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Cry for Life- Generic Solutions [1]: Public health and Intellectual Property Rights - India

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Abstract: ***The developing Nations are the harvest ground for the multinational pharmaceutical companies. Therefore any proposal by these countries is looked down with scorn and a threat to the 'Big Pharma' and never reach the discussion stage in TRIPS. It was for the first time that at the Declaration at Doha WTO Ministerial 2001 on public health recognized the gravity of health problems in many developed and least developed countries especially those having cases of HIV/AIDS, tuberculosis, malaria and epidemics.***

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1. Introduction

The developing Nations are the harvest ground for the multinational pharmaceutical companies. Therefore any proposal by these countries is looked down with scorn and a threat to the _Big Pharma' and never reach the discussion stage in TRIPS. It was for the first time that at the Declaration at Doha WTO Ministerial 2001 on public health recognized the gravity of health problems in many developed and least developed countries especially those having cases of HIV/AIDS, tuberculosis, malaria and epidemics.They also recognized the role of TRIPS to extent its intellectual development into these areas. Access to antiretroviral medications (AVT) was a key matter in the debate leading to the adoption of the Declaration.

Article 31(f) of the TRIPS Agreement requires that medicines produced under compulsory licence conditions should be predominantly for the supply of the domestic market of the WTO Member authorizing such use. This constituted a major problem for WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector, since these countries would be unable to make effective use of compulsory licensing because an exporting producer might be limited in the quantity of medicines it could export pursuant to a compulsory licence. Paragraph 6 of the Declaration on TRIPS and Public Health recognized this problem. After negotiations, on 30 August 2003, WTO Members agreed on a temporary waiver to Article 31(f) and (h) to allow for the export of medicines under compulsory licences. However, the 30 August Decision involved only a temporary waiver. On 6 December 2005 an amendment to the TRIPS Agreement was agreed, to make permanent the waiver of article 31(f) and (h). The amendment is, however, subject to the approval by two thirds of the WTO Members. The 6 December 2005 agreement was criticized by a number of civil society groups and non-governmental actors—in particular, the international humanitarian aid organization Médecins sans Frontières (MSF)[2], which expressed alarm that the decision to amend the TRIPS Agreement was based on a mechanism that had failed to prove that it could improve access to medicines.[3]

2. History

The Paragraph 6 Solution of August 30, 2003 has its beginning in a proposal submitted by developing countries wanting an interpretation of Article30 of the TRIPS Agreement to permit manufacture and export of patented medicines by third parties (compulsory licensing) to countries lacking the capacity to manufacture such products. Now the exporting country can export such drugs only when it has made a notification to the Council for TRIPS:a. specifying the names and expected quantities of the products needed, b. confirming that the importing Member does not have the manufacturing capacity or has insufficient manufacturing capacities in the pharmaceutical sector for the product(s), c. confirming that a compulsory licence has been issued in its territory under Article 31 of the TRIPS Agreement.

The compulsory licence by the exporting Member, apart from the condition mentioned in Article 31, must contain additional conditions that only the amount necessary to meet the needs of the eligible importing Member may be manufactured under the licence, and the entirety of this production must be exported to the Member, which has notified its needs to the Council for TRIPS. Paragraph 3 of the Paragraph 6 Solution, which deals with remuneration, says that the supplier from the exporting countries (generic manufacturers) must pay remuneration to the patent holder whereas the receiver is waived from such payment. This argument was pushed by the developed states, though there was no such clause in the TRIPS.[4] The developing countries requested in their October 4, 2001 proposal that a compulsory licence which is issued by a member to supply medicines should be allowed to be given effect by another member under Article 30 of TRIPS (general exceptions).

3. Key Element of the Declaration

Doha Declaration contained in its Paragraph 4, according to which:

TRIPS Agreement does ---not prevent Members from taking measures to protect public health. ----- 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.

Paragraph 5 of the Doha Declaration states: Accordingly and in the light of Paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, ---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.Under Article 31 of the TRIPSAgreement a compulsory licence can be granted by a government, to allow a third party to produce a generic version of a patented pharmaceutical product without the authorization of the patent holder, in so doing allowing low-price generic pharmaceuticals to be produced locally or imported from abroad.

The issue of access to medicines to meet critical public health needs arose during the deliberate spread of anthrax in the US by unknown parties in 2001. A shortage of the antibiotic ciprofloxacin pressurized calls for the manufacturer Bayer to agree on a voluntary license. After intense negotiations, the US and Canada reached agreement in October 2001 that Bayer should supply increased amounts of the drug at lowered price, though they did not opt for compulsory licensing. This shows that while poor countries maybe more vulnerable than others to public health threats, no country remains out of reach in a world of increasing globalization.

Another problem is that many bilateral and regional trade agreements do not allow the so-called bolar Provision (article 30). This exception allows a potential competitor to use an invention to undertake acts necessary for obtaining regulatory approval and registration of a generic product before the expiry of the patent term without the authorization of the patent holder.

4. Indian Experience

India allows patent of addition but proving their case has now become difficult after the Novartis. If the application for "new use" does not succeed, the process of application can create considerable delays.To ensure that the constitutional right to life is respected, Section 3(d) of the Indian Patents (Third Amendment) Act of 2005 set out that the mere discovery of a new form of a known substance is not to be considered an invention but that this could be regarded as such if it enhances the efficiency of a known invention. An explanation to that Section clarified that salts, polymers and other new versions are to be treated as the same substance and not as new, patentable forms unless they differ in their properties significantly with regard to efficacy. Although raising concerns for patentees that Section 3(d) excludes some applications that, on the usual criteria of patentability, would qualify as inventions, the provision has been described as an essential tool for keeping open the door for generic manufacture of medicines.

As a result of Section 3(d), a patent claim relating to a pharmaceutical product may relate to an active ingredient as such independently of or jointly with formulations, salts, prodrugs, isomers and so on, or cover any of these subject matters separately, but subject to a higher standard of inventive activity. This provided India with flexibility to determine what constitutes an invention for the purposes of granting a patent and allows it to draw a distinction between genuinely patentable inventions and the practice of ‗ever greening' or so called inventions. Section 3d of the Indian Patents Act prescribes a higher criteria for patentability for certain inventions: ―the mere discovery of any new property of new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;" that has a profound impact on the grant of pharmaceutical patents in the country. Further, the Indian Patents Act provides for the grant of compulsory licences without prior attempt to obtain a licence from the patentee on reasonable terms and conditions in case of anti-competitive practices adopted by the patentee [Section 84.6(iv)], as well as the right to export any products produced under such licences, if necessary.

In April 2013, the Supreme Court of India ended a seven-year old battle around the patentability of imatinibmesylate for the treatment of chronic myeloid leukaemia, marketed by Novartis under the trade name Glivec/Gleevec, and refused the grant of the patent. The Supreme Court rejected the patent application claim for a specific crystalline form (β-crystal form) of imatinib on the grounds that this form is not a new substance, was already known and does not show enhanced therapeutic efficacy.

5. New Developments

The Doha Declaration provides additional relief for LDCs. Article 66 of the TRIPS Agreement affords LDCs the right to not comply with the provisions of the agreement until 1 January 2006. This date was extended by the Doha Declaration on the TRIPS Agreement and Public Health (August 2003) till 1 January 2016.It is to be noted that recently, the Council for TRIPS has provided for extension of the transition period for LDC Members by their decision of 11 June 2013 until1 July 2021.

The Doha Declaration Paragraph 6 Waiver requires that developing countries notify WTO of their intention to become an eligible importing member. Countries must notify the products and quantities that they intend to import. Rwanda was the first Member State to notify the intent to use the Waiver in July 2007, stating that it ―wanted to purchase 260 000 packages of a triple-drug antiretroviral (ARV) therapy, enough to treat 21 000 people for one year". Canada was one of the first countries to enact domestic legislation – Canada's Access to Medicines Regime (CAMR) – for this purpose.[5]Brazil has extensively utilized TRIPS flexibilities. In 2001, Brazil successfully usedthe threat of issuing compulsory licences to receive significant discounts for Merck &Roche medicines. The pharmaceutical company Gilead has provided voluntary licences to eight Indian generic firms to produce two important AIDS drugs

for sale in 95 countries. The royalty rate in this agreement is set at 5%.

Now the pharmaceutical industry is also more responsive than before, and is developing new cooperation models. Gilead says it also plans to license its new therapy to Indian generic manufacturers, which will then supply lower-cost versions of the drug to India. The company‘s two pricing moves were made in order to help narrow the access gap for hepatitis C drugs among the world‘s poorer nations. This opens up scope for development of new models of cooperation between Big Pharma (the originator drug companies) and generic pharmaceutical companies.[5] This also leads to an acceptance and developmentof differential pricing models, i.e. pricing the drugs differently for developed and developing countries. This enables a seemingly balance of interests of developed nations who provide a strong social security scheme while this aspect is missing in developing nations which are in dire of low cost medicines to help save lives .

References

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