PARALLEL IMPORTATION UNDER INDIAN LAWS WITH SPECIAL REFERENCE TO MEDICINES[1]

Introduction

Parallel importation is the importation of a copyrighted, patented or trademarked product from the country in which it is already marketed to another country without the permission of the intellectual property owner. An important fact to note is that it is not a counterfeit.[2] The goods are produced and sold legally, and are subsequently exported. It is referred to as the grey market because this is done without the authorisation of the intellectual property owner. Parallel importing is regulated differently in different jurisdictions; there is no consistency in laws dealing with parallel imports between countries but it is not explicitly prohibited by either the Berne Convention or the Paris Convention. Generally, IPRs are exhausted once the goods or services which incorporate such rights are put on the market. This means that once an article has been sold by the IPR owner, the further sale or distribution of this article can no longer be controlled by him.[3] This principle is called the 'exhaustion of rights' and is accepted in all countries within their national jurisdictions. The doctrine of exhaustion imposes certain limits on the patentees' exclusive rights. According to this doctrine, 'a patented item's initial authorised sale terminates all patent rights to that item.[4] In other words, he cannot control the re-sale or re-distribution of the particular good that had already been sold once.[5]

History in India

The Indian Patents Law clearly favours parallel imports and India follows "international exhaustion regime". The origin of the Indian patents system lies in the Patents Act, 1856 which was finally consolidated into the Patents and Designs Act of 1911. The first step towards parallel importation was taken by Ayyangar Committee (1957-59) which

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[2] Patent Rights in Pharmaceuticals in Developing Countries Major Challenges for the Future, Jakkrit Kuanpoth, U.S.A: Edward Elgar Publishing Ltd., 2010, Patents and Access to essential medicines at p. 189.
[3] Intellectual Property Rights UIn The WTO and Developing Countries
[4] *Quanta Computer Inc v. LG Electronics Inc,* 553 U.S. 617 (2008).
[5] *Glass Equipment Development Inc v Besten Inc.* 174 F.3d 1337.

recommended that granting patents in critical arenas like food and medical must be analysed throughly since the high price of the products could make them inaccessible to the "Aam Aadmi" and would violate the Fundamental Right enshrined under Article 21 of the Indian Constitution[6]. Due to its recommendation, several manufactuers could at the same time own patents for different processes of manufacturing the same pharmacheutical[7]. Compulsory licenses were issued for public advantage under the Indian Patents Act, 1970. This received a major setback due to the TRIPS agreement to which India had agreed, not taking into consideration the fact that it would result in increased costs of pharmaceutical products due to the new international norms requiring patent protection[8] regardless of the products in question. The government did not entertain the views and advise of the Non-Governmental Organisations(NGO). This was because at that time few NGOs worked on intellectual property in the context of social matters The National Working Group on Patent Laws was formed in 1988 as a response to India's involvement in the Uruguay Round of the GATT to focus on easy availibility of cheap medicines. One crux factor is that the India being a WTO member can determine for itself what an "invention" is and how the patentability requirements are to be applied which is particularly important for the pharmaceutical industry[9].

The Four People's Commissions

The First People's Commission, convened in 1993, criticised the Indian Government for failing to understand the implications of WTO agreements on the Indian People. It also brought into light the Supreme Court's conclusion that right to health including right to medicine is a Fundamental Right and argued that the Indian Patent Act cannot be rewritten to allow grants for pharmaceutical products which would violate Article 21 of the contitution. As a developing member, India could delay in meeting the new obligations[10] (until 1st

[6] Raghavan 2006, p.285
[7] Rangnekar 2005, p.4; Ragavan 2006, p.289
[8] Mattews 2007, p. 31
[9] *See*, for example, Sudip Chaudhuri, Chan Park and K. M. Gopakumar (2010) Five Years into the Product Patent Regime: India's Response, UNDP, New York. Available at: http://apps.who.int/medicinedocs/documents/s17761en/s17761en.pdf; Carlos Correa (2011) Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing, Research Paper No. 41, South Centre, Geneva. Available at: http://www.southcentre.org/index.php?option=com_content&view=article&id=1601%3Apharmaceutical-innovation-incremental-patenting-and-compulsory-licensing&catid=41%3Ainnovation-technology-and-patent-policy&Itemid=67&lang=en.
[10] Article 64.2 of the TRIPS Agreement

January 2000) and an additional delay of five years for pharmaceutical products[11]. The TRIPs Agreement failed to mobilize the NGOs dealing with disease like AIDS/HIV. The Second People's Comission, set up in 1999, reiterated the government to make full use of the flexibilities under the TRIPs Agreement for its benefit. The National Working Group on Patent Laws played a significant role in the introduction of a systemof granting Exclusive Marketing Rightsto ensure that India fulfills its obligationsunder Article 70.9 of the TRIPs Agreement on 26th Agreement 1999.The National Working Group on Patent Laws continued to work for increasing the netwok of supporters and hosted the New Delhi syposiumon on the TRIPs Agreemnt and acess to medicines. It brought into focus the adverse effects of the TRIPs Agreement if India implements it and how the public health would deteriorate. The Doha Declaration in November 2001 affirms that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health". In this regard, the Doha Declaration enshrines the principles WHO has publicly advocated and advanced over the years, namely the re-affirmation of the right of WTO Members to make full use of the safeguard provisions of the TRIPS Agreement in order to protect public health and enhance access to medicines for poor countries. The Doha Declaration refers to several aspects of TRIPS, including the right to grant compulsory licenses and the freedom to determine the grounds upon which licences are granted, the right to determine what constitutes a national emergency and circumstances of extreme urgency, and the freedom to establish the regime of exhaustion of intellectual property rights.

The principle of exhaustion states that once patent holders, or any party authorized by him, have sold a patented product, they cannot prohibit the subsequent resale of that product since their rights in respect of that market have been exhausted by the act of selling the product. Article 6 of the TRIPS Agreement explicitly states that practices relating to parallel importation cannot be challenged under the WTO dispute settlement system. The Doha Declaration has reaffirmed that Members do have this right, stating that each Member is free to establish its own regime for such exhaustion without challenge.

The Breakthrough

The Parliamentary Committee which was scrutizing the draft Patents Bill reported to both Houses Of Parliament that the flexibilities and freedoms of the TRIPs Agreement and Public Health had not been implemented in the revised Patents Bill which was passed with few

[11] Article 65.4 of the TRIPS Agreement

amendments in May 2001. The Third People's Commission, convened in January 2002, highlighted the link between access to medicines and human rights and made stringent efforts to maintain the momentum amongst the NGOs to ensure that the flexibilities of the TRIPs Agreement, are utilised to the maximum in India according to which India can determine for itself what is an "invention" for granting a patent[12]. The Fourth People's Commission emphasized for a fundamental review of the TRIPs Agrement. It criticized the draft Patents(Amendment) Bill of December 2003. It advocated for the retention of pre-grants opposition because then the third parties cannot not challenge the grant of a patent. Jan Swasthya Abhiyan, founded in 2000, utilised the principles of human rights to mobilize the activists and raise public awareness about the impact of patenting pharmaceutical products for access to medicines. The Patents (Third Amendment) Act, 2005 allowed product patents for all patentable subject matter including inventions related to food, pharmaceuticals and chemical products and extended the term of protection afforded by a patent to 20 years. An explanation to the Section 3(d) 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[13]. The act also incorporated a completely new idea of "post-grant" opposition. Further 92A states that patented medicines and pharmaceuticals can be manufactured and exported to another country by providing it with a compulsory license.

The Patents (Third Amendment) Act, 2005 is a boon in disguise for India and India can parallely import medicines without infringing any of the Sections of the TRIPs Agreements. Despite the gravity of the HIV pandemic in sub-Saharan African countries, in 1998 multinational pharmaceutical companies legally challenged the implementation of TRIPS-compatible measures (parallel importation in particular) by the South African government, in a bitter court dispute that lasted approximately for three years and ended only after a massive domestic and international campaign mounted in support of the government by treatment

[12]Section 27.1, TRIPs Agreement

[13]Thus, Novartis has challenged a decision that prevented it from patenting imatinib messylate. It argued that Section 3(d) of the Patents Act is inconsistent with the TRIPS Agreement and that the definition of 'efficacy' should be broad enough to include increases in bioavailability and not an enhanced "therapeutic effect in healing a disease", as defined by the Madras High Court that rejected its patent application. See, for example, Lawyers Collective (2011) *Novartis case: background and update – Supreme Court of India to recommence hearing.* Available at: http://www.lawyerscollective.org/news/126-novartis-case-background-and-update-supreme-court-of-india-to-recommence-hearing.html.

activists and several organizations.[14] This incident made India realize the menace of TRIPs Agreements as the medicines for HIV/AIDS made in foreign countries is expensive and inaccessible to the masses. Patented medicines almost always cost much more than the equivalent, unpatented, 'generic' versions.[15] Numerous oppositions have specifically targeted patent applications of people living with AIDS/HIV.[16]

Concluding Remarks

The right to health is present in several legally binding international human rights treaties,[17]in select regional treaties,[18] and in numerous national constitutions.[19] The right to health has been interpreted broadly to include a right to treatment, more specifically, a right of access to medicines. The Directive Principles of State Policy as enumerated in the Part IV of the Constitution is guidelines to the central and state governments of India, to be kept in mind while framing laws and policies. The directive principles lay down certain economic & social policies to be pursued by the various governments in India. Article 47 of DPSP provides for the duty of the state to improve public health. However, the Supreme Court has always recognized the right to health as being an integral part of the right to life. The Supreme Court, in *Paschim Banga Khet mazdoor Samity & ors v. State of West Bengal & ors*[20], while widening the scope of Article 21 and the Government's responsibility to provide medical aid

[14]See, for example, William W. Fisher III and Cyrill P. Rigamonti (2005) The South Africa AIDS Controversy. A Case Study in Patent Law and Policy, Harvard Law School, available at cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf.

[15]A recent report notes that, in general, "[O]riginator brand medicines generally cost substantially more than their generic equivalents. Patients purchasing medicines in the private sector in developing countries pay, on average, 2.6 times more for originator brands than for their lowest-priced generic equivalent", United Nations, The Global Partnership for Development (2011) *Time to Deliver, MDG Gap Task Force Report 2011*, UN, New York, p. 54.

[16]F Hoffman-La Roche Ltd. And Anr v Cipla Limited 48(2008) DLT 598, MIPR, 2008 (2) 35 (Roche v Cipla)

[17]These include the Universal Declaration of Human Rights, G.A. Res. 217 (III) A, and UN Doc. A/RES/217(III), art. 25 (Dec. 10, 1948), available at: http://www.un.org/en/documents/udhr/, the International Covenant on Economic, Social and Cultural Rights, G.A. res. 2200A(XXI), 21 U.N.GAORSupp. (No. 16) at 49, U.N. Doc. A/6316, art. 12 (1966), 993 U.N.T.S. 3, *entered into force* Jan. 3, 1976. For a fuller listing of relevant treaties and related instruments, see OHCHR& WHO(2008) *Right to Health: Fact Sheet 31*, WHO, Geneva. Available at: http://www.ohchr.org/Documents/Publications/Factsheet31.pdf.

[18]For instance, the American Declaration of the Rights and Duties of Man (1948), O.A.S. Res. XXX, adopted by the Ninth International Conference of American States, O.A.S. Official Record OEA/ser. L/V1.4 Rev. (1965); American Convention on Human Rights (1969), O.A.S. Treaty Service No. 36, O.A.S. Official Record OEA/Ser. K/XVI/1.1 doc. 65 rev. 1 corr. 2 (1979); Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (1988), art. 10, 28 I.L.M. 156, 164; Organization of African Unity (1981), *Banjul Charter on Human and Peoples' Rights*, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982).

[19]International Commission of Jurists, Courts and the Legal Enforcement of Economic, Social and Cultural Rights (2008), available at : http : / / www .unhcr. org/ refworld/category,POLICY, HANDBOOK, ,4a78405 62,0.html.

[20](1996) AIR SC 2426.

to every person in the country, held that in a welfare state, the primary duty of the government is to secure the welfare of the people. Providing adequate medical facilities for the people is an obligation undertaken by the government in a welfare state. Thus, the concept of parallel importation seems to be consistent with the commitment to right to health of India enabling it to provide cheaper medicines to the people of the country.

Since many patented products are sold at different prices in different markets, the rationale for parallel importation is to enable the import of lower priced patented products. Parallel importing can be an important tool enabling access to affordable medicines because there are substantial price differences between the same pharmaceutical products sold in different markets.[21] The Indians, on the whole, have not understood the role of "Parallel Importation" in making the medicines and pharmaceuticals cheap as the concept of intellectual property is miles away. In fact, it is the Rural India that will face the consequences of the regime of international Intellectual Rights.

The Directive Principles of State Policy as enumerated in the Part IV of the Constitution, is guidelines to the central and state governments of India, to be kept in mind while framing laws and policies. The directive principles lay down certain economic & social policies to be pursued by the various governments in India. Article 47 of DPSP provides for the duty of the state to improve public health. However, the Supreme Court has always recognized the right to health as being an integral part of the right to life. The Supreme Court, in *Paschim Banga Khet mazdoor Samity & ors v. State of West Bengal & ors*[22], while widening the scope of Article 21 and the Government's responsibility to provide medical aid to every person in the country, held that in a welfare state, the primary duty of the government is to secure the welfare of the people. Providing adequate medical facilities for the people is an obligation undertaken by the government in a welfare state. Thus, the concept of parallel importation seems to be consistent with the commitment to right to health of India enabling it to provide cheaper medicines to the people of the country.

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