

STATEMENT BY INDIA AT COUNCIL FOR TRIPS MEETING ON 13 JUNE 2017

INTELLECTUAL PROPERTY AND THE PUBLIC INTEREST: COMPULSORY LICENSING

At the outset, I would like to thank delegations of Brazil, China, Fiji and South Africa who are also co-sponsors of this agenda item. We would also support the statement made by South Africa while introducing our submission contained in document **IP/C/W/630**.

- Madam Chair, the TRIPS Agreement attempts to strike an appropriate balance between the interests of rights holders and users. The TRIPS Agreement also recognizes that the principles of IP protection are based on underlying public policy objectives. 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.
- Madam Chair, during the 1980s and 1990s the antiretroviral medicines used to treat HIV/AIDS were priced beyond the reach of most people who needed them in developing countries. Countries like Brazil, Thailand, South Africa and others have used flexibilities under the TRIPS Agreement, including compulsory licenses to bring down the price by increasing the supply of generic ARV medicines for a fraction of the price of the patented equivalents. Indian generic companies, especially CIPLA played an important role by announcing in early 2001 that that triple therapy could be manufactured for less than a dollar a day from the price of standard triple therapy from \$US 10,000 per patient/year. Indian generic companies made ARV medicines accessible to all those who needed the drugs but had previously not been able to afford them.

Compulsory licensing:

- Madame Chair, Article 31 provides members the complete freedom to decide the grounds for issue of the compulsory license. The Doha Declaration on the TRIPS Agreement and Public Health has also duly 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.
- There have been many studies that examine the possible grounds for issue of compulsory license. For instance, the diversity in the grounds for issue of compulsory license is documented in the United States Congressional Research Service Article titled “Compulsory Licensing of Patented Inventions” by John R. Thomas dated 14 January 2014, which mentions that “depending upon particular national laws, the grounds for government award of a compulsory license may include:

- Circumstances of national emergency or extreme urgency.
- Where the invention serves vital public health needs.
- A strong societal interest has arisen in access to the patented invention.
- The patent owner has failed to practice the patented invention in the jurisdiction that granted the patent within a reasonable period of time.
- The patent owner has abused its economic power in such a manner as to violate the antitrust laws.
- In circumstances where multiple patents held by different owners cover a particular technology. For example, combination therapies—such as triple antiretroviral drugs—may be subject to more than one patent. In such cases, if one patent owner refuses to license, then the technology may not be marketed absent a compulsory licensing”

- Madame Chair, I would like to share with you briefly the details of India’s law with regard to CL. Sections 83 to 94 of India’s Patent Act contains detailed provisions regarding compulsory licenses including those that generic companies can apply for, government use licenses, those issued in cases of national emergency, extreme urgency and public non-commercial use and compulsory licenses for exports.
- India has issued only one compulsory license so far. In March 2012, Indian generic manufacturer NATCO Pharma was granted compulsory License to manufacture Bayer’s drug Sorafenib Tosylate (Nexavar) used for the treatment of Kidney and Liver cancer. Bayer was granted a patent and received marketing approval for Nexavar for the treatment of liver and kidney cancers in 2008. Bayer would have supplied 200 patients in 2011, which was a little more than two percent of the affected population. The primary reason for the abysmally low coverage vis a vis the need was the exorbitant treatment cost of nearly Rs.2,84,000/- (US \$4,370) for a month’s treatment which priced the medicine out of reach of almost all people in India. Patent rights cannot be allowed to impede protection of public health.
- NATCO proposed to sell the generic form of Nexavar for Rs/-8,800 (US \$ 135) a month. The Controller of Patents in India granted a compulsory license under section 84 because the TRIPS Agreement allows members to adopt measures to protect public health and Bayer did not meet its duty under the Indian Patents Act as the patented invention was not available to the public at a reasonable price, and it was not worked in the territory of India. The Indian Courts, have upheld the decision of Controller General of Patents to grant Compulsory License to NATCO Pharma to manufacture the generic version of Nexavar in India.
- Madame Chair, now, I would like to provide brief details of use of CL in few other Members. According to an article entitled “Compulsory licensing of patented pharmaceutical inventions: evaluating the options” by Jerome H. Reichman published in the Journal of Law, Medicine and Ethics in 2009, 37 (2): 247-263, the United States threatened Bayer with a compulsory license on ciprofloxacin (Cipro) in 2001, which the U.S. intended to stockpile as a defense against anthrax. Bayer drastically lowered its price in response. The Italian Competition Law authorities issued

compulsory licenses against Merck, on certain antibiotics, for abuse of a dominant position in 2005; against Glaxo, for refusal to license a patented migraine headache drug in 2006; and against Merck again for a refusal to license a treatment for baldness in 2008.

- Madame Chair, in *Apple Vs Motorola* case filed in in the United States District Court for the Northern District of Illinois (Eastern Division), Judge Richard Posner, in June 2012, while dismissing with prejudice the patent infringement suits cited the decision in *eBay Inc. v. MercExchange, L.L.C* and specifically noted that a "compulsory license with ongoing royalty is likely to be a superior remedy in a case like this because of the frequent disproportion between harm to the patentee from infringement and harm to the infringer and to the public from an injunction".
- The September 2016 report of the UNSG's High-Level Panel (HLP) states that many governments have not used the flexibilities available under the TRIPS Agreement, including compulsory licenses for various reasons, ranging from capacity constraints to undue political and economic pressure from states and corporations, both express and implied.
- The HLP report also refers to resolution no 2475 by the Ministry of Health of Colombia that was a pathway for issuance of CI to access of Imantib, in public interest for treatment of Leukemia. The report also states that many domestic and foreign parties have tried to dissuade the Colombian government from issuing a compulsory license as provided by the TRIPS Agreement and the Doha declaration. We request the delegation of Colombia to share their experiences in this regard.
- Madame Chair, 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 and as reaffirmed by the Doha Declaration.
- I conclude by quoting the recommendations in the HLP report on Compulsory Licenses. "Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and particularly with regards to essential medicines. The use of compulsory licensing must be based on the provisions found in the Doha Declaration and the grounds for the issuance of compulsory licenses left to the discretion of governments".
- We look forward to listening from other delegations on their experiences on using the TRIPS flexibility, compulsory licensing.

Thank you Chair.