



INTELLECTUAL PROPERTY AND THE PUBLIC INTEREST

COMMUNICATION FROM BRAZIL, CHINA, FIJI, INDIA AND SOUTH AFRICA

The following communication, dated 31 May 2017 is circulated at the request of the delegations of Brazil, China, Fiji, India and South Africa.

1. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO) established minimum standards of protection that each government has to give to the intellectual property of fellow WTO Members. Each of the main elements of protection is defined, namely the subject matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection. WTO Members have the flexibility to design their national intellectual property (IP) systems within the minimum standards set by the TRIPS Agreement, in cognizance of a country's economic, developmental and other objectives, including public health.

2. The TRIPS Agreement attempts to strike an appropriate balance between the interests of rights holders and users. Article 7 of the TRIPS Agreement entitled "Objectives" recognizes that the protection of intellectual property should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of users and producers of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations. The search for a balance between the need to protect IPRs to provide incentives for R&D on the one hand and, on the other hand, to address concerns about the potential impact of such protection on the health sector – in particular its effect on prices – has been an important consideration in the WTO's work.¹

3. The TRIPS Agreement also recognizes that the principles of IP protection are based on underlying public policy objectives. Article 8 of TRIPS Agreement entitled "Principles" states that WTO Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. Article 8 (2) further states that appropriate measures may be needed to prevent the abuse of IPRs by right holders, or to resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

4. In furtherance of the objectives and principles of TRIPS enshrined in Articles 7 and 8, a number of safeguards or flexibilities have become an integral part of the TRIPS framework. These flexibilities can be used to pursue public health objectives. However, to implement these flexibilities, action is needed at the domestic level by incorporating them into national IP regimes

¹ *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade* by WHO, WIPO and WTO, 2013, available at https://www.wto.org/english/tratop_e/trips_e/trilatweb_e/trilat_web_13_e.htm. This document is more commonly known as the "Trilateral Study".

keeping in mind each country's individual needs and policy objectives. Key TRIPS flexibilities include transition periods for LDCs (extended by the WTO until 01 January 2033), differing IP exhaustion regimes, refining the criteria for grant of a patent (patentability criteria), pre-grant and post-grant opposition procedures, as well as exceptions and limitations to patent rights once granted, including the regulatory review exception ("Bolar" exception) to facilitate market entry of generics, compulsory licences and government use.

5. For pharmaceutical patents, these flexibilities have been clarified and enhanced by the 2001 Doha Declaration on TRIPS and Public Health.² WTO Members have the flexibility to interpret and implement TRIPS provisions in a manner supportive of their right to protect public health. Another new flexibility was added by the Doha Declaration, which was put into practice in 2003 by the WTO with a Decision³ enabling countries that cannot manufacture medicines themselves, to import pharmaceuticals made under compulsory licences. In 2005, Members agreed to make this decision permanent through a Protocol Amending the TRIPS Agreement, which entered into force on 23 January 2017 after two thirds of Members accepted it. The amendment provides legal certainty⁴ that generic versions of patent-protected medicines can be produced under compulsory licences specifically for export to countries with limited or no pharmaceutical production capacity.

6. Many governments have not used the flexibilities available under the TRIPS Agreement for various reasons, such as capacity constraints or political pressure from states and corporations mentioned in the UN Secretary-General's High Level Panel Report on Access to Medicines. Moreover, even where some developing countries used the flexibilities available to them under the TRIPS Agreement to address public interest objectives through measures which are fully consistent with the TRIPS Agreement, these attempts have been challenged legally as well as politically. Political and economic pressure placed on governments to forgo the use of TRIPS flexibilities violates the integrity and legitimacy of the system of legal duties and rights created by the TRIPS Agreement, as reaffirmed by the Doha Declaration.⁵

7. A slew of regional trade agreements containing "TRIPS plus" standards of IP protection and enforcement have the potential to significantly affect the policy space available for effective and full use of the TRIPS flexibilities. The most common "TRIPS plus" provisions in free trade agreements (FTA) that affect the pharmaceutical sector are: the definition of patentability criteria; patent term extensions; test data protection; the linkage of regulatory approval with patents and enforcement of IPRs, including border measures. Such provisions can delay market entry of generics and increase prices of medicines.⁶ Investor-State disputes under regional or bilateral investment protection agreements are also emerging as significant threats to the use of TRIPS flexibilities in the public interest.

8. Ironically, the abovementioned challenges to the use of TRIPS flexibilities to further the public interest objectives underlying IP protection, have been occurring in spite of the emergence of laws and jurisprudence in developed countries that seek to limit the scope of IP protection and enforcement. For example, in the *Myriad Genetics* (2013) case⁷, the US Supreme Court had ruled unanimously that naturally occurring genes cannot be patented, even if they are isolated. In 2003, the US Federal Trade Commission had proposed tightening the non-obviousness standard, in order to limit the grant of unwarranted patents.⁸

9. There is a growing concern about an imbalance between intellectual property and the public interest. With regard to health technologies, for example, patents and related monopoly rights in

² https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

³ See document WT/L/540, General Council Decision of 30 August 2003.

⁴ https://www.wto.org/english/news_e/news17_e/heal_30jan17_e.htm

⁵ The Report of the UN Secretary-General's High Level Panel on Access to Medicines is available at <http://www.unsgaccessmeds.org/final-report/>

⁶ Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade, 2013, see footnote 1.

⁷ Association for Molecular Pathology v. Myriad Genetics, USCC No. 12-398 (569 U.S. _ June 13, 2013)

⁸ <https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf>

test data, without sufficient use of balancing exceptions and limitations to protect the public interest, permit companies to maintain high prices and exacerbate crises of access around the world, where many patients cannot afford medicines, and force governments with finite health budgets to ration care. Increased copyright protections create similar problems of access to knowledge goods, limiting the ability of many people around the world to access print, audio, or visual works of education or entertainment that we take for granted. These are only a few examples of the problem. There is a need to pursue a development-oriented approach towards formulating IP laws and policies rather than pursue an iconoclastic approach of IP for development.

10. More than 20 years after the adoption of the TRIPS Agreement, there is a need for discussion in the TRIPS Council on the relationship between IP and the public interest and to broaden the understanding of how the IP system can be more responsive to public interest considerations. While this issue is very pertinent for developing countries, it has also been a topic of significant policy debate even in developed countries. During the course of the meetings of the Council for TRIPS in this year and later, WTO Members could exchange views and experiences on measures within the IP system that they have adopted to promote the public interest, including but not limited to compulsory licensing, patentability criteria, IP and competition, and Bolar exception. For the 13-14 June 2017 meeting of the Council for TRIPS, the sponsors of this communication invite delegations to share their experiences on the use of compulsory licenses for accessing health and other technologies.

Compulsory Licensing

11. Compulsory licensing occurs when a government allows someone else to produce the patented product or process without the consent of the patent owner.⁹ Article 31 TRIPS lays down a set of conditions for issuing compulsory licenses of patents. The Doha Declaration on the TRIPS Agreement and Public Health states that, "Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted".¹⁰ In spite of the clarity of this language, WTO Members around the world seeking to make use of compulsory licences as a tool to increase access to affordable medicines have faced various challenges/barriers.

12. Some possible grounds for compulsory licensing are suggested in Article 5A of the Paris Convention (e.g. abuse of patent rights, including failure of the patent holder to work the invention) and in Article 31 of the TRIPS Agreement (e.g. national emergency and public non-commercial use). However, this list is not exhaustive. The Doha Declaration on the TRIPS Agreement and Public Health confirmed what was already implicit in the TRIPS Agreement – that WTO Members have the freedom to determine the grounds upon which compulsory licenses are granted. They are thus not limited to emergencies or other urgent situations, as is sometimes mistakenly believed. A range of grounds have been set out in national laws like (i) non-working or insufficient working, (ii) anti-competitive practices, (iii) public interest, (iv) dependant and blocking patents, (v) Government use¹¹.

13. The sponsors of this communication invite Members to share their national experiences and examples of using compulsory licenses. The information exchange could serve to enhance understanding of Members on various grounds available for issue of compulsory licenses and problems faced by Members while using them.

Guiding questions:

- What grounds are available in their national laws to issue compulsory licenses?
- What are the difficulties faced by WTO Members in using compulsory licenses, including constraints, such as insufficient or no manufacturing capacities?
- How the measure of compulsory licence was used by governments to obtain price reduction from patent holders?
- What was the result of using compulsory licenses in terms of price and access to affordable products and technologies?

⁹ https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

¹⁰ https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

¹¹ Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade, 2013, see footnote 1.