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Gujarat Institute of Development Research

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Abstract

The Doha Declaration provides for access to medicines particularly by simplifying the compulsory licensing (CL) clause. This paper tries to provide a comprehensive review of the working of CL in the developed and developing countries with some useful case studies. It shows that majority of the countries that have utilized the CL option have done so to ensure their access to the HIV/AIDS medicines. Patents and higher prices of these medicines would be a cause of concern for the countries which are fighting this epidemic. The CL for the exports has greatly facilitated the access to medicines for the developing countries which have been able to extend the scope of treatment to more patients. The case of South Africa and Thailand indicate that though the flexibilities in the TRIPS are complicated still the case of human rights to health would prevail on pressures. Nevertheless, higher prices due to patents and lack of competition have prevented access to these medicines in those countries. Because some of these drugs have not been patented in India or because the companies have made sufficient investments in these drug projects, the Indian companies have been able to supply these drugs to the needy developing and least developed countries. However, in the post 2005 scenario where India has opened its mail box and started granting patent applications, it is possible that some of the newer HIV/AIDS drugs get their patents in India and thus the generic supply would get affected. Patents will be a cause of concern for the countries which are facing the HIV/AIDS epidemic as patients are prone to be immune to particular course of drugs and need to be shifted to newer drugs and regimens. The discussion further points out that though the Doha declaration does not reform the TRIPS measures as such, it definitely provides space for the developing countries to make provisions within the Agreement to get access to medicines.

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

JEL Classification : I111, I118, P48

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N. Lalitha*

1. Introduction

The case for human rights to health clearly stands out when the intellectual property rights for medicines are sought. However, intellectual property rights have not clearly emphasised the notion of human rights though they mention of the socio economic dimensions. The potential danger to access to medicines arising due to the implementation of the TRIPS Agreement in the area of pharmaceuticals particularly in the developing and least developed countries has resulted in a fresh look at some of the flexibilities available in the Agreement to emphasise on the human rights to health. While the scope of the time bound flexibility available in the form of transition periods is clear, use of other flexibilities such as compulsory licensing (CL), public and non-commercial use of patents, parallel importation and the limits on data protection require prior considerations and involves multiple stakeholders. So far utilisation of these flexibilities has brought in objections and criticisms and thereby raise concerns on the issue of access to medicines for the developing and the least developed countries. While there have been many instances of the developed countries like the US and Canada utilising the option of CL, yet, controversies arose when the developing countries tried utilising these options. The Doha declaration on public health cleared a few of the controversies that developing countries encounter in the process of implementing the TRIPS Agreement and in a way exposed the gaps between the multilateral agreements and the concerns on human rights to health.

The crux of this paper is on the situations that lead to Doha declaration concerning the use of CL in accessing medicines, which is presented in Section 2 that follows. Section 3 discusses the use of compulsory licensing by developing countries following the Doha declaration. Section 4 concludes the paper.

2. Situations Leading to Doha Declaration

As mentioned elsewhere in the paper, though the TRIPS Agreement provides certain flexibilities that are intended to help the member countries to fulfil their obligations to meet the rights and socio-economic welfare of their subjects, yet the riders associated with some of these aspects kept the flexibility options away from the developing and least developed countries. Majority of the discussion centres on Article 31 that specifies CL as evident from Box 1.

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Box 1. The TRIPS Agreement: Article 31

Article 31 states that:

..where the law of a Member allows for other use of the subject matter of a patent without the 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 the 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 the 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;

[…]

Source: TRIPS and Pharmaceutical Patents, Fact Sheet, 2006, (http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm)

Thus, though TRIPS mention that CL option can be exercised, under circumstances of refusal to deal by the patentee, national emergency non-commercial use and anti competitive tendencies, the actual use of the flexibilities is not simple as there are different stakeholders and a country has to analyse its trade interests with major countries as well.

In what follows, we present the cases of South Africa and Brazil which are hard hit by HIV/ AIDS and which used the TRIPS flexibilities to provide access to medicines to the disease victims[1].

2.1. The South African case

The South African (SA) law facilitated important measures to improve access to HIV/AIDS medicines in terms of: (a) production or importation of generic products to replace the patented products in the market; (b) parallel importation of the patented product; and (c) implementation of a transparent pricing system. By the first measure, the SA government intended to provide access to generics that are cheaper. It also facilitated the pharmacist to provide the consumers with the option to substitute with cheaper generics provided the prescription had scope for substitution. The second measure provides for parallel importation of a product by a person other than the patent holder on the condition that the imported product has the same name, composition and quality of the patented product. The third measure as introduced by the SA government required the multinational companies to demonstrate their production costs and the Ministry of Health, SA prohibited sales of any drugs which are priced above the level fixed by it. Fearing that other developing countries could also follow the example set by SA, the pharmaceutical companies formed a cartel and initiated action against the SA government contesting that the measures initiated by the government is against the TRIPS norms, particularly the parallel importation. As per the SA government measures, anybody other than the patent holder could import the product similar in all respects to that of the patented product (provided such a product exists in the market), while the TRIPS says that only the patent holder has the right to import a product. But as the principle of exhaustion holds that once the patent holder sells his product either directly or through an authorised person, he loses his rights over the product as he had received the due payment and thus can not prevent the further sales of the product. This interpretation is accepted in most of the member countries, though with few exceptions. But a final decision on the interpretation emerged only during the Doha meeting in 2001. However, at the intervention of the WHO and the strong opposition from NGOs and public, pharmaceutical industry had to abandon its challenge in April 2001. Varella (2004) demonstrates that besides the legal and the view point of international agreements, the NGOs presented non-legal points that are very valid for the developing countries. The NGOs argued that patents of the pharmaceutical companies resulting from

[1] The discussion draws substantially from Varella, 2004.

the research funded by the governments are contestable. According to the NGOs, the research cost claimed by the companies is false as significant part of the research is funded by the public money. They showed that half of the thirty medicines studied were funded by the US government at all stages of research and of the seventeen medicines invented in the US, twelve benefited by the government funding. Further, developed countries including the UK fix the profit margin of the pharmaceutical companies between 17-21 per cent for the drugs procured by the government. As a result of these multiple pressures, the companies offered to (1) reduce the price of the HIV/AIDS medicines; (2) supply the necessary inputs for the AIDS cocktail free of cost to facilitate local production; and (3) Bristol-Mayer Squibbs offered to supply Didanosina and Estavudina at one dollar a day and not to impose patent norms in the Sub-Saharan region. Though the SA government accepted the price reduction, it refused to revoke the law, as the government felt that it would make SA dependent on the multinational companies and the benefits offered by the companies were confined only to the HIV/AIDS medicines. Also the SA case was not to get the medicines produced locally but was to enable the country to import the same from other countries such as India at a lower cost.

2.2. The Brazilian Case

The Brazilian patent law provided for CL in cases: (a) if the patent owner uses his right in an abusive manner; (b) lack of exploitation of the patent in the country or non-utilisation of the patent unless it is due to economic unfeasibility; and (c) insufficient availability of the product or due to national emergency. In the first three cases, any qualified person could apply for CL (a CL could be sought after three years of granting of the patent). A CL would not be granted if the patent holder has legitimate reasons for not utilising the patent. Using this provision, Brazil issued a CL for Nelfinavir (produced by Roche), Lopinavir/Ritonavir (product of Abott) and Efavirenz (product of Merck). At the time of discussion on CL these three medicines alone constituted 70 per cent of the total resources of the Brazilian governments' fight against AIDS.

The US bringing the case before the Dispute Settlement Body (DSB), claimed that the 'lack of exploitation of the patent and the need for domestic production' clause is against the TRIPS. Brazil insisted on the domestic production clause as ever since the patent laws came into picture, the multinational companies in Brazil, closed down their production and instead started importing the drugs resulting in higher domestic prices of the drugs. This lack of local production was considered as non-utilisation of the patent and hence justified for the case of CL. The Brazilian justification was in full conformation with the Paris Convention and the TRIPS Agreement as well, which states that `nothing in Part 1-IV of the Agreement shall derogate from existing obligations that members may have to accomplish each other

under the Paris Convention' (Article 2.2). Therefore Brazil's case is legal and genuine. Though the US challenged this decision of Brazil, it withdrew its complaint due to the international attention. After a considerable negotiation, Merck offered a 60 per cent reduction in the prices of HIV/AIDS drugs and Roche offered a 87 per cent reduction in the price than that is offered in the North American region 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.

Both these cases received lot of international attention as both the countries have a larger population affected by HIV/AIDS and it also created awareness about the role of multilateral agreements in impeding the access to important medicines. However, uncertainties regarding their rights and other pressures have restricted the other developing countries to emulate either the SA model or the Brazilian model. Hence, a declaration on health was made in the ministerial meeting held at Doha in November 2001 in order to arrive at a solution on intellectual property rights factors that impede access to medicines for the developing and the least developed countries that individually do not have the wherewithal to take on the multinational companies and other pressures.

3. The Doha Declaration

The Doha Declaration states that:

1. 'We recognise 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 recognise that intellectual property protection is important for the development of new medicines. We also recognise 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 recognise 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 recognise 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' (http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips e.htm).

Though the Doha declaration was initially received very well, anxiety was widespread about the interpretation of Paragraph 6 of the Declaration (that the CL would be predominantly for

the supply of domestic market). A decision regarding the same was announced in 2003 and was adopted in the form of waiver of Article 31 (f) 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 have to notify the WTO once they intend to import a drug under compulsory license and also supply information when they actually 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 the system would be used in totality (i.e. to satisfy their access to medicines needs) or in a limited manner in the sense that they would use it only on 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.

Following this Rwanda, one of the least developed countries, became the first country to inform the WTO on July 17th, 2007 about its intention to import cheaper generics under CL from elsewhere as Rwanda is unable to manufacture the medicines locally. 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.

On 6 December 2005, the WTO members approved changes to the TRIPS Agreement by incorporating the waiver of 2003 into a permanent amendment on TRIPS. The amendment of Article 31 (f) is in three parts. They deal with: (a) permitting pharmaceutical products made under CL to be exported to countries lacking production capacity; (b) avoiding double remuneration to the patent holder, regional trade agreements involving least developed countries; and (c) non violation and retaining all existing flexibilities under the TRIPS Agreement (http://www.wto.org/english/news_e/pres05_e/pr426_e.htm).

This amendment makes it easier for poorer countries to obtain cheaper generic versions of patented medicines. Once two thirds of members have formally accepted the amendment, it

would be formally built into the TRIPS Agreement and will replace the 2003 waiver. The deadline to ratify the change has been extended from December 1 2007 to December 31, 2009 and 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. In 2006, Norway, Canada and India have informed the WTO that they have already amended their national laws. Table 1 indicates the list of 16 countries that have already amended their national laws.

Table 1: List of Countries that have amended their National Laws

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

Source: WTO

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

As per the paragraph 7 of the Doha declaration, least developed countries need not protect pharmaceutical patents and test data until January 1, 2016. They also need not provide exclusive marketing rights for patent applications till January 1, 2016. However, a least developed country member has to establish that it 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 extend on request and on mutually agreed conditions, technical and financial cooperation in order to facilitate its implementation**.**

3.1. 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. In this regard, Hu (2006) and the WHO (2008) discuss a few country cases from the perspective of the (a) legal basis for granting CL; (b) decision making process; and (c) public health benefits derived from such utilization of CL. A brief discussion on these cases is attempted here. In all the cases as presented, it was obvious that 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 mostly for the government use.

The Minister of Justice, Legal, and Parliamentary Affairs, Zimbabwe declared a period of emergency in May 2002 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 antiretroviral 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. Out of the drug budget of 193.6 US $ million of the Malaysian government, 3.6 US $ million was going towards the antiretroviral and 75 per cent of the patients could not afford the high price of the antiretroviral (Ling 2006). Since the epidemic was knocking Malaysia's door, the government wanted to increase the coverage of patients getting treatment from the government health care and started negotiating with the companies. When this negotiation failed with the patent holding companies, the government decided to authorize imports by the local company Syarikat Megah Pharma and Vaccines to import Didanosine, Ziduvudie and a fixed dose combination of Didanosie and Zidovudine from Cipla in India. The authorization was valid for a period of two years beginning from November 2003 and only for government use. Though one of the patent holders filed a lawsuit against the government use, it was not pursued. Both Glaxo and Bristol Myers Squibbs threatened the Malaysian government with reduced foreign investment but the government went ahead with the CL. As a result of this CL, the average cost of treatment was reduced by about 81 per cent and the number of patients treated in government hospitals increased from 1500 to 4000 (Ling, 2006). On November 1, 2005, the authorization expired but the government did not renew it, as the price reduction offered by the companies was satisfactory as evident from Table 2.

Table 2: Prices of Patented Medicines (US$)

Medicines	2001 prices	2004 prices	% reduction
1. Glaxo SmithKline			
Combivir (60 tablets)	286.28	57.99	80
AZT (100 tablets)	77.58	36.08	53
3TC (60 tablets)	141.75	46.39	67
2. Bristol-Myers Squibb			
Didanosine (100mg) 60 tablets	63.55	32.68	49
Didanosine (25mg) 60 tablets	44.49	8.17	82

Source: Ling (2006)

The Ministry of Industry and Commerce of Mozambique issued a CL to Pharco Mocambique Lda to produce a triple compound of Lamivudine, Stavudine and Nevirapine. In granting the license, the government noted that though the combination (Lamivudine, Stavudine and Nevirapine) proved to be the most effective and economical in anti-retroviral treatment, the three international owners of such single drugs failed to reach an 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 case of Mozambique. However, here the CL would be valid from August 1, 2004 to 31 July 2009. 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 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. This 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 Royal 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 was prohibitively high and the budgets of the Thai government did not 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, 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 reason cited here 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 Thai 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 restricted to those covered under the National health scheme. The royalty however is fixed at 0.5 per cent.

The decision to use CL on the anti-cancer drugs by Thailand was again the centre of controversy in the recent past as the decision taken by the interim government was brought under review by the new government which was interested in revoking the CL. Epidemic like HIV/AIDS is one of the important diseases prevailing in Thailand with more than 100,000 new cases reported every year with 30,000 deaths reported annually. The anti-cancer drugs are under patent in Thailand and priced prohibitively high inhibiting access to those affected by it. Therefore the Thai government decided to bring the same under the universal access to essential medicines by all beneficiaries under the National Health Security System. Though in order to use CL it need not enter into negotiation with the companies, the government had twelve rounds of negotiations with the companies about the price reduction (Table 3). Once the negotiations failed[2], the government issued CL on these four anti-cancer drugs.

On bringing seven patented drugs under CL (including the anti-cancer drugs), it was debated by the pharmaceutical companies whether it indicates a trend that all patented drugs would eventually be brought under CL for government use. However, the Thai government clarified that the decision would depend on whether: (a) there are problems in accessing the medicine; and (b) it creates a financial burden for the national health insurance systems (Thailand Government, 2008).

[2] Novartis agreed to provide free access to Imatinib to all those patients whose HH income is less than 1.7 million Baht per year and need 400mg of Imatinib per day or whose income is less than 2.2 Mn Baht per year and need 600Mg of Imatinib per day if indicated by the attending physician. However, to ensure continuity and sustainability of this commitment from Novartis, a conditional government use of patent was proposed (Royal Thai Government, 2008).

Table 3: Prices of Anti-cancer drugs

Name of the drug	Trade name	Used against	Price of the originator (THB)	Price of the generic manufacturer (THB)
Docetexel(80mg inj)	Taxotere	Lung/breast cancer	25000	4000
Letrozole(2.5mg)	Femera	Breast cancer	230	6-7
Erlotinib(150mg)	Tarceva	Lung cancer	2750	735
Imatinib(100mg)	Gleevac	Myeloid leukaemia and gastrointestinal Stromal tumor	917	50-70

Note: Prices are expressed in Thai Baht (THB) for one unit of drug
Source: Compiled from the document of National Health Security Office, Thailand (2008)

In 2008, under the threat of moving under the ‘ priority foreign country list’ by the US, the new Thai Government tried to revoke the CL. But due to the vehement opposition from the various civil groups and the support it received from the WHO, the CL on the anti-cancer drugs continues.

The Thai case highlights the effective use of CL by which the patented medicines would be made available to the needy patients through 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 these cases, existing domestic patent laws already incorporated CL provisions. Further, in all the cases, the countries have had negotiations with the companies and the willpower to withstand international pressures. CL has also been used as a negotiating tactic (by Brazil as 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, 2007) lists several countries where the CL has spread as a movement and has been used quiet often. In North America both the US and Canada have used the CL. Similarly, in Europe, UK, Belgium, France, Italy and Germany have provided for the use of CL. Italy needs special mention as it used the CL system to check anti-competitive practices in the case of Imipenem cilistantina (an antibiotic in June

2005), Sumatriptan succinate (migraine drug in Feb. 2006) and Finastreride (prostate cancer and baldness drug in March 2007). In Asia, China, Malaysia, Indonesia, Korea, India, Taiwan and Thailand have used CL. In Latin America, Argentina, Dominican Republic, Chile Peru Ecuador, and 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, Guinea, Ghana, Eritrea, Mozambique, South Africa, Swaziland, Zambia and Zimbabwe have used CL. In the Middle East Israel, is the 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 by the government for public health purposes. The US has used CL on number of occasions including to review the merger cases. 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.

3.2. Use of CL by India

A special mention needs to be made here about the use of CL in India. India has also amended its Patent Act to provide for CL. Sections, 84, 91, 92 and 92A provide for the use of CL. As per Section 84 the three grounds of CL are: (a) reasonable requirements of the public with respect to the patented invention have not been satisfied; or (b) the patented invention is not available to the public at a reasonably affordable price; or (c) the patented invention is not worked in the territory of India (Khader, 2007: 717). Section 91 deals with licensing of related patents. According to this, 'any person who has the right to work any other patented invention either as patentee or licensee may apply to the Controller for the grant of license of the first mentioned patent on the ground that he is prevented or hindered without such license from working the other invention efficiently or to the best advantage possible' (Khader, 2007: 729). Section 92 allows CL in the case of national emergency, extreme urgency and for public non-commercial use and Section 92- A provides for the grant of compulsory license for the export of patented pharmaceutical products. It defines pharmaceutical products as `any patented product or product manufactured through a patented process of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use'. These provisions plus those already provided under TRIPS (refusal to deal by the patent holder and anti-competitive situations) place India on a safer plane. However, practical issues would definitely emerge when CL is used under any of these provisions. Already some of the Indian generic manufacturers like Cipla, Emcure and Hetero are supplying to other countries

under the CL for the export clause. The quality of the generic anti retroviral supplied by these manufacturers has also been good. A few of these manufacturing facilities have been certified by the US Food and Drug Administration which makes it easier for exports. It is estimated that more than half of those receiving treatment in the developing world are treated with generic ARVs produced in India (Shadlen, 2007: 564).

Before generic competition entered, the antiretroviral treatment cost was US $ 10000 per person per year in the year 2000. With the onset of competition, particularly the generic producers from India, prices were dropped to US$ 350 per patient per year in March 2001. In July 2006, the ARV triple- combination supplied by Cipla cost US$ 132 per patient per year (http://www.msfaccess.org/main/hiv-aids/introduction-to-hivaids/pushing-prices-down/).

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 is considered to be automatic CL on the patented products but 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' (Grace, 2005). Because of this provision some of the generic producers producing anti retroviral can continue with the production. Thus, while the amendment is in favour of generic producers, conflicts could still arise in defining 'reasonable royalties, and significant investments' which need to be clarified. However, a concern about the generic manufacturers arises here.

The Indian pharma majors' investment in R&D point out that they are interested in capturing the generic market of those products whose patents are about to expire. The mergers and acquisitions in the US and the Europe since 2005 have been carried out with the intention of acquiring the IP assets and manufacturing facilities so that they have ready access to the generics in the regulated markets (Lalitha, 2007). The ARVs supplied by the Indian generic players could be categorized as hybrid generics. 'Hybrid generics (HGs) are drugs that are under patent in some countries but not in the country where being produced (or if produced locally done so under compulsory license. HGs generally cannot be exported to countries where the drugs are patented, but they can be sold in any country that either does not have pharmaceutical patent or where the originator firm did not obtain a patent or where the importing country has issued a compulsory license' (Shadlen, 2007, p.570).

But the HIV/AIDS drugs are such that the patients develop immunity over a period of time and they have to be shifted to a newer regimen which means newer drugs that is patented. As India and Brazil have also started issuing pharmaceutical patents it is likely that the originators would secure their rights by getting patents in these countries also. Hence, the generic manufacturers would not have the benefit of continuing with the same generics and will have to invest in newer R&D to reverse engineer their products. This juncture would call for a decision whether they want to focus on the lucrative generics in the regulated markets or the other less lucrative market in the developing and least developed countries with price caps.

4. Conclusion

The discussion points out that though the Doha declaration does not reform the TRIPS measures as such, it definitely provides space for the developing countries to make provisions within the Agreement to get access to medicines. 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. It is also observed that most of the countries discussed in the paper have used the CL option before and after the Doha declaration to avail the HIV/AIDS medicines. Higher prices due to patents and lack of competition have prevented access to these medicines in those countries. Because some of these drugs have not been patented in India or because the companies have made sufficient investments in these drug projects, the Indian companies have been able to supply these drugs to the needy developing and least developed countries. However, in the post 2005 scenario where India has opened its mail box and started granting patent applications, it is possible that some of the newer HIV/AIDS drugs get their patents in India and thus the generic supply would get affected. Patents will be a cause of concern for the countries which are facing the HIV/AIDS epidemic as patients are prone to be immune to particular course of drugs and need to be shifted to newer drugs and regimens. While voluntary licensing would be an ideal situation, patent pools that are being talked about by the multinationals would also improve the access to medicines if it is implemented. However, it is also essential that some of the generic suppliers are able to respond to this situation to bring in the competition element to bring down the prices so that governments with limited resources are also able to extend the scope of treatment.

The CL so far has overwhelmingly been used to obtain access to HIV/AIDS medicines. However, besides the HIV/AIDS medicines, diseases like diabetes and cancer are treated with relatively new drug classes which have little therapeutic competition and substitution

and therefore would fall in the higher price category. Similarly studies have shown that antibiotics and anti-infective used for tuberculosis and malaria and pneumonia have already started showing resistance in patients in many countries (Grace, 2005). This implies that only newer patented medicines will be the alternative and developing and least developed countries may not have access to these medicines. Thailand stands apart in the country cases that were presented here in its bold attempt to include the anti-cancer drugs under CL for government purposes. The Thai model may probably be emulated by the developing and the least developed countries in future in their fight for human right to health.

References

Cecilia Oh (2006), 'Compulsory Licenses: Recent Experiences in Developing Countries', International *Journal of Intellectual Property Management*, 1 (1&2): 22-36.

Chokevivat Vichai (2007),'Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents in Three Patented Essential Drugs in Thailand', Document to support strengthening of social wisdom on the issue of drug patent by Ministry of Public Health and the National Health Security Office, Thailand.(http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf, accessed June 20, 2008)

Grace Cheri (2005), 'A Briefing Paper for DFID: Update on China and India and Access to Medicines, DFID Health Resource Centre, November 2005.

Lalitha N, (2007), 'Gujarat's Pharma Industry 1907-2007', a Report Submitted to Zydus Cadila Healthcare, Ahmedabad, November.

Ling Chee Yoke (2006), 'Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the 'Government use' Option, Intellectual Property Rights Series 9, Thirdworld Network.

Khader Feroz Ali, (2007), ' The Law of Patents-With a Special Focus on Pharmaceuticals in India', LexisNexis Butterworths, NewDelhi.

Medico sans Frontierhttp://www.msfaccess.org/main/hiv-aids/introduction-to-hivaids/pushing-prices-down/ (accessed on May 18, 2008).

Musungu Sisile and Oh Cecilia (2006), ' The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines', South Centre, WHO, Geneva, April.

Shadlen Kenneth (2007), 'The Political Economy of AIDS Treatment: Intellectual Property and the Transformation of Generic Supply' *International Studies Quarterly*, 51, pp: 559-581.

Thailand (2008) '10 Burning Questions on the Government Use of Patents on the Four Anti-Cancer drugs in Thailand' Ministry of Public Health and National Health Security Office, Thailand. http://www.moph.go.th/hot/Second_white_paper_on_the_Thai_CL_[EN].pdf (accessed on May 18, 2008).

Varella Marcelo Dias (2004), 'The WTO, Intellectual Property and AIDS-Case Studies from Brazil and South Africa, Journal of World Intellectual Property, 7/4, PP523-547.

World Health Organisation (2008), ‘Improving Access to Medicines in Thailand: The Use of TRIPS Flexibilities’ A report of a WHO Mission.

http://www.moph.go.th/hot/THAIMissionReport%20FINAL15feb08.pdf (accessed on May 18, 2008)

Zachariah Anand (2006) Access to Health care for all What can we Learn from the AIDS Movement?, *Economic and Political Weekly*, June, pp. 2522-2525.

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