THIRD WORLD NETWORK

Practical experiences on the effectiveness of and challenges associated to exceptions and limitations to patent rights in addressing development issues

Submission by the Third World Network (TWN)

Introduction

Use of exceptions and limitations of patent law has become the dominant approach to address development concerns related to patents. One of the important strategy in this regard is to use of TRIPS flexibilities in order provide optimum scope of exceptions and limitations in the domestic patent law. However, this approach is based on several assumptions, which are often unrealistic and flawed in the context of developing countries. Apart from these assumptions, TRIPS-plus provisions in the free trade agreements (FTAs), bilateral investment treaties (BIT), pressures from developed countries, voluntary licenses and IP enforcement initiatives are adversely impacting the actual use of limitations and exceptions.

First part of the submission focuses on the effectiveness of the use of exceptions and limitations to patent rights. Second part list major challenges on the use of exceptions and limitations..

Part I: Effectiveness of Exceptions and Limitations to Patent Rights

Even though there is no systematic assessment of contribution of TRIPS flexibilities to access to patented medicine among the all WTO Member States the experiences of various developing countries shows that the use of TRIPS flexibilities facilitates access to patented medicine. For instance, the use of compulsory license for HIV/AIDS medicine in Malasyia in 2003 resulted in 81% drop of cost of treatment.[1] The cost per person came down from USD 325 to USD 58. The compulsory license also forced the patent holder to reduce the price of ARVs in Malaysia. Similarly, use of government use license in Thailand for 6 medicines for the treatment of HIV/AIDS, Hypertension and cancer resulted in a cost saving of nearly USD 370 million during the first five years of the government use of license.[2] Similarly, in Brazil the use of compulsory license for the HIV/AIDS medicine Efavirenz brought down the price to USD.0.46 per pill from USD 1.10 per pill offered by the patent holder Merck.[3] Similarly, the use of compulsory license in India has brought down the price of Sorfenib from USD 5,600 per month to Rs. 8,880 (about USD 176 as per the 2011 March Exchange rate. As per the exchange rate on 26th September USD 132).[4] Using the flexibility on the threshold level of patentability criteria the Egyptian Patent Office rejected patent on Sofosubuvir, a new drug introduced for the treatment of Hepatitis C.[5] Similarly, China also rejected patent on Sofosubuvir[6]

Structural Challenges

[1] Chee Yoke Ling, Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the 'Government Use' Option, P. 14, TWN, 2006

[2] Adun Mohara, The Impact of the Government Use License on the Drug Expenditure on Seven Medicines in Thailand, Value Health Vo 15 , pp 595-599, 2012 https://www.ispor.org/consortiums/asia/ViH/3rdIssue/Impact-of-the-Introduction-of-Government-Use-Licenses.pdf

[3] Johanna von Braun, Use of Compulsory Licenses Selected National Experiences, presentation available at http://unctad.org/Sections/dite_totip/docs/tot_ip_0018_en.pdf

[4] http://www.twn.my/title2/intellectual_property/info.service/2012/ipr.info.120304.htm

[5] http://america.aljazeera.com/articles/2015/5/20/hepititis-c-patent-would-cut-access-for-millions.html

[6] http://www.doctorswithoutborders.org/article/china-rejects-gilead-patent-hepatitis-c-drug-sofosbuvir

The strategy of using limitations and exceptions to protect public interest and development needs such as access to medicine cannot be used by all WIPO member states. There are certain structural constraints, which prevents many WIPO Members from using the exceptions and limitations. Some of the important structural challenges for the use of exceptions and limitations are mentioned below.

First, lack of technological capacities especially manufacturing capability prevents many WIPO Member States from using exceptions and limitations to patent rights. For instance, vast majority of the developing countries and all LDCs, except Bangladesh, lack the manufacturing capacity in the pharmaceutical sector. Many developing countries are net importers of pharmaceutical products, especially the active pharmaceutical ingredients (APIs).[7] In the absence of local manufacturing capabilities, many developing countries cannot use the TRIPS flexibilities effectively without depending on another country. Article 31(f) of the TRIPS restricts the issuance of CL predominantly for export purpose and restrict the issuance of compulsory license exclusively for export. In order to address this issue there is a decision on 30 August 2003 to waive TRIPS obligation under Article 31(f) of the TRIPS Agreement. This waiver is later translated into an amendment of Article 31(f). However it failed to offer an effective solution.[8] The Agreement on Trade Related Investment Measures (TRIMS) and other investment rules, which are part of the Free Trade Agreements (FTAs), also compromise the efforts of many developing countries to achieve self-sufficiency in manufacturing of medical products by making the application of many local production stimulation tools like local content rule, export obligation, etc. as illegal.[9] Therefore for countries do not have manufacturing capability in pharmaceutical sector the incorporation and use of exceptions and limitations will not ensure access to patented medicine without the availability of generic version of patented medicine in another country.

Second, use of exceptions and limitations assumes the existence of institutional and administrative mechanisms in the developing countries. Due to the lack of institutional and administrative mechanisms, many developing countries do not incorporate the TRIPS flexibilities to the optimum level. Without the incorporation of flexibilities in the domestic law, it is impossible to use the TRIPS flexibilities.[10] Further, many countries do not have examination system for patents, and therefore not in a position to apply flexibilities on the scope of patentability.[11] Even those countries having patent examination system need resources and infrastructure to use the flexibilities related to patentability. Often, the technical assistance programs of developed countries and international organizations like WIPO are not directed to optimize the use the TRIPS flexibilities but to reduce the scope of flexibilities.[12] [13]

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[7] For Instance, According to the Arab Organization for Industry and Mining, local production accounts for 45 per cent of consumption, with more than 220 manufacturing units.OIC, Pharmaceutical Industry in OIC Member Countries: Production, Consumption and Trade <http://www.sesric.org/files/article/433.pdf>.

[8]The offered solution contains cumbersome procedures and makes it almost impossible for countries, which do not have manufacturing capabilities to use the mechanism to obtain medicines through a CL exclusively for export purpose from another country. So far, there are only two instances of using this mechanism to facilitate access to medicines for HIV/AIDS. Even though there is greater policy space for the promotion of local production compared to IP, the existing trade and invest regime creates obligations on developing countries, preventing them from providing a policy environment to promote local manufacturing. See MSF, Seven Years On, 'August 30 Decision' has Failed to Improve Access to Medicines and Remains Virtually Unused WTO Must Reform the Rules <http://www.msfaccess.org/about-us/media-room/press-releases/seven-years-'august-30-decision'-has-failed-improve-access>.

[9] Ibid

[10] According to the MDG Gap Taskforce Report, many countries are yet to amend their national laws to incorporate TRIPS flexibilities fully. MDG Gap Taskforce Report 2012 < http://www.un.org/millenniumgoals/2012_Gap_Report/MDG_2012Gap_Task_Force_report.pdf>.

[11] For instance, South Africa does not have an examination system in place Government of South Africa, National Policy on Intellectual Property (IP) of South Africa, 31-32 <http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf>.

[12] According to Prof. Drahos, "[o]ver the years the steady drip of technical assistance leads to the formation of technocratic trust in the EPO's systems. A strong belief forms that the EPO's systems produce quality results and that belief in turn forms the basis of decision-making by patent examiners in under-resourced developing country patent offices. Technocratic trust thus fosters a circle of decision-making in which the EPO trains developing country examiners to make decisions in their own countries that predominantly benefit foreign companies, including European companies."Peter Drahos, "Trust Me": Patent Offices in Developing Countries, *Working Paper*, Centre for

Third, apart from well functioning institutions for the patent administration the effective use of exceptions and limitations also depend on the existence of robust public health institutions. It is important to build up a public health objective while invoking CL or government use such as prevalence of a disease condition and number of people requires access to the medicine in question etc. The absence of such information alone prevents the use of TRIPS flexibilities. [14] In the absence of public health institutions to monitor diseases burden, medicine sales, availability of medicines etc. it would be extremely difficult to us these flexibilities because it such decisions would be challenged by the patent holder at the domestic courts. .[15] The lack of local manufacturing capability acts as a major barrier against the optimal use of CL. Political pressure also prevents many developing countries from opting for CL. Often pharmaceutical MNCs control the larger share of pharmaceutical market in developing countries with an exception like India, Bangladesh, etc. As a result, most developing countries may succumb to the pressure of pharmaceutical MNCs and may not use CL. There is no institutional mechanism in many developing countries to monitor the impact of patented drugs on access to medicine and to invoke timely measures like CL or government use provisions to facilitate the introduction of affordable generic version of the patented medicine. This institutional gap would delay the invocation of government use provision for meeting the public health needs of the country.

Four, Often developed countries oppose the use of TRIPS flexibilities and attempt to restrict the scope of flexibilities to only essential medicines. Developed countries exert political pressure on developing countries against the use of TRIPS flexibilities.[16] [17] [18] US and Switzerland exerted political pressure on Colombia against the use of compulsory license is a latest example of political pressure against the use of exceptions and limitations to patents.[19] Apart from the political pressure industry also exert pressure on many developing countries against the use of exceptions and limitations to patent rights such as compulsory license. According to the US India Business council submission to USTR shows that the US

Governance of Knowledge and Development <http://www.anu.edu.au/fellows/pdrahos/pdfs/2007Drahostrustmessrn.pdf>.

[13] An external review of WIPO's technical assistance programme notes: "the Review Team found that when discussing international treaties, the orientation of plans was toward promoting accession to international treaties administered by WIPO. While the importance of flexibilities was noted, practical and proactive advice on how to use such opportunities was limited." See WIPO, An External Review of WIPO Technical Assistance in the Area of Cooperation for Development < http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_8/cdip_8_inf_1-annex1.pdf >.

[14] For instance, the Indian Patents Office rejected a compulsory license application for diabetic medicine Saxagliptin. One of the ground for rejection was the lack of evidence to prove whether the said medicine is available at affordable price. The decision states that " in the absence of exact quantum of Saxagliptin required and the number of patients *vis-a-vis* doctors prescriptions as against the opther options existing in the market, the question of accessibility and affordability cannot be determined". Lee Pharma Ltd v Astra Zenaca AB C.L.A No 1of 2015

[15] Reed Beall and Randall Kuhn, Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis, PLOS Medicine, Vol.9.1, January 2012 , available at http://www.plosmedicine.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pmed.1001154&representation=PDF

[16] Ellen t' Hoen, *The Global Politics of Pharmaceutical Monopoly Power* (AMB Publishers, Diemen, 2009) 44--58.

[17] The political pressure forced India to enter into a bilateral discussion with the US on the protection and enforcement of IP. Further, it in a way created a chilling effect on India's effort to declare certain patents as public health important to facilitate speedy issuance of CL. Dilasha Seth & Soma Das, DIPP Defers Decision on Issuance of Compulsory Licence for Cancer Drug Dasatinib, *The Economic Times* (16 October 2014) < http://articles.economictimes.indiatimes.com/2014-10-16/news/55106950_1_cancer-drug-dasatinib-health-ministry-compulsory-licence >.

[18] The US pressure forced India in 2014 to set up a bilateral process with the US to discuss IP issues. The US India Joint Statement dated 30 September 2014 states: "Agreeing on the need to foster innovation in a manner that promotes economic growth and job creation, the leaders committed to establish an annual high-level Intellectual Property (IP) Working Group with appropriate decision-making and technical-level meetings as part of the Trade Policy Forum" < https://www.whitehouse.gov/the-press-office/2014/09/30/us-india-joint-statement>.

[19] https://www.statnews.com/pharmalot/2016/05/11/obama-novartis-patents/ . Also see http://www.keionline.org/node/2312

India Joint Business Council obtained a verbal assurance for the non-use of compulsory license from the Government of India.[20] Thus political pressure developed countries and pressure from industry play an important role in preventing developing countries from using the exceptions and limitations.

Fifth, There are attempts to influence the developing country judges in order to delay or reduce the use of exceptions and limitations to patent rights in developing countries. For instance, since 2003, the George Washington University (GWU) Law School coordinates an IP lobby programme known as the India Projects. Under this project, GWU coordinates an annual lobby visit of a US delegation consisting of pro-IP academic, corporate executives and judges of Federal Circuit Courts.[21] This delegation meets the judges of High Courts and the Supreme Court to advocate the need for strong IP protection.[22] Further, Indian judges were invited to attend the conferences organised by the pro-IP lobby abroad.[23] Similarly the US India Business council submission shows that the business council trained the Indian examiners.

Apart from the above-mentioned constraints the following paragraphs examine certain specific threats related to the use of exceptions and limitaions.

TRIPS plus provisions

The logic of TRIPS plus provisions is to further limit the scope of flexibilities available under the Agreement by imposing TRIPS plus obligations on developing countries through FTAs.[24] working paper prepared by WTO states that some 54 Regional Trade Agreements (RTAs) were found to contain at least one of the pharma-related provisions. Further, it also found that the provision most frequently included in RTAs relates to patentability criteria and exclusions, with over one-quarter of the 165 agreements in the sample.[25] According to this paper, *"RTAs involving the United States are primarily responsible for this trend. Indeed, the majority of the United States' RTAs incorporate pharma-related provisions, many of which include several provisions on the eleven sub-categories covered by this study. While far behind the United States, Mexico also contributes significantly to the prevalence of pharma-related provisions in RTAs involving parties from the Americas. EFTA members are the trading bloc that includes pharma-related provisions in their RTAs more frequently, although the number of such provisions in a typical EFTA agreement is not high".*[26]

IP enfoncement initiatives

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[20] http://www.ip-watch.org/2016/03/22/india-rocked-by-report-of-secret-assurance-to-us-industry-on-ip/

[21] For a brief description of the India Project, see http://www.law.gwu.edu/Academics/research_centers/india/Pages/Overview.aspx , accessed on 31October 2009. Also see the interview of the Dean of GWU Law School, available at: http://www.law.gwu.edu/Academics/research_centers/india/Documents/India_article.pdf

[22] The Programme brochure shows that on 22 February 2009, this delegation had programme titled "Dialogue with Judiciary". Soft copy of the brochure is with the author. The sixth visit was jointly organised by the US –India Business Council, GWU Law School and the Confederation of Indian Industry (CII).

[23] Two of the Indian Supreme Court Judges attended the International Judges Conference, 20--21 April, 2009, Washington DC. This conference was organised by the IP Owner's Education Foundation promoted by the IP Owner's Association, a pro IP lobby claiming to serving the intellectual property community in the US and worldwide. To see the list of participants visit: http://www.ipo.org/AM/Template.cfm?Section=International_Judges_Conference&Template=/CM/ContentDisplay.cfm&ContentID=22075

[24] A WTO working paper states that some 54 Regional Trade Agreements (RTAs) were found to contain at least one of the pharma-related provisions. Further, it also found that the provision most frequently included in RTAs relates to patentability criteria and exclusions, with over one-quarter of the 165 agreements in the sample. See Raymundo Valdés & Runyowa Tavengwa, Intellectual Property Provisions in Regional Trade Agreements, WTO Economic Research and Statistics Division, <http://www.wto.org/english/res_e/reser_e/ersd201221_e.pdf>.

[25] Raymundo Valdés and Runyowa Tavengwa, Intellectual Property Provisions in Regional Trade Agreements, WTO Economic Research and Statistics Division, available at: http://www.wto.org/english/res_e/reser_e/ersd201221_e.pdf

[26] Ibid

These multilateral, plurilateral and unilateral initiatives on IP enforcement contain TRIPS plus enforcement provisions. Firstly, they expand the scope of border measures to both imports and exports. Secondly, they expand the scope of border measures to all forms of IP, unlike the Agreement, which obligates countries to apply border measures only to counterfeited trademarks and pirated copyrights. Thirdly, most of these initiatives promote criminal sanctions, except for patents, for the enforcement of IP rights. Lastly, these initiatives impose intermediary liabilities for the infringement of IP and target the raw material suppliers to prevent them from cooperating with generic manufacturers.

Voluntary license and differential pricing

Originator companies use the voluntary licences (VLs) to prevent the use of TRIPS flexibilities. VL with restrictive conditions would prevent the use of CL and forestall competition in the market. Often VL would prevent the local production and allow the licensee to market the originator's product in a different brand name. Further, it imposes geographical restrictions on the licensee and often leaves out middle-income countries from the scope of the licence. MPP to approach the VL from public health perspective also failed to bring a qualitative change in VLs.[27]

International Investment Agreements (IIA)

Another important instrument used by pharmaceutical industry to deter developing countries from using TRIPS flexibilities is the investment protection clauses contained in the Bilateral Investment Treaties (BITs) and other international investment protection agreements like FTA. The International Investment Agreement (IIA) contains provisions to protect the investment from foreign investors.[28]

As evident from above, irrespective of various political declarations and resolutions of international organisations, there are major challenges to the full implementation and actual use of TRIPS flexibilities in reality. Major institutional, legal and political barriers have been erected to further minimise, if not eliminate, the use of exceptions and limitations.

[27] MSF, *Untangling the Web of Antiretroviral Price Reductions* (16th edn) (2013) <http://www.msfaccess.org/sites/default/files/AIDS_Report_UTW16_ENG_2013.pdf>.

[28] Pharmaceutical MNC Eli Lilly already filed arbitration notice against Canada seeking CND 500 million compensation for the rejection of patents on Strattera and Zyprexa under the investment protection provisions of the North American Free Trade Agreement (NAFTA), See Public Citizen, U.S. Pharmaceutical Corporation Uses NAFTA Foreign Investor Privileges Regime to Attack Canada's Patent Policy, Demand $100 Million for Invalidation of a Patent < http://www.citizen.org/documents/eli-lilly-investor-state-factsheet.pdf>.