

Section II: Public Health Safeguards in the TRIPS Agreement

2.1 Flexibilities in TRIPS Agreement

As the TRIPS is not an international law, countries have the flexibility to interpret it based on their national situation. They can include in national legislations measures that may limit exclusive patent rights, so that the objectives and principles of the TRIPS Agreement may be achieved. Articles 7 and 8 of the TRIPS agreement set out some of the broad objectives of the agreement, including: promotion of technological innovation, transfer and dissemination of technology; and measures to protect public health and nutrition and to promote the public interest. Further, the Doha Declaration (at the time of the WTO Ministerial meeting in 2001) affirmed the right of countries to use to the full, the flexibility in TRIPS

The flexibilities or public health safeguards available in TRIPS and clearly affirmed by the Doha Declaration (see later) include the following:

- ◆ Government use
- ◆ Compulsory licences
- ◆ Parallel importation
- ◆ Exceptions to patent rights (e.g., Bolar exception)

Government use: This 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 authorised by the government to use an invention, for public, non-commercial purposes. e.g., public sector production of generic medicines, or import of generics for use in public hospitals. This provision allows for "fast-tracking" of compulsory licences, i.e. licenses to generic manufacturers can be issued even before the country's law allows generic production in the normal course through issue of compulsory licenses. Government use provisions are part of many country laws on patent protection, including broad provisions

in the laws of developed countries, such as in the US and UK (known as "Crown use").

Compulsory licences are non-voluntary licences 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 compulsory licence, and such grounds are not limited to emergencies. The main conditions for grant of a compulsory license are prior negotiations with the patent holder, payment of compensation and an appeals procedure.

Parallel import is the import and resale of a patented product in another country, without consent of 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. TRIPS does not prohibit parallel imports, Article 6 allows countries to decide which regime for "exhaustion of rights" to adopt. The principle under which exhaustion of rights operates is that the rights of the patent holder are exhausted once the product is put for sale in the market, and a resale of the same does not constitute an infringement of the rights of the patent holder. Many countries, viz. S.Africa, Malaysia, Argentina, India, etc. 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 generic product once the patent expires. Other exceptions include exceptions for research, and experimental use. For a country to make use of this flexibility specific exceptions must be provided for in the national law.

2.2 Use of Flexibilities to Safeguard Public Health

Most developed countries have TRIPS safeguards in their laws, and have used them (e.g. the extensive use of compulsory licensing in the US). Ironically, 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 exploit the flexibility in TRIPS;
- ◆ Ensure that these flexibilities are implemented through clear, unambiguous, easy to use, regulations
- ◆ Adopt clear, easy to apply, and transparent guidelines for setting compensation rates;
- ◆ Ensure that appeal procedures that do not suspend execution of licence;
- ◆ Adopt straightforward, transparent and speedy procedures.

Public-health sensitive patent laws: The UK Commission on Intellectual Property Rights (2001) lists an useful set of guidelines for formulating public health sensitive patent laws, which include the following:

- ◆ Limit the scope of patentable subject-matter
- ◆ Impose strict requirements for patent ability and breadth of patent commensurate with inventive contribution and disclosure made
- ◆ Facilitate competition - restricting ability of patentees to prohibit others from building on or designing around patented inventions
- ◆ Provide extensive safeguards to ensure patent rights are not exploited inappropriately

2.3 Doha Declaration on TRIPS and Public Health

Since the signing of the TRIPS agreement in 1995, there has existed a tension between what TRIPS requires countries to do and their negative impact on public health. The HIV-AIDS epidemic and the exorbitant pricing of Anti-retroviral drugs has highlighted this tension. The balance between patent protection and public health concerns have been further skewed through a number of Bilateral trade agreements that, in fact, provide for even higher degree of patent protection than what is mandated by TRIPS. The response to the public health crisis has been inadequate even as regards the resources pledged for addressing it. The Global Fund, for example, received total contributions of US\$4,603 million between 2000-2005, while the projected requirement for the Fund in 2006 alone is US\$12,000 million.

Against this backdrop the African Group (later joined by India and Brazil) requested that a special session of the WTO - TRIPS Council be held to discuss IPR and public health. This was accepted by WTO Members and the meeting laid the ground for the Doha Declaration on TRIPS and Public Health on 14th 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.

Interpretation of the Doha Declaration

There were contentious debates leading up to the finalisation of the content of the declaration. This is reflected in the first paragraph itself, where the US wanted to limit the scope of the declaration to a few selected diseases like TB, Malaria and HIV. This was rejected by developing countries and finally it was agreed to include all diseases in the scope of the declaration, and also vaccines and diagnostic kits, in addition to medicines.

Paragraph four is in many senses the key portion of the declaration. While the paragraph has been interpreted in differing ways by different interest groups, 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 where a clear priority it gives to public health concerns.*

The other important facet of the declaration is that it confirms that flexibilities are available in the TRIPS agreement. The declaration does not add to flexibilities already available in the TRIPS agreement, but is an authoritative interpretation of TRIPS confirming that members can decide their own grounds for application of the flexibilities. Before the Doha declaration an interpretation of TRIPS was sought to be proposed by some, which argued that Compulsory licenses can be granted on very limited grounds. *The declaration makes clear that CLs can be granted on a large number of grounds related to public health concerns, and countries have the freedom to define these.* The declaration clarifies that governments can decide what constitutes an emergency (as a ground for granting compulsory licenses) and this decision cannot be challenged.

Problems of countries without manufacturing capability

Paragraph six of the Doha Declaration stated: "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 section addressed the problems of countries without domestic capacity, as they cannot effectively exercise right to grant CL as there are no domestic generic producers who can produce cheaper generics by making use of the CL. Their only option is to import from foreign producers. If they were to issue a CL to import, they would be faced with the restriction in Article 31(f) of TRIPS

which restricts exports of generics produced under a compulsory licence "predominantly for the supply of the domestic market". It was also clear that the problem would be confounded after 2005 as countries which were able to supply generic drugs to such countries because patents on pharmaceuticals did not apply - viz. India - would have to change to a regime that allowed patents on pharmaceutical products.

Solution by TRIPS Council (new section Art.31(bis)): The WTO Paragraph 6 Decision which was eventually agreed to permits manufacturers to produce and export under compulsory licence to countries without manufacturing capacity. For such exports, it provides for waivers of TRIPS obligations in Art. 31(f) (necessity to manufacture predominantly for domestic market), and Art. 31 (h) (necessity to provide compensation to the patent holder in the importing company). The decision also allows a regional Trade Agreement to export as a single entity. This decision has been in place since August 30th, 2003 and its formal incorporation in the TRIPS Agreement was agreed on 6 Dec. 2005. It becomes Art. 31 (bis) and comes into force in 1 December 2007, when two-thirds of WTO Members ratify the amendment. However, no country has yet made use of this system, which may point to its use being perceived as problematic.

All LDCs and developing countries who notify the TRIPS Council their intent to use the system 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 show that access to a needed product that is protected by a patent has been refused/hindered (on grounds such as high price, inadequate production, etc.). The country has to notify the TRIPS Council about its intention to use the system. Further, both the importing and the exporting countries must have enabling provisions in their national laws to allow this. Enabling provisions need to include CL provisions for import and export (in

the importing and exporting countries respectively) and waiver of remuneration to innovator company in importing country. Enabling legislations allowing exports through this system have been passed in Canada, Norway, India, China, and is under preparation in the EU.

The WTO August 2003 decision, as mentioned earlier, is yet to be used. Much of the reason for this is the cumbersome procedure involved requiring importing countries to notify the TRIPS Council about its requirement every time it wants to use the facility and the large number of legal provisions that need to be incorporated in national laws. Moreover, given that each requirement needs to be notified and sanctioned, manufacturers in exporting countries do not see a ready and assured market, thereby making them reluctant to produce for exports in such conditions.

2.4 Experiences in the Use of Flexibilities under the TRIPS Agreement

2.4.1 Use of Compulsory License

There has been considerable debate as to why the compulsory licensing provisions in the TRIPS agreement are seldom used by developing countries to improve access to medicines. Interestingly most developed countries have strong compulsory licensing and government use provisions in their domestic laws. For example, the United States provides for broad Government use provisions in its law (covered by USC 1498). The only remedy to the patent holder, that is available, is award of compensation and not an injunction on the unauthorised use by the Government. Further, the provision covers private parties who are contracted by the US Govt. to use a Patent on its behalf.

The use of non-voluntary (compulsory) licenses in the US and Europe has a very long history and has contributed to the development of many important sectors. In 1917, the US created the Manufacturers Aircraft Association (MAA) patent pool (a pool of essential patents with 60 manufacturers as users) to overcome barriers

Country	Description	Date of issue	Date of Expiry	Royalty	Drugs Covered	Patent Holder
Malaysia	Authorization for import of antiretrovirals for use in government hospitals (government use)	Nov-2003	Nov. 2005	Payment after each importation	Didanosine Zidovudine Nevirapine+ Zidovudine	Bristol Myers Squibb(BMS) Glaxo Smith Kline (GSK) Boehringer Ingelheim (BI) Glaxo Smith Kline
Indonesia	Authorisation for domestic production of antiretrovirals (government use)	Oct-2004	Not stipulated	0.5% of net selling values of generic	Nevirapine Lamivudine	Boehringer Ingelheim (BI) Glaxo Smith Kline
Zambia	Compulsory License for local production	Sept-2004	July, 2009	Maximum 2.5% of net sales	Stavudine + Lamivudine + Nevirapine	GSK and BI
Mozambique	Compulsory License for local production	April-2004	When HIV/AIDS related emergency ends	Maximum 2% of net sales	Stavudine + Lamivudine + Nevirapine	GSK, BMS and BI
Zimbabwe	Compulsory License to produce, import or use any drug	May-2002	Ongoing	Not known	All HIV related drugs	GSK, BI, Roche
Thailand	Government Use	Jan-2007	Dec. 2011	0.5% to 2% of sale value	Efavirenz Lopinavir+ Ritonavir Clopidogrel	Merck Sharp and Dohme Abbott Laboratory Sanofi-Aventis
Brazil	Government Use	May-2007	Ongoing	1.5% of purchase value of drug from Indian generic manufacturer	Efavirenz	Merck Sharp and Dohme

Decree Issued by Government of Indonesia

A notification enabling the issue of a compulsory license can be issued by a sovereign government, as long as it is consistent with domestic laws and TRIPS obligations. The TRIPS agreement has no format for such a notification and countries are free to choose the language and modality of such a notification. Given below is the notification issued by the Indonesian Government in 2004 as one such example.

In 2004, a Presidential Decree enabled 'Government Use' of certain patented ARVs. The Decree (Decree no.83) stated:

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***
- ◆ In this regard, MoH 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 exploit the patent of Nevirapine and Lamivudine

for the scaling up of aircraft manufacturing. The decision was taken when the US Govt. was on the verge of joining the 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.

While TRIPS safeguards continue have been used sparingly by developing countries, there has been a surge in the number of compulsory licenses issued in recent years. The Following Table lists compulsory licenses issued by different countries since the signing of the TRIPS agreement.

2.4.2 Determining Royalty Rights in Case of a Compulsory License

When a non voluntary license is issued, a matter of contention is often the computation of royalty rate that compensates the patent holder. There is no internationally accepted authoritative guideline which helps compute such rates, and hence, extensive flexibility is available in how to compute royalty rates.

An interesting concept to be kept in mind while computing royalty rates is an US Court observation based on US 28 USC 1498

Country	Mechanism	Licensee	Exports	Royalty
Indonesia	Government use	One Manufacturer		0.5%
Malaysia	Government use	One Importer		4% offer
Mozambique	Emergency plus compulsory license	One Manufacturer		2%
South Africa	Competition	Small number Manufacturers	In Africa	5%
Swaziland	Emergency	Open		Nil
Zambia	Compulsory license	One Manufacturer	No	2.5%

Public Health Safeguards in Indian Patents Act

(Government use without authorisation), where it observed that: "*the proper measure is what the owner has lost, not what the taker has gained*". If we apply this concept in a situation like in Thailand, where the initial price for Fluconazole was 200 Baht, but fell to 6.5 Baht when generic competition was allowed, the compensation should look at the lower figure and not at the higher one obtained in a monopoly situation. It should also be remembered that in certain situations, viz. when a CL is issued to remedy an anti-competitive environment or measure, royalty can be zero.

Royalty rates that have been decreed or offered vary widely today, as the following table of some recent compulsory licenses for ARVs show: