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Doha Declaration and Public Health Issues

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Adhering to the TRIPS Agreement in the pharmaceutical sector poses several questions before developing countries and least developed countries concerning public health. These are: Would the TRIPS Agreement and product patent regime affect access to medicines for the public? What are the options available for countries that face health crises? The Doha Declaration provides for access to medicines particularly by simplifying the compulsory licensing (CL) clause. A brief look at the countries that have utilized the CL option highlights that all such countries have been facing a rapidly spreading HIV/AIDS epidemic, medicines for which are produced under patents by multinationals. Hence, while some countries have actually issued a CL to a third party or a government department to produce or import the patented drug, some countries have used the CL option as a negotiating strategy to get a steep reduction in the price so as to facilitate access to medicines in the public health care. The amendments carried out by the Indian government also facilitate production of generic versions of patented drugs that would facilitate exports under the CL option as well. Though the Doha Declaration facilitates access to medicines, some of the free trade agreements are drafted in such a way that the least developed countries can not exercise the flexibilities. However, in order to facilitate the options available in the Doha Declaration, countries will have to incorporate the necessary changes in their national laws.

Keywords: Doha Declaration, compulsory licensing, HIV/AIDS, access to medicines

In the knowledge based pharmaceutical industry, technology becomes obsolete fast due to 'creative destruction' of innovations. As, many innovations actually' stand on the shoulders of giants' providing stronger intellectual protection to pharmaceutical innovations goes against the interest of countries which do not have adequate manufacturing and technological capacity. Adhering to the TRIPS Agreement in the pharmaceutical sector poses several questions before developing countries and least developed countries. These are: Would the product patent regime affect the access to medicines for the public or do the intellectual property rights (IPR) totally endanger the access to medicines? What are the options available in the TRIPS Agreement to meet their welfare objectives and is it possible for them to avail those options? Even if they avail the options, will the pharmaceutical industry in developing countries be able to face the challenges of product patent regime and would they be able to assess various options and continue to operate in the WTO regime? Because of the uncertainties regarding how TRIPS flexibilities would be interpreted, developing and least developed countries were not sure whether their rights to use the flexibilities will be respected or given due consideration. A debate on these questions across developing nations culminated in the adoption of the Declaration on the TRIPS Agreement and Public Health at Doha famously referred to as the Doha Declaration.

Implicit in the Article 7 of the TRIPS Agreement is that, that TRIPS regime should facilitate free flow of trade, investment and technical know-how among the member countries by resolving barriers that exist in the form of differences in the standards of intellectual property in a manner conducive to fulfil the socio economic welfare and rights obligations. Towards this end, the TRIPS Agreement has two types of flexibilities.[1] One is time bound in the form of transition periods, which allow developing and least developed countries time to implement their TRIPS obligation. As per this, the developing countries were allowed time from 1995-2005 to bring in changes in their national laws and implement the TRIPS Agreement. For the least developed countries, though

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originally were given time from 1995-2006, it was extended to 2016, in order to provide patents on pharmaceutical products and exclusive marketing rights. The second types of flexibilities are called substantive flexibilities. These concern flexibilities regarding, compulsory licensing, public and non-commercial use of patents, parallel importation, exception to patent rights, exemptions from patentability and limits on data protection. Article 30 states that `*members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interest of third parties'*. As per this, following types of exceptions may be provided: 'Acts done privately and on a non-commercial scale or for a non-commercial purpose; use of the invention for research or teaching purposes; experimentation on the invention to test or improve on it; preparation of medicines under individual prescriptions; experiments made for the purpose of seeking regulatory approval for marketing of a product after the expiration of a patent; use of the invention by a third party that had used it before the date of application of the patent and importation of patented product that has been marketed in another country with the consent of the patent owner.[2,3] While these exceptions provide some flexibility that would server limited experimental or research purpose, implementing the TRIPS flexibilities for public health purposes pose a challenge for the developing and least developed countries. While the TRIPS Agreement mentions the flexibilities available for the WTO members, the Doha Declaration and the WTO decision on Paragraph 6 of Doha Declaration help the developing and least developed countries in practical use of the flexibilities in order to achieve public health goals. The crux of this paper centres on the discussion of these flexibilities and practical use of the same. Section 2 following this introduction discusses the flexibilities that cause concern and the resultant Doha declaration. Section 3 cites the Indian scenario. Section 4 highlights the issues that could come up when countries sign the free trade agreements. The last section presents the conclusion.

Though the TRIPS Agreement provides certain flexibilities intended to help the member countries to fulfil their obligations to meet the rights and socio welfare of their subjects, yet the riders associated with some of these aspects kept the flexibility options away particularly from the developing and least developed countries. Particularly, majority of the discussion centres on Article 31 and its sub-clauses.

Article 31 states that 'where the law of a member allows for other use of the subject matter of a patent without authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(b) such use may only be permitted if prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a member in case of a national emergency or other circumstances of extreme urgency or in cases of public non commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall nevertheless be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor ,without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive

(f) Any such use shall be authorized predominantly for the supply of domestic market of the member authorizing such use

(h) The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions, which led to such authorization, are likely

to recur'.[4] Those marked in italics (emphasis added by the author) indicate where uncertainties of interpreting them cause concern for the member countries.

TRIPS mention certain clauses under which the CL option can be exercised, though the options are not limited to these alone. These are: Refusal to deal by the patentee, national emergency and non-commercial use and anti competitive tendencies. For instance, Germany has included 'non-availability of the patented medicine in adequate quantity in its national law as a clause under which a CL can be sought. Similarly, China has stated that CL option could be exercised if the patentee has turned down the request from a qualified person/firm.

Similarly, the government can also decide on the grounds that could be termed as national emergency. Currently diseases like malaria, TB and HIV/AIDS have been included in the public health list. Some more of the prevailing diseases depending on the morbidity and mortality rates can be included in the list and any breakthroughs in this sector could be utilized under CL.

Situations Leading to Doha Declaration

Though the TRIPS Agreement states that use of the patent without authorization of the patent owner will be allowed but the Thailand experience shows that the developed countries could really put pressure on the developing countries so as not to use the flexibility at all. For instance, in the 1990s, due to international pressure, Thailand implemented strong IPRs.[5] The Government Pharmaceutical Organisation (GPO) is a Thai public unit which manufactures the drugs supplied to public hospitals. GPO developed a generic version of the anti-AIDS treatment DDL which was patented in 1987 and was marketed in Thailand by American firm, Bristor-Myers and Squibb (BMS) at prohibitive price. In 1992, BMS patented an improved formulation of DDL and asked for market exclusivity. It did obtain a temporary monopoly and sold the drug at $2.5 per tablet in a country where the daily minimum wage averaged $ 3.84. GPO had to stop its manufacturing programme aimed at providing required medicine at an affordable price. In 1997, GPO filed a request for a CL, a provision provided by the 1992 Thai Act and later by the TRIPS Agreement. However, under the pressure of the USA, the government gave up and put an end to the procedure for the issue of a CL. GPO had to produce a new DDL formulation in powder form, so as not to infringe the patent obtained at that moment by BMS for its improved formulation. The branded price of the DDL powder was set at $1.20, while the generic is sold at 0.62. Health activists sued BMS in 2001 and asked for the revocation of the patent for lack of novelty. Though BMS patent was not invalidated since then, yet its scope has been reduced, so that GPO could not produce tablet larger than 100mg dosage form. At the end, under the pressure of the civil society, BMS gave up its patent, but a US FTA is presently under consideration.

Article 31.6 of the Agreement says that use of CL should be 'predominantly for the supply of the domestic market of the Member authorizing such use'. Particularly the rider that the supplies made under the compulsory licensing would be predominantly for the supply and use of the domestic market of the member authorizing such use created lot of criticisms from the governments, and health activists as this condition would leave behind those countries which do not have adequate manufacturing facilities or know how to produce the drug under compulsory license. This will benefit only members with a reasonably well-developed domestic industry and therefore will deny access to members without domestic production facilities. However, some intellectuals[3,6,7] interpret that the term 'predominantly' indicate the scope for exports under CL. Initially, developed countries were trying to restrict the scope of CL by restricting exports because of the fear that using the differential pricing strategy such products might be exported to the home market affecting the profits of the patentee.

Another important issue, which may come in the way of utilizing the CL and the exceptions to exclusive rights or even the Bolar exception, is the debate to extend the protection of undisclosed information submitted by the companies to obtain patent from the regulatory authorities. Some of the developed countries have adopted legislations providing that the approving authorities cannot use the test data submitted by the first applicant for approval of subsequent applications for market authorizations for a period of five years. The pharmaceutical companies are advocating that the rules should be modified to provide that such data should remain secret and should not be used by the regulatory authorities in examination of the second application for a period of ten years.[3] This provision if accepted will lead to providing inadequate

information in the patent application, which will prevent a qualified person from using these data. Bolar exception permits the pre-market testing of generic products during the patent term, so that they can be marketed immediately upon expiration of the patent. However, if the clinical data are protected under the data exclusivity provision, the Bolar exception can not effectively be put to use.

Parallel trade is one of the flexibilities for the countries to look for cheaper options of drugs. Parallel trade is known as the principle of exhaustion of rights or commonly known as parallel trade. Objectively, the patent owner looses his rights once he has sold his innovations. TRIPS leave the decision on rights of national or international exhaustion to national laws. The US adopts a national exhaustion principle whereby the patent owner will have no control over the product once it is placed in the domestic market. But he can exercise his rights outside the US market regarding the price and quantity of the product. The European Union applies the regional exhaustion principle whereby the rights are exhausted within the EU region. International exhaustion gives no right to the patent owner once he has sold his product. The international exhaustion is consistent with the objective of TRIPS Agreement mentioned in Article 7. The advantage of international exhaustion is that developing countries such as India can scout for cost advantages of the patented product and also make use of the price differentials. Both national and international exhaustion have their merits and demerits. While the international exhaustion disallows exclusive rights of the patent owner globally, yet an unscrupulous patent owner/manufacturer can restrict the supply of the product that is exported. Besides, using the international exhaustion, lot of 'grey' goods could also be traded. Parallel trade could eventually be used to export the drugs from markets where they are priced lower to markets where they came from, especially in cases where CL is exercised. Hence, the developed countries were of the opinion that the principle of exhaustion should not be applied in the case of CL. In other words, the principle of exhaustion would come in the way of exporting a cheaper generic version of a patented product. It is suggested[6] that there should be an international agreement or understanding to bar parallel imports into high income countries from low-income or price controlled jurisdictions while allowing parallel exports to low-income countries, including exports from price-controlled jurisdictions. This agreement according to them would allow low-income countries to permit parallel imports and prohibit parallel exports, whenever it is in their interest to do so. Rege[3] observes that under the principle of exhaustion, countries may be permitted to export to other countries where the said drug is not patented and thus provide access to patented medicines. Some of these concerns in utilizing the flexibilities were actively voiced by the least developed countries, which were settled at the Doha Ministerial Conference in November 2001. Here where the members stressed the importance of interpreting the TRIPS Agreement in such a way that it supports the public health cause and then adopted as a separate declaration on TRIPS and Public Health.

The Doha Declaration

The Doha Declaration stated

1 We recognize the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2 We stress the need for the WTO Agreement on TRIPS to be part of the wider national and international action to address these problems.

3 We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4 We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and 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. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement which provide flexibility for this purpose.

5 We recognize that these flexibilities include

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed in particular, in its objectives and principles.

(b) Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licenses are granted.

(c) 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.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 &4.

6 We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7 We reaffirm the commitment of developed country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least developed country members to pursuant to Article 66.2, We also agree that the least developed country Members will not be obliged with respect to pharmaceutical products, to implement or apply Sections 5&7 of part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement'.

Guidelines of the Use of Doha Declaration

Though the Doha Declaration was initially received very well, anxiety again was widespread as about the interpretation of Paragraph 6 of the Declaration specifying when countries can import drugs produced elsewhere under compulsory licensing. A decision regarding the same was announced in 2003 and was adopted in the form of waiver of Article 31 (f) (that the CL would be predominantly for the supply of domestic market) in December 2005. As per this waiver, a country could issue a compulsory license on the basis of public health need either for domestic use or for export.

Countries which want to import under the Paragraph 6, system has to notify WTO in two ways, once when they intend to make use of the system (namely to import a drug under compulsory license) and they have to supply information whenever they use it. However, least developed countries need not notify the WTO as an eligible importing member. While the WTO provision requires that members notify their intention to be an eligible importing member, they also have to notify the WTO whether they would use the system in whole or in a limited way. For instance, the eligible importing member has to state whether they would use the system as a whole (i.e. to satisfy their access to medicines needs) or in a limited manner in the sense that they would use it only in national emergency or other circumstances of extreme urgency. In this context, some members have announced that they would not use this provision as an importer while some other members have notified that they would avail the facility only under situations of national emergency or extreme urgency.

When a country wants to import, it has to provide the following notifications to the Council:

1 The name of the product to be imported and the expected quantities of the product to be imported

2 The country in question has also to establish that it has insufficient or no manufacturing capacity in the pharmaceutical sector for the products mentioned

3 If the product is patented in the member wanting to import, the said country should also provide confirmation regarding the grant of compulsory license or its intention to grant a compulsory license

4 These notifications have to be made available publicly or through the WTO website.[8]

Following this, Rwanda on 17 July 2007, became the first country to inform the WTO about its intention to import cheaper generics under compulsory licensing elsewhere as Rwanda is unable to manufacture the medicines locally. Though as a least developed country it need not do so, still

Rwanda notified. It notified the WTO that it would be importing 260,000 packs of Triavir which is a fixed dose combination of Zidovudine, Lamivudine and Nevirapine over two years from Apotex, a generic manufacturer from Canada. The imported drug would be called as Apotriavir. To this effect, Canada also notified the Council in October 2007, again a first notification from any government, that it has authorized a company to make a generic version of the patented drug for export under the special WTO provisions agreed in 2003. By way of notification, Canada has to inform the TRIPS Council

(a) the conditions attached to the use of CL
(b) name of the drug and the quantity of the drug to be exported
(c) The website address where the company which is manufacturing the said drug under CL would post information regarding the quantities and the features of the product that is exported (to be done before shipment).[9]

The WTO members on 6 December 2005 approved changes to the TRIPS Agreement by incorporating the waiver of 2003 into a permanent amendment on TRIPS. This amendment makes it easier for poorer countries to obtain cheaper generic versions of patented medicines. This amendment will be formally built into the TRIPS Agreement when two thirds of the WTO members have ratified the change by 1 December 2007. This deadline has been extended up to 31 December 2009. Once two thirds of members have formally accepted the amendment, the amendment will take effect in those members and will replace the 2003 waiver. For others, the waiver will continue to apply till they accept the amendment. The waiver remains in force until then. The permanent amendment to the Article 31 (f) of the TRIPS Agreement will allow any member country to export pharmaceutical products made under compulsory license. Such countries will have to change their own national laws also. Already in 2006, Norway, Canada and India have informed the WTO that they have already amended their national laws. Table 1 indicates the list of those countries that have amended their national laws.

Table 1—List of countries that have amended their national laws

Country	Amendment date
United States	17 December 2005
El Salvador	19September 2006
Rep. of Korea	24 January 2007
Norway	5 February 2007
India	26 March 2007
Philippines	30 March 2007
Israel	10 August 2007
Japan	31 August 2007
Australia	12 September 2007
Singapore	28 September 2007
Hong Kong, China	27th November 2007
China	28 November 2007
European Communities	30November 2007
Mauritius	16 April 2008
Egypt	18 April 2008
Mexico	23 May 2008

Though all WTO member countries can avail the system, 23 developed countries decided that they would not use the system to import the drugs. A number of countries like Hongkong China, Israel, Korea, Kuwait, China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and United Arab Emirates have announced that if they use the system (of CL) as importers it would only be for emergencies or extremely urgent situations.

According to WTO, amendment of Article 31 (f) is in three parts. They deal with (1) permitting pharmaceutical products made under CL to be exported to countries lacking production capacity, (2) avoiding double remuneration to the patent holder, regional trade agreements involving least developed countries and (3) non violation and retaining all existing flexibilities under the TRIPS Agreement.

The waiver and the subsequent amendment have been described by the former Director General Supachai Panitchpakdi as ‘it proves once and for all that the organization can handle humanitarian as well as trade concerns’. The decision covers all pharmaceutical patented products, or products produced using patented processes, active ingredients, and diagnostic kits.

As per the Paragraph 7 of the Doha Declaration, least developed countries need not protect pharmaceutical patents and test data until 1 January 2016. They also need not provide exclusive marketing rights for patent applications till 1 January 2016. However, the least developed country member has to establish that the said country does not have manufacturing capacity to produce the said product in question. Also under the conditions, the exporting country would be manufacturing under the CL only the expected quantities required for export. This product would be clearly distinguishable through packaging or coloring and also ensure that such a distinction does not have an impact on price. These special features need to be put on the website.

The WTO also notifies that where a CL is granted by an exporting member under the system, adequate remuneration shall be paid to the member taking into account the economic value of the product to the importing member. The condition also states that the products imported under the system is used for public health purposes alone and prevent the re-exportation of the products that have actually been imported. In case least developed country member experiences difficulty in implementing the provision, developed country members shall provide on request and on mutually agreed conditions, technical and financial cooperation in order to facilitate its implementation.

As mentioned in the Paragraph 5 (b) of Doha Declaration on the TRIPS Agreement, where the members can decide on the grounds on which CL could be issued, Musungu and Oh[1] lists the seven possible grounds that are currently in practice in different countries. These are: (1) refusal to license by the patent holder to enter into a voluntary licensing agreement on the reasonable commercial terms offered by the applicant (2) Public interest: Though most patent laws do not define public interest or provide a non-exhaustive or illustrative list of what may constitute public interest, granting of compulsory license on the grounds of public interest are common in most patent laws (3) Public health and nutrition: A compulsory license may be granted on the grounds that the interests of public health and nutrition including that of the need to ensure availability and affordability of medicines require it (4) National emergency or situation of extreme urgency: Most countries provide for the use of patented inventions without the consent of the patent holder in emergency situations such as war, famine, natural catastrophe etc. In such situations, prior negotiations are also waived. (5) TRIPS Agreement itself states that the CL could be used to correct anticompetitive practices. Here again the prior negotiations for a voluntary license are waived along with exports under the CL. However, these should be provided for in the domestic law. (6) A compulsory license may also be granted where a new invention requires the use of a pre-existing patent (7) Failure to exploit or insufficiency of working: If a patent has been granted but the invention is not being exploited in the territory of the country or is insufficiently exploited, this may constitute a ground for granting of CL. However, Article 27.1 of the TRIPS Agreement has been interpreted as to exclude possibility of requiring the local working of a patented invention. But the Doha Declaration provides the WTO members to determine the grounds for the granting of CL. Here it may be interesting to cite the example of Brazil, which when had to amend its patent laws to suit the international IPR regime, introduced a provision to issue a CL if the patented medicine is not produced in the country within three years of the issue of the patent. Using this provision, Brazil issued a CL for Nelfinavir (produced by Roche), Lopinavir/Ritonavir (product of Abott) and Efavirenz (product of Merck), to reduce the prices of these medicines, which forced the companies to reduce the price.[10] Though the US challenged this decision of Brazil, it withdrew its complaint. After a considerable negotiation, the companies agreed for price reduction in return of not to use CL option by Brazil. It was eventually agreed between the two countries that Brazil would first consult the US if it intended to make use of the local working provision.

Use of CL by Developing Countries

In the post Doha years, there have been instances of a few cases where CL provision has been utilized by developing countries on grounds related to public health and access to medicines. Hu[11] discusses a few country cases from the view point of the (1) legal basis for granting CL (2) decision making process and (3) public health benefits derived from such utilization of CL, which is highlighted below. In all the cases presented here, the fast spreading HIV/AIDS has resulted in national emergency situations and the CL has been used to produce the generic version of patented medicines for HIV/AIDS. The Minister of Justice, Legal, and Parliamentary Affairs, Zimbabwe in May 2002 declared a period of emergency on HIV/AIDS in view of the rapid spread of HIV/AIDS. This declaration of emergency situation enables the government to authorize any government department or third party to use the patented inventions or import the same for the service of the state. Initially declared for a period of six months, it was extended for a period of five years from January 2003 to December 2008, in the absence of challenge from the pharmaceutical companies. After the extension of time, a number of companies applied for the grant of authorization under the emergency declaration. In April 2003, Varichem Pharmaceuticals (Pvt) Ltd, was granted authority to produce antiretroviral drugs and supply three-quarters

of its product to the health institutions of the state. The company agreed to supply the generic version of Combivir at US $15 per month, whereas the different manufacturers' price ranged from US$197-US$237 per patient per year. This product was supplied in the market in October 2003. Besides Varichem, Datlabs and Omahn have been authorized to import the antiretrovirals from Ranbaxy and Cipla respectively.

In the case of Malaysia, the Ministry of Health was seeking price discounts on a number of HIV medicines in July 2001 to increase the coverage of HIV treatment in the country. When this negotiation failed with the patent holding companies, the government decided to authorize imports from the generic manufacturer. Though, after the authorization the patent holding companies decided to reduce the prices of the drugs, the government went ahead with its decision to import. After the introduction of the generic supply, the monthly cost of the treatment had reduced from US$362.63 in 2001 to $115.14 in 2004.

The Ministry of Industry and Commerce of Mozambique issued a CL to Pharco Mocambique Ltd to produce a triple compound of lamivudine, stavudine and nevirapine. In granting the license, the government noted that though the combination of (lamivudine, stavudine and nevirapine) proved to be the most effective and economical in anti-retroviral treatment, but the three international owners of such single drugs failed to reach agreement to produce this combination. The CL to Pharco Mocambique Ltd would be valid until the conditions of HIV/AIDS pandemic come to an end. The remuneration to be paid to the patent holders of the medicines was to be not exceeding 2 per cent of the total turnover of the said product.

The Zambian case of granting CL to Pharco Ltd to produce the triple fixed dose combinations of lamivudine, stavudine and nevirapine under the brand names of Normavir 30 and Normavir 40 is very similar to the Mozambique's case. However, here the CL would be valid from 1 August 2004 to 31 July 2009 and the product would not be exported. The license also stipulates the royalty payment of not exceeding 2.5 per cent of the total turnover of the products.

In the Indonesian case , the CL came into effect by a decree of the President of Indonesia to control HIV/AIDS epidemic. The decree authorizes the minister to appoint a pharmaceutical factory either for the production or for import of the patented medicines (nevirapine and lamivudine) at a compensation rate of 0.5 per cent of the net sales of the medicines.

The most recent case of utilization of CL for government use is that of Thailand in 2007 which created lots of debate and ultimately resulted in the issue of official letters from the US government and the WHO that they respect the decision of the Thai government to use CL to meet the needs of more than 600,000 Thais suffering from HIV/AIDS. The CL in question was issued on Efovirenz (Stocrin of Merck), Lopinovir+Ritonavir (Kaletra of Abott lab) and Clopidogrel of Sanofi Aventis.

In November 2006, the Thai government announced its decision to use the CL on Efavirenz by invoking Article 51 of the Thai Patent Act. Under this, the use of patent right of Efavirenz would be effective till December 2011 and will be used for providing this drugs to 200,000 patients covered under the National Health Security Scheme. The notice also said that a royalty of 0.5 per cent of the total value of sale of Efavirenz either by way of imports or by way of local production would be paid to the patent holder. Efavirenz is considered to be one of the very effective drugs with very less side effects. However, the price of the drug is prohibitively high and the budgets of the Thai government doesnot allow it to make it accessible to all those patients covered under the National Health Security Scheme.

Similarly, the combination of Lopinovir+Ritonavir (Kaletra) is one of the effective drugs for HIV/AIDS for patients who are resistant to basic formulations of HIV/AIDS drugs. In this case again, the public use of the patent rights would be limited to the 250,000 patients covered under the National Health Security Scheme and would be effective till 31 January 2012. Like Efavirenz, the royalty has been fixed at 0.5 per cent of the total sale of the product. The reasons cited here again is the huge cost of the medicine in the absence of competition due to patent rights. Chokevivat points out that the monthly price of the patented combination would be 6,000 Baht in 2007. It could cost 72,000 Baht per person for a year. If the medicine is to be provided for 50,000 persons then the required budget would be 3600 million Baht which is more than the total budget for antiretroviral of the Thai government in 2007.

Clopidogrel is a drug used in myocardial ischemia again priced prohibitively high restricting the use and coverage of persons under the national health security scheme. In this case, the Thai government decided

that the CL would be effective as long as the patent expires and the number of people covered would be unlimited but covered under the National health scheme. The royalty however is fixed at 0.5 per cent.

Thus, the Thai case highlights the effective use of CL by which the patented medicines would be made available to the needy patients though the National Health Security Scheme. The Thai experience has been applauded all over the world by the health activists and other governments and will serve as a model for countries wanting to utilize CL.

Besides these countries, India (automatic authorization, discussed later), South Africa and Cameroon have used the CL for government use to access medicines. In all of these cases, existing domestic patent laws already incorporated CL provisions. Further, in all the cases the countries have had negotiation with the companies and the will power to withstand international pressures. CL has also been used as a negotiating tactic by Brazil (mentioned earlier), Canada and the US (in the anthrax scare) to reduce the prices and increase the availability of drugs.

In addition to these countries, Chokevivat[12] lists several countries where the CL has spread as a movement and has been used quiet often. In the North America, both the US and Canada have used the CL. In Europe, UK, Belgium, France, Italy and Germany have provided for the use of CL. In Asia, China, Malaysia, Indonesia, Korea, India, Taiwan and Thailand have used CL. In Latin America, Argentina, Dominican Republic, Chile Peru Ecuador, Brazil have either used CL or used it as a negotiating tactic to get the patented product at reduced prices. Africa according to this report has used CL more often though the cases were not so publicized. In Africa, Cameroon, Guinee, Ghana, Eritrea, Mozambique, South Africa, Swaziland, Zambia, Zimbabwe have used CL. In the Middle East Israel is one country which has used CL so far. In all these cases except the US, the CL has been used to get access to pharmaceutical products and in majority of cases to gain easy access to the antiretroviral. The US has used CL on number of occasions including to review the merger cases. While in some cases it has been used as a negotiating tactic in others the countries have actually issued the CL for government use for public health purposes. Also majority of the countries have utilized the CL between 2001 and 2006. From the list of countries mentioned here it proves that the CL is indeed a powerful tool for the countries to get access to patented pharmaceutical products.

Indian Scenario

The post 2005 and the impact of adopting stronger patent regime in the context of India generated debate not only within India but also outside, since India is one of the larger generic drug manufacturing countries in the world which ranks…. In terms of production and volume, India's export reaches a number of developing and least developed countries which show the dependency of the other countries on India.[13] India's pharmaceutical industry is also making footprints in the developed countries as well.

India's transition towards the product patents came gradually.[1] As a signatory to the TRIPS Agreement, India amended her Patent Act of 1970 once in 1999 and again in 2002 to introduce, mailbox facility to accept product patent applications, exclusive marketing rights (EMR) to provide marketing rights for products granted patents elsewhere and applied for patents in India, provisions relating to granting of compulsory license and finally granted full patent protection in all fields of technology including pharmaceuticals from 1 January 2005. While this is expected to curtail the generic industry's capacity to introduce generic drugs during the life of the patented product, yet the amendments made to the Patent Act to a large extent ensure that India can exercise flexibility. This was passed through an ordinance in December 2004, which was followed by the Patent (Amendment) Act passed by Parliament in March 2005. Some of the key aspects are discussed in the following paragraphs.

The Indian government in its second amendment to the patent law has provided for adopting CL and Sections 82 to 94 in Chapter XVI deal with CL in the amended Patent Act of India.[14] These sections provide details of: general principles applicable to working of patented inventions; grounds for grant of CL; matters to be taken into account by the controller of patents while considering applications for CL; procedures for dealing with CL applications; general purposes for granting CL and terms and conditions of CL. Under Section 87, when the controller is satisfied that the application for the grant of a CL or the revocation of the patent after the grant of CL has a prima facie merit, the applicant will have to serve copies of the

[1]India had practiced product patents in the pharmaceutical sector before 1970s, and shifted to process patents in the mid seventies which prevailed till 2004 December.

application to the patentee and to advertise the application in the official gazette. The patentee or any other person may oppose the grant of the CL within the period specified by the controller, who can also extend the time. Thereafter the controller will decide on the case after hearing both sides. Any decision by the controller to grant a patent can be contested. Under Section 117 A, an appeal can be made to the Appellate Board. The applicant will be able to use the CL only if and after the Appellate Board turns down such appeals. The problem with the amended provisions is that the entire process is excessively legalistic and provides the patentees the opportunity to manipulate by litigation. The huge expenses involved in fighting the large pharmaceutical companies holding the patents may dissuade the non-patentees from applying for licenses in the first place. Chaudhuri[14] observes that there is enough justification to carry out further amendments to simplify the general provisions of CL in the Act to enlarge its use. For any drug in the public health list, the controller may immediately after receiving an application, grant the CL fixing a royalty rate using the royalty guidelines.

The definition of the pharmaceutical substance to mean any new entity involving one or more inventive steps invited lots of criticisms as it would include both new chemical entity as well as medical entity (the later would pave way for ever-greening of the patents). A committee was set up to look into the definition of pharmaceutical substance. This committee's report has not been accepted by the government and hence there is still uncertainty regarding this aspect. However, the exceptions to patentability which reads as `the mere discovery of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or 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', are efforts to keep at bay the ever greening type of measures.

The Patent Amendment Act brought in March 2005 categorically excludes derivatives such as salts, esters, ethers, polymorphs and similar forms and combinations of known substances, unless their properties differ significantly in the context of efficacy. Grace observes that while this could decrease the likelihood of ever-greening, yet the inexactness of some of the language leaves scope for interpretation and therefore expensive and time-consuming litigation is likely to ensue as experienced in the case of Gleevac.[16] In this context, what constitutes enhanced efficacy of a drug in general is not yet settled. [15] So also how much difference should there be to show that the drug is significantly different in properties is not clear. Hence, more cases of litigation could come up in the future.

The cancer drug Gleevac produced by Novartis that was granted EMR in 2003. After the EMR the other Indian firms producing the generic version of Gleevac had to stop manufacture of the same. A generic manufacturer, Natco initiated a pre-grant opposition claiming that Novartis's crystalline modification of the treatment constitutes an ever-greening strategy and the 'polymorph' that is claimed is the same molecule with a patent date of 1993. In January 2006, Novartis's patent application for Gleevac was rejected by the Chennai patent office. If the patent were granted to Gleevac, the generic producers will have to stop production and the cost of Gleevac which has to be taken lifelong by the cancer patients would cost Rs 1,20,000 a month as against Rs 8000 a month if produced by the generic companies. The Indian patent office has now refused the grant of patent on Gleevac which facilitates the generic producers to continue the production. The point emphasized here is both the pre-grant opposition introduced in the patent amendment and the clause to prevent ever-greening have both helped the generic producers to continue with the production and thus help millions of people to have access to this essential medicine.

Recently the Indian Pharmaceutical Alliance has highlighted the case of Aventis that got a second (US) patent for its 'substantially pure' Fexofenadine hydrochloride in 1996, thereby extending its patent life to 2006. IPA considers this as a case in point because, Aventis obtained first patent for the product in 1979 without any reference to purity. Thereafter, a patent is sought for a 'substantially pure' compound. The second patent becomes a hurdle for generic products. Under the Ordinance, this drug would have become eligible for product patent as a post- 1995 molecule. The sale of the product in India is Rs 30 crore. The IPA also pointed out the case of Novartis obtaining a second patent for Oxcarbazeopine in 2003 claiming difference in the particle size of the new product. Here the first patent was obtained for the compound without any reference to particle size.

Thereafter, a patent was sought for a particle size compound which delays the generic entry. The total sale of Oxcarbazepine in India is Rs 16 crore. IPA fears that of the 7000 odd mailbox applications, majority could be of similar requests.[15]

In view of the cases discussed above, the reintroduction of pre-grant position, exception to patentability, quantification of the term reasonable period (for negotiating with the patent holder) as six months and following the Doha Declaration, compulsory licence may be allowed to manufacture and export patented pharmaceutical products to any country without adequate manufacturing facility. Further, when a CL is granted to check anti-competitive practices, the licensee will be allowed to export the product. These measures would help the generic manufacturers as we progress further in the post 2005 era.

An interesting feature of the Amendment which takes care of the interests of the generic industry is that after a patent has been granted for a product in the mailbox, no infringement Act can be initiated against a generic manufacturer who can continue to produce that product subject to certain conditions. This considered to be automatic CL on the patented products is subject to certain conditions. The amendment states that 'a currently marketed generic product can continue to be commercialized once the branded original has been granted patent protection provided that domestic generic manufacturers pay reasonable royalties to the patent holders, the generic firm had marketed the product prior to 1 January 2005 and the generic firm has made significant investments'[17]. Because of this provision some of the generic producers producing anti retroviral can continue with the production. Thus, while the amendment is in favor of generic producers, conflicts could still arise in defining 'reasonable royalties, and significant investments' which need to be clarified.

The Supplementary Protection Certificate as adopted by France enhances the patent protection by five years, basically to make up for the time lost in the processing of the patent applications at the patent office. Similarly the patent term restoration provision of the Hatch-Waxman Act for a new drug is to extend the patent term for balancing the delays taking place during the pre market federal regulatory approval. One of the purposes of adopting TRIPS Agreement is to bring in uniformity in the period of protection. By such individual efforts of countries the impact is that entry of generic products is delayed. The other problem emerging is that the protection of the undisclosed part of the data (clinical trials) which is demanded by the multinational companies. Article 39.3 of the TRIPS Agreement which requires the undisclosed data be protected against unfair commercial use, is being interpreted by some of the developed countries such as US to mean that WTO member countries are required to grant data exclusivity for a specified period of time. It may be noted that the Hatch-Waxman Act also allows the generic producers to rely on the patentee's data and approved uses to support approval of their generic products to show that the said generic products are safe and effective. However as Correa has argued, countries can check the `unfair commercial use' by prescribing situations where a competitor obtains the results of testing data through fraud, breach of confidence or other dishonest practices and derive a commercial advantage. Basically this clause is being used to continue with the monopoly status of the drug and prevent the entry of generic drugs. India luckily has not provided for data exclusivity, the stand if it continues in future will be beneficial for the generic industry. The committee report on `Steps to be taken by Government of India in the context of data protection provision of Article 39.3 of the TRIPS Agreement, recommended that in the case of pharmaceuticals where the impact of product patents is yet to be seen, a transitional period may be specified during which the impact of providing higher protection on data could be examined for adoption.[17]

FTAs and Access to Medicines

Though the Doha Declaration simplifies the TRIPS Agreement, so that in practical terms, countries could have access to medicines, yet, the regional and free trade agreements (R&FTA) signed between the developing and the developed countries introduce TRIPS plus provisions which impede access to medicines. Every FTA includes a chapter on IPRs. But unlike the TRIPS Agreement, this chapter may or may not clearly spell out the objectives and purposes of these agreements. In addition, some agreements state that parties can implement a more extensive protection and enforcement than the FTA requires. Most often, though the FTAs provide minimum standards for the protection and enforcement of IPRs, but parties are free to implement more constraining provisions. Mostly, the FTAs tend to add restrictions in the criteria of patentability, patent territory, patent duration and disclosure of clinical data, which restrict

the flexibility otherwise provided by the TRIPS Agreement. A few such cases are mentioned here.[2]

In the Morocco-USA FTA, criteria of patentability, patent territory, have been defined in such a way to satisfy the demands of USA. For instance, as stated in the TRIPS Agreement, patents shall be available for any inventions in any field for product and process. Yet the definition of an invention is enlarged to include `any new cases or methods of using a known product, including new uses of a known product for the treatment of humans and animals. As a consequence, if a firm is granted a patent for the development of a drug, precisely for one medical indication, it can obtain a second patent for a new medical indication and so on. This enables the firms to extend the scope of protection and ever greening of a patent. The `object and purpose of intellectual property protection and the balance required with respect to public health and other sectors of vital importance to developing countries has not been as clearly spelt out in the FTAs except for in the United States –Chile agreement which makes an attempt to maintain the object and purpose of intellectual property protection and a number of agreements which also preserve the flexibility available with respect to the control of anti-competitive practices'.[1]

Most often the FTAs are used to extend the patent term. In the United States-CAFTA Agreement, it is stated that `each party shall make available a restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of marketing approval process'. Similarly while the Article 39.3 provides for the protection of the test data submitted to the governments for regulatory procedures, Article 15.10 of the US-CAFTA and other similar provisions in other FTAs go far beyond these requirements and introduce layers of complex protections and extend data exclusivity to all new medicines irrespective of whether such medicines would qualify for patenting at all[1]. However, the silver lining in this is the exception noted by the USTR. The USTR states that `if circumstances ever arise in which a drug is produced under a CL and it is necessary to approve that drug to protect public health or effectively utilize the TRIPS/health solution, the data protection provision of the FTA would not stand in the way'[1]. However, as these authors note, a limited number of FTAs restrict the grounds on which CL can be issued thereby nullifying the Doha Declaration. For instance, the US-Singapore agreement specifies the situations based on which a CL could be issued. These are: (1) to restrict anti competitive practices; (2) when used in cases of national emergency, CL is limited to use by government entities or third parties authorized by the government; the patent owner is provided with reasonable compensation for such use and manufacture and the patent owner is not required to transfer undisclosed information in technical know-how related to the patented invention.[1] The implication of the last aspect is if the party does not have the technical know-how it has to enter into a separate agreement with the patent owner. Musungu and Oh highlight the fact that Singapore is one of the countries which has agreed to use the CL only in cases of national emergency and has agreed to limit the use of CL to these situations.[1]

While most of the countries refrain from patenting plants or animals, the US-Morocco FTA provides that except in cases where it is necessary to protect public morality, to protect human, animal or plant life or health or to avoid prejudice to the environment, patents should be available for the `inventions on plants and animals and patents shall be available for any new uses or methods of using known products, including new uses of known products for the treatment of humans and animals'.[1] It is obvious that such protection will have implication on availability of medicines. The US-Morocco also restricts parallel importation by stating that 'each party shall provide that the exclusive right of the patent owner to prevent importation of a patented product or a product that results from patented process without the consent of the patent owner shall not be limited by the sale of distribution of that product outside the territory (however, this prohibition may be limited to cases where the patent owner has placed restriction on importation by contract or other means).

Thus, this brief overview of the FTAs do indicate that the provisions in these FTAs could prevent the use of flexibilities and thereby the access to medicines.

Conclusion

The Doha Declaration is one of the significant achievements of the efforts of the developing and the least developed countries to gain access to the

[2]Drawn from Guennif and Lalitha (2007), and Musungu and Oh (2006)

patented medicines. Particularly it facilitates use of the patent right of the innovation without authorization of the patent holder for public uses. Paragraph 6 and the waiver introduced enable now the countries to utilize the CL not only for the domestic purposes but also for export purposes which would significantly help those countries without pharmaceutical production capacities. The paper listed some of the experiences of countries that have utilized CL by importing the generic product from elsewhere. This provision nullifies the concerns among the least developed countries and health activists, created by major generic producers such as India adhering to the TRIPS Agreement. The domestic patent law amendments made in the case of India also facilitates production of patented drugs and thereby access to medicines to a large extent both within and outside the country.

In any case, the prior requirement in utilizing the Doha Declaration to the fullest level is in incorporating the necessary clauses in their national laws so as to utilize the flexibilities, followed by the willpower to withstand the international pressures. Though the Doha Declaration enables utilization of flexibilities, yet, countries coming under the FTA scanner have restrictions and have to look for ways to get access to medicines as these are the cases where the regional trade agreements become more powerful than the multilateral agreements. However, as the discussion highlighted, the movement of utilizing the CL as facilitated by the Doha Declaration gains more momentum, the role of drug cartels could be reduced with more contribution by generic producers such as India and Brazil.

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