research and experimental use.

For a country to make use of these flexibilities, they must be explicitly provided for in the national law.

The use of safeguards

Most developed countries have safeguards in their patent laws, and have used them (e.g. the extensive use of compulsory licensing in the USA, for example in the area of communication and information technology\(^5\)). Meanwhile, many developing countries have not included all TRIPS safeguards in their national laws. The challenge is to make sure that all available safeguards are provided in national laws to enable countries that need such safeguards to use them whenever necessary. In order to use these safeguards, countries may need to review, compare and amend their laws to:

- fully incorporate the flexibility in TRIPS;
- ensure that these flexibilities are easy to implement by establishing clear, unambiguous and easy to use regulations;
- adopt clear, easy to apply and transparent guidelines for setting compensation rates for the patent holder;
- ensure that appeal procedures do not suspend execution of license;
- adopt straightforward, transparent and speedy procedures, and set a timeframe for them.

\(^4\) The TRIPS Agreement does not refer directly to the “Bolar” exception. However, in a dispute between Canada and the EU, it was clarified that this exception does fall within the permitted exceptions under TRIPS Article 30.

\(^5\) However, in the USA, compulsory licensing for pharmaceuticals is not common.
The Doha Declaration on TRIPS and Public Health

Since the signing of the TRIPS Agreement in 1995, there have been concerns regarding the implications of TRIPS requirements on public health. The HIV-AIDS epidemic and the exorbitant pricing of antiretroviral drugs has highlighted this tension. A major event that set the stage for the Doha Declaration was the Medicines Act of South Africa, which incorporated provisions to enhance access to medicines. Following its approval in 1998, 39 pharmaceutical companies challenged the Act in the South African courts on the basis that it went against the global consensus on IPR as enshrined in the TRIPS Agreement.

Against this backdrop, the African countries (later joined by Brazil and India) requested that a special session of the WTO-TRIPS Council be held to discuss IPR and public health. Several meetings on this topic laid the ground for the Doha Declaration on TRIPS and Public Health on 14 November 2001, at the WTO Ministerial meeting in Doha. The Doha Declaration was particularly important in clarifying that international trade rules could not and should not undermine the legitimate right of countries to protect public health. It represented a first step in making the multilateral trading system compatible with public health interests.

The debate leading up to the finalization of the Declaration was contentious. Some developed countries wanted to limit the scope of the Declaration to a few selected diseases such as TB, malaria and HIV/AIDS. This was rejected by developing countries. Finally it was agreed not to limit the diseases, and to include vaccines and diagnostic kits, in addition to medicines.

Paragraph 4 (see the box below), in many senses the key portion of the Declaration, is a masterpiece of diplomatic language which has been interpreted in differing ways by different interest groups. Some interpret it as saying that TRIPS can be implemented in a manner compatible with public health concerns, and that there are no fundamental contradictions between the two. Others see the paragraph as indicating that in case there is a contradiction between the two, public health priorities should prevail and commercial interests cannot override these priorities. The importance of this section lies in the fact that in case of disputes – national or international – legal opinion would need to refer to this paragraph and the clear priority it gives to public health concerns.
Doha Declaration on the TRIPS Agreement and Public Health

Adopted on 14 November 2001

Paragraph 4: “We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.

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.”

The other important facet of the Declaration is that it confirms the available flexibilities in the TRIPS Agreement. The Declaration does not add to flexibilities already available, but confirms that countries can decide their own grounds for application of the flexibilities.

The Doha Declaration clarifies that:

- compulsory licenses can be granted on a large number of grounds, including public health, and countries have the freedom to define these;
- parallel imports can be used by countries to source cheaper medicines;
- governments are free to decide what constitutes an emergency (as one of the grounds for granting compulsory licenses).

Extending enforcement of patents for LDCs until 2016

The Doha Declaration also allows least-developed countries (LDCs) to extend the transition period available for implementing pharmaceutical patents until 2016. Paragraph 7 states that least-developed Members of the WTO do not have to implement or enforce patents and data protection with respect to pharmaceutical products until 1 January 2016.

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6 As of Dec. 2007, the following countries in the WHO South-East Asia Region are LDCs: Bangladesh, Bhutan, Maldives, Myanmar, Nepal and Timor-Leste.
Given this decision of the TRIPS Council, a simple executive order by an appropriate authority may be sufficient to allow an LDC member of the WTO to make full use of the waiver allowed in enforcement of pharmaceutical patents, even where the country's laws allow for patents on pharmaceuticals. Following is an example of possible language for such an executive order:

Example of Certification of Non-Recognition and Non-Enforceability of Patents and Data Protection in Respect of Pharmaceutical Products

Whereas

Further to Paragraph 7 of the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference on 14 November 2001 (WT/MIN(01)/DEC/W/2), the WTO Council for TRIPS decided on 27 June 2002 (IP/C/25) that least developed country Members of the WTO need not enforce patents and data protection with respect to pharmaceutical products at least until 1 January 2016.

The 30 August 2003 Decision by the WTO General Council on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540) acknowledged that the system established by the Decision is without prejudice to the exemption granted to least developed country Members pursuant to Article 66.1 of the TRIPS Agreement.

The [insert title of government official] hereby confirms that:

(a) patents and data protection with respect to pharmaceutical products shall not be recognized or deemed enforceable within and with respect to [insert country name] at least until 1 January 2016;

(b) importation, manufacturing, use, sale, and offering for sale of pharmaceutical products is authorized notwithstanding any patents which may have been granted or data protection rules which may be applicable with respect to those products; and

(c) patents and data protection rights may not be enforced by holders thereof within and with respect to [insert country name] with regard to any actions by the government or third parties undertaken during the period extending at least until 1 January 2016.

Source: Correa, Guide for the application and granting of compulsory licences and authorization of government use of pharmaceutical patents, WHO (draft, 2006).
Given the waiver granted to LDCs on enforcement of pharmaceutical patents till 2016, complaints that pharmaceutical patents are not granted/enforced in an LDC would be misplaced. However, if the national law of an LDC allows patents on pharmaceuticals (and many LDCs do allow pharmaceutical patents in their national laws), a company may file a complaint within the country on the basis of the national law. Thus, while the decision cannot be challenged under international law, it could be challenged under national law. For the country, on the other hand, options for avoiding such challenges are either to change the national law or pass an executive order as suggested above—the intent in either case being to make explicit the use of the provisions of the waiver.

**Doha Declaration paragraph 6: Countries without manufacturing capability**

Paragraph 6 of the Doha Declaration states:

"WTO Members with insufficient or no manufacturing capacity 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 … before the end of 2002."

This paragraph describes the problem for countries without domestic capacity, who cannot effectively exercise the right to grant CLs as there are no domestic generic manufacturers to produce the product in question. Their only option is to import from foreign producers. But if they were to issue a CL to import, the exporting country could be in conflict with Article 31(f) of TRIPS, which restricts exports of generics produced under a CL “predominantly for the supply of the domestic market.”

This problem will progressively worsen, because countries that did not grant pharmaceutical product patents in the past (such as India) have had to change to a regime that allows such patents. Thus, their capacity to produce (and export) generic versions of medicines that are still under patent in developed countries will be diminished. As a result, increasing problems will be faced (for example as second-line ARV drugs will be needed in larger quantities) because there will be little or no generic competition.
Due to diverging views, a range of solutions were proposed during negotiations, leading to a major delay in spite of the Declaration calling for an “expeditious” solution. The solution that was eventually agreed upon (which is at times referred to as “paragraph 6 solution”) permits manufacturers to produce and export under compulsory license to countries without manufacturing capacity. For such exports, it provides for waivers of the obligations in TRIPS Article 31(f) to manufacture predominantly for domestic market. In addition, TRIPS Article 31 (h)—the requirement to provide compensation to the patent holder—is waived for the importer. This decision has been in place since 30 August 2003.

Language to formally amend the TRIPS Agreement by incorporating this decision in TRIPS was agreed in principle on 6 December 2005. The amendment will come into force when two-thirds of WTO members ratify it. However, as of December 2007, only one country (Rwanda) has tried to made use of this system, which may point to the perception that it is problematic or too complex.

Requirements for implementation of the “Paragraph 6 solution”

All LDCs and developing countries who notify the TRIPS Council of their intent to use the decision are eligible to use it. The system covers “any patented product … of the pharmaceutical sector needed to address the public health problems”. In order to use the system, the importing country needs to have established that it has “insufficient or no manufacturing capacities” for the concerned product. The country must also notify the TRIPS Council about its intention to use the system, and provide details of the products that it requires. In addition, both the importing and the exporting countries must have enabling provisions in their national laws.

Such provisions need to include:

- compulsory licensing provisions that allow for import and export (in the importing and exporting countries respectively);
- waiver of remuneration to innovator company in importing country (but not the manufacturing, exporting country).

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7 Least-developed countries are exempt from this.
To optimize the use of CLs, when drafting their legislation, importing countries may wish to consider:

- incorporating a wide range of grounds for CLs, including for government use;
- specifying a time limit on prior negotiations to prevent inordinate delays; and
- avoiding restrictions on products or diseases that are eligible for CL.

Legislation allowing exports through this system has for instance been passed in Canada, China, India, and Norway.

As mentioned earlier, thus far, there is very little experience in applying the WTO 2003 decision. This may be related to the cumbersome procedure involved, requiring importing countries to notify the TRIPS Council about its requirement for medicines, and, if the medicine is patented in the importing country, about the fact that it has granted or intends to grant a CL. In addition, the exporting country also has to issue a CL and provide details thereof to the WTO TRIPS Council. Countries may also need to amend their national law before they can make use of this mechanism. These notifications are to be undertaken by each individual country up front; therefore, there is a risk that the market will be small and fragmented. Under these uncertain conditions, manufacturers in exporting countries may be reluctant to initiate production for exports.

**Challenges to the use of safeguards**

While developed countries have been able to successfully utilize safeguards to their advantage, in developing countries, important challenges to the use of safeguards include the following:

- lack of adequate administrative and legal infrastructure in developing countries, making it difficult to determine patent status of medicines;
- changes to national laws to incorporate TRIPS safeguards are slow or inadequate;
- external pressures, including TRIPS-plus obligations in free trade agreements, inhibit the use of safeguards.
5. The use of safeguard mechanisms in practice

Use of safeguards in developed countries

There has been considerable debate as to why the safeguard mechanisms provided in the TRIPS Agreement (notably compulsory licensing and government use) are seldom used by developing countries to improve access to medicines. As already noted, most developed countries have strong compulsory licensing and government use provisions in their domestic laws.

The United States provides for broad government use provisions in its law (covered by USC 1498). The only remedy that is available to the patent holder is award of compensation, but there is no injunction on use of a patented invention by the government.

U.S. courts are also known to set compensation (royalty) rates at as low as 1% in cases of government use of a patented product, as for example in a case involving the US government and Hughes Aircraft Company in 1994. In 2001, in the wake of the anthrax scare in the country,
the U.S. government threatened to use the government use provision against the patent on ciprofloxacin. This resulted in a substantial price reduction by the originator.

The United States has also regularly used compulsory licenses as remedy to anticompetitive practices. Prominent examples of this include Monsanto corn patents and Microsoft patents.

The use of nonvoluntary licenses in the U.S. and Europe has a long history and has contributed to the development of many important sectors. In 1917, the United States created the Manufacturers Aircraft Association patent pool (a pool of essential patents with 60 manufacturers as users) to overcome barriers for the scaling-up of aircraft manufacturing. The decision was taken when the United States was on the verge of entering World War I and needed to scale up aircraft manufacturing in the country. Later evidence shows that this step was instrumental in promoting the aircraft industry across the globe. Similar experience exists in the area of radio technology.

The patent law of France also has broad provisions for issuing of CLs with specific remedies in anticompetitive cases: “When the license aims at correcting a practice found to be anticompetitive or in case of an emergency, the minister responsible for industrial property is not obligated to seek a voluntary agreement”.8

Another example of a provision enabling the grant of CLs in Europe can be found in Directive 98/44 of the European Parliament on the legal protection of biotechnological inventions; this directive provides for guaranteed access to a compulsory license for genetically engineered plant varieties on payment of a fee.9

These examples illustrate how developed countries have used the patent system to promote their concrete technological and developmental needs in a particular period in which laws have evolved in order to keep pace with the stage of development. Within the patent system, the compulsory licensing system has been regularly used and continues to be used in developed countries to act as a check on the monopoly powers that patents confer.

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8 French patent law 2004.
Use of safeguard mechanisms in developing countries

While TRIPS safeguards have been used sparingly by developing countries, some countries have started to use them. In 2002, Zimbabwe declared an emergency (in line with Zimbabwe’s national law; however, this is not a TRIPS requirement), which was followed by the issuing of a compulsory license. This compulsory license is broad; it covers all HIV/AIDS-related drugs and covers local production as well as importation. Zambia also issued a compulsory license for local production of specific HIV/AIDS drugs (see table 2).

In Asia, Indonesia and Malaysia have started using TRIPS safeguards to improve access to ARVs (see table 2). Both countries have opted for “Government use”.

### Table 2. Examples of the use of compulsory licenses by developing countries

<table>
<thead>
<tr>
<th>Date</th>
<th>Country</th>
<th>Drugs</th>
<th>Validity</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2003</td>
<td>Zimbabwe</td>
<td>All HIV/AIDS related drugs</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Oct. 2003</td>
<td>Malaysia</td>
<td>didanosine</td>
<td>2 years</td>
</tr>
<tr>
<td></td>
<td></td>
<td>zidovudine</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>didanosine+zidovudine</td>
<td></td>
</tr>
<tr>
<td>September 2004</td>
<td>Zambia</td>
<td>lamivudine+stavudine+ nevirapine (FDC)</td>
<td>Until further notice</td>
</tr>
<tr>
<td>Oct. 2004</td>
<td>Indonesia</td>
<td>Lamivudine nevirapine</td>
<td>7-8 years (end of the patent term)</td>
</tr>
<tr>
<td>Nov. 2006</td>
<td>Thailand</td>
<td>efavirenz</td>
<td>Until 31 Dec. 2011</td>
</tr>
</tbody>
</table>

Other strategies to safeguard access to medicines

Thailand has opted for generic production of ARV drugs that are not under patent in Thailand. This includes the generic production of didanosine in powder form. This was possible because only didanosine tablets were patented in Thailand; thus, the powder form did not infringe the patent. Alongside this, the patent on didanosine has been challenged by activists. Recently, however, Thailand has issued compulsory licenses for two antiretroviral medicines, a cardiovascular drug and several cancer medicines.
Brazil too, is promoting generic production of ARVs not patented in the country. It has also used the threat of issuing a compulsory license a number of times to negotiate price reductions with patent holders in cases where the drugs are patented in Brazil. In May 2007, Brazil issued a CL for efavirenz.

The use of safeguards in Cambodia

Cambodia joined the WTO in 2004, and had to implement the TRIPS Agreement in its domestic law. However, as an LDC Cambodia had the option of not allowing for patents on medicines till 2016. Cambodia enacted a patent law which includes a simple provision withholding patents on pharmaceutical patents until 2016. Article 136 of the Patent Law of Cambodia states:

“The pharmaceutical products mentioned in the Article 4 of this Law shall be excluded from patent protection until January 01, 2016, according to the Declaration on Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health of the Ministerial Conference of World Trade Organization dated November 14, 2001 in Doha of Qatar”.

The experience till date on the use of TRIPS safeguards in developing countries shows that there is still considerable reluctance to use them effectively. Part of the problem is related to the necessity to change domestic laws before such safeguards can be used. As some of the above examples show, it is perhaps not necessary to wait for perfect laws to be enacted; countries can make use of existing laws and procedures to facilitate access to medicines.

Determining royalty rates

When a nonvoluntary license is issued, a matter of contention is often the computation of the royalty rate to compensate the patent holder. There is no international authoritative guideline for determining royalty rates, and hence, extensive flexibility is available in how to compute these rates. The TRIPS text provides some major ground rules for computation. Canada and Japan have developed national guidelines for determining royalty rates. There have also been proposals for a “tiered royalty rate” with a rational relationship between amount of royalty and the ability to pay.
When determining royalty rates, it may be interesting to keep a U.S. Court observation in mind, which stated that, in relation to government use: “the proper measure is not what the owner has lost, but what the taker has gained”\(^{10}\).

If this concept were applied in a situation like in Thailand, for example, where the initial price for fluconazole was 200 Baht, but fell to 6.5 Baht when generic competition was allowed, the compensation would be based on the lower figure (6.5 Baht) and not on the higher one (200 Baht). It should also be remembered that in certain situations (e.g. when a CL is issued to remedy an anticompetitive environment or measure) the royalty can be zero. Royalty rates that have been decreed or offered vary widely, as the following table of some recent compulsory licenses for ARVs shows:

<table>
<thead>
<tr>
<th>Country</th>
<th>Indonesia</th>
<th>Malaysia</th>
<th>South Africa</th>
<th>Thailand</th>
<th>Zambia</th>
<th>Zimbabwe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanism</td>
<td>Government use</td>
<td>Government use</td>
<td>Competition law</td>
<td>Government use</td>
<td>Compulsory license</td>
<td>Compulsory license</td>
</tr>
<tr>
<td>Licensee</td>
<td>One manufacturer</td>
<td>One importer</td>
<td>A small number of manufacturers</td>
<td>Government Pharmaceutical Organization</td>
<td>One manufacturer</td>
<td>One manufacturer</td>
</tr>
<tr>
<td>Export allowed</td>
<td>Not indicated</td>
<td>Not indicated</td>
<td>Export to other countries in Africa allowed</td>
<td>Probably not (intended for persons covered by national health insurance)</td>
<td>No</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Royalty</td>
<td>0.5%</td>
<td>Not indicated (4% offered)</td>
<td>5%</td>
<td>0.5%</td>
<td>2.5%</td>
<td>Not indicated</td>
</tr>
</tbody>
</table>

6. **Recent developments**

The TRIPS Agreement was instrumental in developing a new set of standards for patent protection. In 1986, around 40 countries did not grant patents for pharmaceutical products. The TRIPS Agreement obliged changes in many national laws, including an obligation to grant patents for

\(^{10}\) Leesona Corp. v. United States, 599 F.2d 958, 969 (Ct. Cl. 1979).
pharmaceuticals. This has led to an increase in the level of IP protection across the globe. The Doha Declaration was significant for its recognition that public health issues have a high priority and deserve attention during trade negotiations. This scenario has since changed dramatically.

**Free trade agreements**

Faced with difficulties to introduce higher levels of IP protection in the context of the multilateral WTO system, some developed countries have chosen to rely increasingly on a bilateral approach. Thus a number of countries have signed or are negotiating free trade agreements—for example with the United States, in order to obtain or maintain access to the large U.S. market for their export products. In return, they are being asked to increase their level of IP protection beyond what is required in TRIPS. Such IP measures have been referred to as “TRIPS-plus.”

For example, in separate FTAs with Singapore (already signed) and Thailand (being negotiated), the United States has insisted on the incorporation of a chapter on IPRs that provides for strong IP protection. The FTAs may also limit the TRIPS flexibilities. Some provisions in these agreements that may have negative consequences for public health are the following:

- patent terms exceeding 20 years to compensate for delays in patent examination and marketing approval for pharmaceutical products;
- data exclusivity (see below) for pharmaceutical products, which constitutes the creation of a new right;
- drug regulatory authorities would not be allowed to provide marketing approval for pharmaceutical products if there is a patent on the drug. This goes beyond provisions that exist in the United States and Europe. In the United States, for example, the FDA just informs the patent owner of a request for marketing approval by a generic competitor.

**Data protection and data exclusivity**

Medicines the world over are subject to two sets of national rules: intellectual property rights (which include patent protection) and
registration of drugs before marketing approval. The former is regulated by a country’s patent laws while the latter is regulated by the drug regulation authorities. In the case of patents, a patent is a private right that the patent holder enjoys, and the onus is on the patent holder to ensure that the patent is not infringed, i.e. that someone else does not make the patented substance during the patent period. If an infringement occurs, it is the duty of the patent holder to take action (e.g. take the infringer to court). On the other hand, a drug regulatory authority is a public authority. Its function is to ensure, in the public interest, that drugs given marketing approval meet the criteria of safety, efficacy and good quality.

Data exclusivity refers to a practice whereby, for a fixed period of time (usually five years), drug regulatory authorities may not rely on the safety and efficacy data that the originator company files to get marketing approval, in order to register a generic version of the same medicine. This means that during the data exclusivity period, generic versions of a medicine cannot be registered. The generic producer would have to conduct fresh clinical trials before its version of the drug can be registered (which may be difficult in practice), or will have to wait till the end of the exclusivity period. Thus, data exclusivity delays the marketing of generic medicines, through a mechanism that is different from and operates independently of patents.

TRIPS does not require data exclusivity, but it does require “data protection”. There is a clear distinction between these two concepts. Data exclusivity involves a monopoly right over test data for a certain period of time, whereas in case of data protection, no monopoly right is involved. Data protection only requires authorities to keep the data confidential. TRIPS only requires data protection, and not data exclusivity.

It should be noted that in relying on the data of innovator companies, drug regulatory bodies are not compromising on safety or efficacy, because they usually require proof of bioequivalence, i.e. evidence that the concentration of the active ingredient in the human body after use of the generic product is the same as that achieved by the originator company’s drug. In addition, regulatory agencies make sure that all companies follow good manufacturing practices to ensure quality.
Impact of data exclusivity

There are several situations where data exclusivity can have implications for public health. First, it may result in a monopoly, even when a country is not required to provide patent protection. For instance, under WTO rules, LDCs do not need to allow patents on medicines till 2016. In their case, introducing data exclusivity would allow companies to have a “patent-like” monopoly for a certain period—usually at least five years. Further, some FTAs provide for data exclusivity for a new use of an existing drug. This can result in extending the monopoly beyond the 20-year patent period, in case a new use is discovered just when a patent is about to expire or after it has expired.

For countries where patents on medicines are allowed, the effect can be different; data exclusivity could interfere with the implementation of a compulsory license. But if data exclusivity is provided for, a CL may not be useful, as the drug regulatory authority may be prohibited from registering a generic product unless the generic company conducts fresh clinical trials before getting marketing approval. Such trials are expensive, and thus they would add to the cost of the drug. They would also be time consuming and significantly delay introduction of the generic product. And most important, it would be unethical to conduct trials involving control groups, when the safety and efficacy of the drug is already known.

It is important to be clear that, first, patents and data exclusivity are two entirely different concepts. The enforcement of data exclusivity can have the biggest impact in situations when patents cannot, or are not, being enforced. Moreover, as mentioned, the TRIPS Agreement does not require data exclusivity; data exclusivity is one of the so-called “TRIPS-plus” provisions (provisions that go beyond the TRIPS Agreement). It can for often be found in FTAs.

Given the negative impact on public health and access to medicines of providing for data exclusivity, it is important that developing countries try to avoid it. If unable to avoid data exclusivity, countries should limit the duration of data exclusivity as well as its scope (e.g., only for new chemical entities, and only for undisclosed data). Countries should also consider creating exemption mechanisms by which they can exempt products from data exclusivity provisions if necessary.
Linkage

Another “TRIPS-plus” provision is “linkage”. It refers to linking patent status and generic registration, meaning that the drug regulatory authority may not register generic versions of a pharmaceutical that is under patent. This would be problematic, since the drug regulatory authority would probably lack the resources and manpower to check the patent status of each product. Moreover, in case there is a patent, regulators may not have the expertise to assess whether the patent is valid and would be infringed. “Linkage” is also problematic in view of the fact that patents are private rights; as such, they should be enforced by the right holders, not by the government.

The WIPO development agenda

The World Intellectual Property Organization (WIPO) was not part of the UN system until 1971; before that time it essentially represented the interests of the developed world. Since then, many developing countries have joined WIPO, and WIPO has become a source of technical advice on patents, copyrights and other IPR. Moreover, the WTO and WIPO have signed an agreement that mandates WIPO to provide technical advice on how to implement the TRIPS Agreement. However, some observers have raised concerns that the interests of WIPO’s original constituency are at times at variance with the interests of developing nations. As a consequence, some observers have expressed concern that WIPO does not adequately represent the interests of developing countries, and does not always respond to their needs. Recently, WIPO has been called upon to address concerns raised in debates about abuses of the IP system.

Developed nations have proposed negotiations in WIPO on a Substantive Patent Law Treaty (SPLT). This is a proposed treaty that aims to harmonize substantive points of patent law. In contrast with the Patent Law Treaty signed in 2000 and now in force, which only relates to formalities (such as the requirements to obtain a filing date for a patent application, the form and content of a patent application, and representation), the SPLT aims to go beyond formalities to harmonize substantive requirements such as novelty, inventive step and industrial applicability. In other words, the SPLT proposes to go beyond the TRIPS Agreement.
As a result of the more liberal granting of patents, the number of patents has considerably increased in many developed countries. Companies today can obtain patents for relatively minor improvements of existing medicines, such as isomers, polymorphs and esters. The result can be the creation of a “patent thicket” that surrounds an invention and that can prevent others from conducting research in that particular area. It can also prevent the introduction of generic drugs.

It is against this background that a proposal was tabled by developing countries at the 2004 WIPO General Assembly, where 14 developing countries (also called the Group of Friends of Development), presented a proposal for the “Establishment of a Development Agenda for WIPO”. The proposal suggests various measures which could be taken in order to ensure that development is at the heart of all WIPO programmes and activities, and that WIPO contributes to the fulfillment of the UN’s Millennium Development Goals (MDGs).

Negotiations in WIPO have long been deadlocked between the developing countries under the banner of “Friends of Development” and developed countries. However, in September 2007, the WIPO General Assembly adopted a Development Agenda.

### The WIPO Development Agenda

The development agenda comprises 45 recommendations, which aim to enhance the development dimension in the work of the World Intellectual Property Organization. These recommendations relate to the following broad areas:

- technical assistance and capacity building;
- norm-setting, flexibilities, public policy and public domain;
- technology transfer, information and communication technologies and access to knowledge;
- assessment, evaluation and impact studies; and
- institutional matters including mandate and governance.
7. Protection of traditional knowledge and public health

An estimated 80% of the global population uses traditional medicines at some point in their lives. There is also, today, a growing demand for traditional and alternative medicines in the developed world, and an awareness that traditional knowledge (TK) needs to be protected if access to traditional medicines is to continue. Protection of TK can include IP-related measures as well as non-IP related mechanisms. However, if the principal intent is to preserve TK, then IP related measures may not be the best option.

Non-IP related measures that can be and are being proposed include:

- Development of mechanisms for prior consent and benefit-sharing: insistence on prior consent from holders of TK if their knowledge is to be a subject matter of further research, and mandatory sharing of benefits with the holders of the TK, if benefits accrue from the research.
- Recording of TK (in the form of databases, archives, etc.) to ensure that it does not die out with the drastic reduction, in some places, of practitioners who use this knowledge. This will also make TK more accessible, but could entail losing rights over this knowledge.
- Support of in situ conservation of medicinal plants and biodiversity, and the use of traditional remedies.
- Measures to preserve land used to grow traditional medicines, preservation of local cultures and recognition of customary laws.

IP related measures essentially provide negative (i.e. defensive) protection, where the object is to prevent misappropriation of TK. Non-IP measures, on the other hand confer positive rights, which can be: exclusive (i.e., others cannot use it without permission); or non-exclusive (providing for remuneration rights). In international forums, several developing countries, including Brazil and India, have been promoting disclosure of the origin of genetic material in patent applications (when relevant), in order to facilitate the process of benefit sharing; this would help prevent misappropriation.
If IP measures are to be used, there is a need to choose from conventional measures such as patents or to opt for sui generis regimes adapted to TK. The use of patents to protect TK may be difficult, since TK is, by definition, knowledge that has existed for a very long time; hence one of the criteria for patent protection (novelty) cannot be met.

Diverse objectives need to be taken into consideration in the context of discussion on protection to TK, including:

- equity–addressing the issue of exploitation of TK by “outsiders” without sharing the benefits with those who have nurtured the knowledge;
- moral recognition–recognition of practitioners of TK, without necessarily assuming that communities will be satisfied with or seek to receive monetary compensation;
- conservation of biodiversity–especially in situations when there is no incentive to preserve biodiversity;
- preservation of traditional cultural practices and lifestyles;
- commercialization–to address the need to make traditional medicines commercially viable and a source of income for local communities and companies;
- dissemination of knowledge in traditional systems with the objective that existing knowledge continues, expands and is used for protecting health of the people;
- promotion of public health goals by facilitating the use of and access to traditional medicines.

Each country needs to prioritize the above objectives while keeping in mind this issue of providing protection for TK. Other issues to consider include determining whether protection is compatible with indigenous cultures and how to ensure that the concerned communities participate. Enforcement of protection also needs to be considered—the system has to be enforceable by or on behalf of traditional communities, who must have faith in the system for this to be viable. For example, in one Latin-American country, a registration system has been set up, but reportedly there are very few cases of registration because traditional communities are distrustful of the system. Issues to consider include the limits of protection, whether or not exclusive rights are provided and the term of protection. Finally,
exclusive rights, if any, must be balanced by the safeguards to enable scientific research and safeguard access to traditional medicine.

National *sui generis* regimes for TK are being designed and tried out in several countries. In Panama, the system provides exclusive right to holders. In Brazil, the primary concern addressed is conservation of biodiversity. In Peru there is a system in place for registration of TK coupled with rights to holders.

### Thailand’s “Traditional Medicinal Intelligence Act”

This Act makes a distinction between different types of traditional knowledge:

*National Formulae* are formulations that belong to the Nation, which are crucial for human health. Commercial use is subject to permission from the government (criminal sanctions are provided for infringement).

*Private Formulae* are formulations over which a private person has the exclusive rights; third parties must obtain permission from the right holder to use the formula. The rights over a registered personal formula subsist throughout the life of the owner and shall continue for a further period of 50 years from the date the applicant dies.

*General Formulae* are well-known traditional formula that are in the public domain and may be used freely by anybody.

8. **New paradigms for supporting research and development**

The global IPR system is increasingly being questioned with regard to both its implications on access to medicines as well as its effectiveness in stimulating research and development (R&D), notably for diseases that are mostly prevalent in developing countries. Meanwhile, the role of public sector investments in medical R&D is probably not always appreciated sufficiently, in spite of several instances where publicly funded R&D has contributed enormously to the advancement of medical knowledge. The Human Genome project is a prominent example. Thus, interest to develop alternative or complementary models to stimulate R&D is growing; this is, among others, illustrated by the relatively recent creation of several public–private partnerships.
Proposed “Global Framework on Essential Health R&D”

Aware of the constraints with regard to R&D for diseases that mainly affect developing countries, in May 2006 the World Health Assembly (WHA) adopted resolution WHA59.24 that urges Member countries to make global health and medicines a priority in research and development, and particularly to focus on the needs of patients in resource-poor settings. The WHA furthermore decided to establish an intergovernmental group to develop a global plan on research and development for diseases predominantly affecting developing countries. This intergovernmental working group is open to all Member countries. Its task is to “draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the commission”. It further suggested that the strategy and plan of action should secure “an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries”. The intergovernmental working group is to complete its work by the Sixty-first World Health Assembly in May 2008.

Several proposals for possible additional or alternative ways to stimulate and fund medical and pharmaceutical R&D have been developed, and are discussed in the context of the intergovernmental working group. These include, but are not limited to, proposals for a prize fund and an R&D treaty.

Medical Innovation Prize Fund

This innovative approach seeks to ensure the affordability of medicines while keeping in mind the therapeutic value of an innovation. The approach proposes that every medicine be treated as a generic drug that can be produced by any manufacturer. A separate fund would be created to compensate and reward the innovators. There are different ways to design a prize fund; e.g. for ten successive years, innovators could be rewarded from this fund, based on the number of people that benefited from the innovation and the extent to which it benefited them. A portion of the fund could be used in a developing country to promote domestic R&D. The key feature of this approach is that it would separate the market for innovation from the market for the product. It would thus potentially create a market-based approach without the high prices created by patent monopolies.
A global R&D treaty

Some argue that there is a need to develop a new paradigm for research that looks beyond the confines of the IPR framework detailed in the TRIPS Agreement. The idea to develop such a treaty is supported by a number of distinguished scientists. The basic obligations for parties to the proposed global R&D treaty could look like this:

- every country is required to support medical R&D;
- the support would be a fraction of GDP, and thus it would depend upon the size of the economy;
- countries would have flexibility in terms of how the R&D was financed and managed;
- purchases of patented medicines, public sector research, prize funds, etc, would be allowed, to the degree that they stimulate R&D.

While discussions on these and other proposals have not yet been completed, the proposals indicate that it may be possible to change the way R&D is being funded.

9. Case studies: Bangladesh and India

9.1 Bangladesh: Increasing self-sufficiency in the pharmaceutical sector

The pharmaceutical sector is one of the fastest growing sectors in Bangladesh, with an average annual growth rate of 9% since 1982. Total retail market size in 2005 was US$ 500 million and the sector is the second-highest contributor to the national exchequer. In the export policy of 2003-2006, the pharmaceutical sector was designated as a high-priority sector.

A total of 164 pharmaceutical companies operate in the country. There are 5300 registered pharmaceutical formulations and 8300 brands based on these formulations. The sector is dominated by local manufacturers; out of the top ten pharmaceutical companies, eight are local companies.
Bangladesh is almost entirely self-sufficient in the production of formulations, with about 96% locally manufactured (except for some selected products like vaccines and insulin). Technologies for manufacture of active pharmaceutical ingredients are being developed and the country is self-sufficient in this regard in some therapeutic categories.

This is a major turnaround from the situation in 1972, when just 30% of formulations were locally manufactured. Even in 1982, eight multinational corporations controlled 75% of the market. In contrast, the market share of multinational corporations in 2005 was just 7%.

This level of self-sufficiency has been achieved without adversely affecting affordability, though some prices have started to go up in recent years.

A major reason for this turnaround has been the Bangladesh Drug Policy, which was implemented in 1982 and which addresses the issues of access and affordability. The implementation of the policy led to a sharp drop in drug prices.

Key features of this policy were:
- restriction on irrational and hazardous drugs;
- control over the pharmaceutical market and promotion of rational use of drugs, with priority given to locally manufactured drugs;
- ban on import of drugs, raw materials and packaging materials that are locally manufactured; and
- drug price control.

Subsequently, policies related to quality control, such as the promotion of good manufacturing practices, were also introduced.

In recent years, major investment has taken place in this sector (estimated at US $250 million over a 3 year period). Bangladesh provides, thus, an example of how an import-dependent sector transformed into a relatively self-reliant industry with export capability.

Pharmaceutical exports from Bangladesh started in the late 1980s, and were initially limited to neighboring countries. Subsequently,
pharmaceutical exports extended to moderately regulated markets. Today, Bangladesh is exporting pharmaceuticals to about 60 countries.

Bangladesh is an LDC and hence is in a position to make use of the waiver delaying provision for patents on medicines until 2016. This provides Bangladesh the possibility of becoming a major source of generic drug manufacturing, not just for meeting its own needs but also for exporting to developing countries and other LDCs. This opportunity is particularly significant given that countries like India are now required to provide for product patents on medicines, making it much more difficult to manufacture and export drugs that are under patent protection.

In order for Bangladesh to make use of this opportunity and further increase its potential to export generic medicines, amendments to the national law would be required.

9.2 India: A pharmaceutical industry in transition

The TRIPS Agreement, once signed, placed a number of obligations on WTO Member countries. For India, this meant that the Indian Patents Act 1970 had to be amended. The most important change for India was the requirement to change to a product patent regime in the area of pharmaceuticals and food; the 1970 Act did not provide for product patents in these areas. It was this simple provision in the 1970 Act that had helped to catapult India to the position of fourth-largest producer of pharmaceuticals in the world and a major supplier of affordable generic drugs to poor developing countries.

In order to conform to the TRIPS requirements, amendments to the Patents Act were enacted in 1999, 2002 and 2005. The 2005 amendment introduced, among others, a unique provision on the patentability of pharmaceuticals.

The patentability of pharmaceuticals

There were serious concerns that the introduction of product patents for pharmaceuticals would lead to a deluge of applications, and that patents might be granted for minor and frivolous inventions. There were further fears that this could lead to “evergreening” of patents—that is, perpetuation of a
patent’s monopoly beyond the stipulated 20 years by repeated patent grants, based on small changes made to the original molecule. The 2005 amendment has, however, restricted the scope for the granting of patents on frivolous claims by clarifying that, “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy” is not patentable. The provision is accompanied by an explanation that: “Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy”.

At the same time, however, Indian law has defined the inventive step (one of the three criteria for patentability) as a feature of an invention that “involves technical advances as compared to the existing knowledge or having economic significance or both”. It has been argued that inventive step really should apply only to technical advances as it defines the innovative content in an invention. Thus, the incorporation of “economic significance” would seem to dilute the criteria for what is an invention. It is yet to be seen how this clause will be interpreted in practice.

<table>
<thead>
<tr>
<th>The imatinib case in India</th>
</tr>
</thead>
<tbody>
<tr>
<td>The drug imatinib has the potential to save the lives of patients suffering from chronic myeloid leukemia. In many countries it is under patent protection, and expensive. Thus, in developing countries its potential benefit is limited to a relatively small number of patients who can afford to pay for it.</td>
</tr>
<tr>
<td>In India, a patent application was filed for the beta crystalline form of imatinib mesylate (Gleevec). The application was rejected, and the patent was not granted in India, since under the above provision it is considered not patentable in India. As a result, generic manufacturers can produce and sell the drug at a significantly lower price in India. Other countries in the Region can import generic versions from India, providing there is no patent in force for this medicine within their territory. Alternatively, they could grant a compulsory license to import generic versions from India.</td>
</tr>
</tbody>
</table>

**Effect on drug prices and availability**

The effect of patent law on drug prices and availability is an issue that is of crucial importance not just for India but for a large number of developing countries dependent on Indian exports for access to affordable, essential
medicines. In the Region these include Myanmar, Nepal and Sri Lanka, and outside the region, numerous sub-Saharan African countries. Medicines already on the market before 1 January 1995 would not be affected by the new rules, but for other, more recently developed medicines it will now take much more time for Indian companies to launch generic versions (unless they request and obtain a compulsory license).

Linked to this are questions regarding the ability of Indian companies to export these new drugs. In principle, there are two options available: one option would be for companies to export a relatively small portion of the drugs being produced through a compulsory license—which, however, is dependant on whether compulsory licenses will be granted. The second option is to make use of the Paragraph 6 system, arrived at after the Doha Declaration (see chapter 4).

10. Conclusion

The TRIPS Agreement requires that all WTO member countries provide for pharmaceutical patents in their national laws. It also incorporates flexibilities that can be used to protect the public health interest and to fit different national contexts. Subsequently, the Doha Declaration clarified that TRIPS safeguards can indeed be used to protect public health, and allows LDCs to postpone the implementation of pharmaceutical patents until 2016. As indicated in this report, some countries have used these safeguards to their advantage, while others have not yet felt the need to do so. Meanwhile all countries should ensure that their national legislation contains safeguards that enable them to protect the public health interest, if and when need arises.

This report furthermore highlights the challenges to access to medicines and public health created by increasingly extensive protection for intellectual property, including “TRIPS-plus” provisions that are promoted through FTAs. Effective policy responses are needed, and will require intersectoral consultations, coordination and cooperation. These responses and discussions should address both national policies and laws, as well as positions taken in international negotiations.
Meanwhile, new approaches may be required to address the need for new medicines for diseases prevalent in the developing world, for which the current system provides insufficient incentives. Countries should be encouraged to support the exploration of alternative ways to promote R&D that can complement strategies based on IPR/patents.

Access to essential and needed medicines is a human right, and a key element of a well-functioning health care system. Thus, the public health interest should be taken into account when trade agreements are negotiated and patent laws enacted. International laws and treaties provide room for manoeuvring, but it is up to each country to make use of that flexibility and to safeguard it.
Glossary

**Compulsory license**

A license to exploit a patented invention granted by a State, without the permission of the patent holder, upon request of a third party.

**Data exclusivity**

A legal provision that data collected (e.g. the results of clinical trials) for the purpose of obtaining marketing approval may not be used for a specified period by the regulatory authorities to grant approval to a generic equivalent.

**Data protection**

An obligation imposed on third parties to protect test data (e.g. the results of clinical trials) usually collected in order to comply with government regulations on safety, efficacy and quality for a range of products (drugs, pesticides, medical devices). TRIPS requires data protection, but not data exclusivity.

**Doha Declaration**

Declaration on the TRIPS Agreement and Public Health agreed at the WTO Ministerial Meeting in 2001 in Doha, Qatar.

**Evergreening**

Popular term to describe patenting strategies that are intended to extend the patent term on the same compound.

**Intellectual property rights**

Rights awarded by society to individuals or organizations over inventions, literary and artistic works, symbols, names, images, and designs used in commerce. They give the titleholder the right to prevent others from making unauthorized use of their property for a limited period.
**Parallel imports**

The purchase of a patented medicine from a lawful source in an exporting country and its importation without seeking the consent of the “parallel” patent holder in the importing country.

**Patent**

An exclusive right awarded to an inventor to prevent others from making, selling, distributing, importing or using the invention, without license or authorization, for a fixed period of time. In return, the patentee discloses the invention to the public. There are usually three requirements for patentability: novelty (new characteristics which are not "prior art"); inventive step or nonobviousness (knowledge not obvious to one skilled in the field); and industrial applicability or utility.

**Patent pool**

An agreement between two or more patent owners to license one or more of their patents to one another or third parties.

**TRIPS**

The Agreement on Trade–Related Aspects of Intellectual Property Rights, which entered into force in 1995 when the World Trade Organization came into being. It is binding for WTO members, and makes it mandatory to adhere to certain standards of patent protection. Before 1995 countries could opt not to grant patents to medicines.

**TRIPS-plus**

Informal term for requirements or provisions to provide a higher level of IP protection than what is required by the TRIPS Agreement.
References and further reading


Annex 1

Doha Declaration on the TRIPS Agreement and Public Health

World Trade Organization

Ministerial Conference
Fourth Session
Doha, 9–14 November 2001

Declaration on the TRIPS Agreement and Public Health
Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

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

   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.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.
Annex 2

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Drawing on the debates at a workshop on intellectual property rights and access to medicines in South-East Asia, held in Dhaka, Bangladesh, this report provides an overview of recent developments related to intellectual property rights/patents and access to essential medicines in various international forums. It also touches on concerns related to traditional medicines and questions regarding pharmaceutical innovation. It tries to put these various concerns and developments in a broad context, and discusses them from a regional perspective.

The report seeks to capture and summarize the issues explored and discussed during the workshop, rather than to promote a particular view. It is intended as a contribution to the debate on intellectual property and access to medicines.