Research/Technical Report

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INTRODUCTION

Access to essential medicines in developing country has been an ongoing debate for a decade now. This debate is an off shoot of various international developments over the decade, like establishment of the WTO[1] and its TRIPS[2] regime. Most of the countries prior to the WTO regime did not have a very strong Intellectual Property rights protection. However, the WTO introduced a mandatory product patent regime. As a result, most of the developing countries amended their patent laws to comply with the WTO. Nevertheless, concerns regarding access to medicines were voiced at many of these WTO forums by developing country members. In 2001, the Doha Declaration[3]

[1] The World Trade Organization (WTO) is an international organization designed to supervise and liberalize international trade. The WTO came into being on January 1, 1995, and is the successor to the General Agreement on Tariffs and Trade (GATT), which was created in 1947, and continued to operate for almost five decades as a *de facto* international organization.

[2] The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the World Trade Organization (WTO) that sets down minimum standards for many forms of intellectual property (IP) regulation. It was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994.

[3] The November 2001 Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO Ministerial Conference of 2001 in Doha on November 14, 2001. It reaffirmed flexibility of TRIPS member states in circumventing patent rights for better access to essential medicines.

In Paragraphs 4 to 6 of the Doha Declaration, governments agreed that:

was instrumental in concretizing these concerns into a policy debate. As a result of these deliberations, the developing country members lead by Brazil and India were able to negotiate for flexibilities within the TRIPS regime. There are instruments within TRIPS that national governments can use to "break" patent monopolies and ensure a supply of affordable generic drugs. One such instrument is compulsory licensing, which allows generic manufacturers to produce pharmaceutical products (in cases of national emergency or public non-commercial use) that are currently subject to patent protection.

> "4. 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. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, 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 licences 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 and 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."

These provisions in the Declaration ensure that governments may issue compulsory licenses on patents for medicines, or take other steps to protect public health.

Compulsory licenses are considered by many as an effective tool to control monopolies by patent holders. The provision has been used by a number of countries in the last few years. Indonesia, Malaysia and recently Thailand are the notable ones. They are particularly significant for countries like India that export drugs to other developing countries. Therefore, the main objective of this research study is to review the international negotiations across forums and assess its impact on the ongoing debate on the issues and explore the feasibility of compulsory licensing as a tool to facilitate access to essential medicines within the current patent regime.

India has been at the forefront of the TRIPS negotiations, representing developing countries along with Brazil and others. The Indian Patent Law has been eulogized as one of the best patent legislations in the world. The Patent Act has been responsible to a great degree for the rise of pharmaceutical industry in India.

The Indian Patent Law and the growing pharmaceutical industry

The growth and expansion of India's generic manufacturing industry in the latter part of the 20th century ushered in a golden age of Access to Treatment. Prior to the 1970s, the Indian pharmaceutical industry was dominated by the foreign subsidiaries of multinational corporations (MNCs). During this time, only two of the ten pharmaceutical firms with the largest retail sales were Indian, and much of the

country's pharmaceutical consumption was met by imports.[4] Fearful of such foreign dependence, the Indian government took steps to promote a strong, self-reliant domestic pharmaceutical industry, culminating in the *1970 Indian Patent Act* (1970 IPA). Among other things, the 1970 IPA: prohibited patent protection on pharmaceuticals/food/agrochemical products, reduced validity periods of process patents from 20 years to 7 years, and introduced "automatic licensing." In addition to this landmark patent legislation, the Indian government placed import restrictions and tariffs on critical inputs and finished drug formulations coming from other countries.[5] The state also strictly enforced ratio requirements, where imports of bulk drugs had to be matched by purchases from domestic sources at a certain fixed ratio. Lastly, the national government passed the 1970 *Drugs Price Control Order,* introducing price controls that made it less profitable for foreign firms to sell patented drugs in the Indian market.[6] With support from such a strong and favourable regulatory environment, the Indian pharmaceutical industry exploded with both finished formulations and APIs (Active Pharmaceutical Ingredients) in the post-1970 period. By 2004, the domestic pharmaceutical market in India was worth approximately $4.3 billion, three-quarters of which was supplied by Indian firms.

[4] Hannah E. Kettler & Rajiv Modi, "Building Local Research and Development Capacity for the Prevention and Cure of Neglected Diseases: The Case of India," 79:8 Bulletin of the World Health Organization (2001) 743.
[5] Jean O. Lanjouw, "The Introduction of Pharmaceutical Product Patents in India: 'Heartless Exploitation of the Poor and Suffering?'" Economic Growth Center Discussion Paper No. 775 (New Haven: Yale University, 1997) 4.
[6] *Ibid*.

Due to the lack of product patents in the IPA, the Indian generic manufacturing sector was able to flourish. To accomplish this rapid development, the majority of Indian generic companies pursued a "reverse engineering" strategy, imitating and producing drugs patented in other countries, and selling them in India and developing country markets.[7] India's lower labour and capital costs (compared with developed countries) allowed for low manufacturing costs crucial to the development of the generic industry.[8] In addition to a lower cost structure, Indian firms also possess advanced chemistry and process engineering skills. By 1991, Indian firms accounted for 70% of the bulk drugs and 80% of the formulations produced in the country, quite a feat considering India's large market size.[9] Generic Anti-Retrovirals (ARVs) manufactured in India were prevalent in the treatment of HIV/AIDS in the developing world. As of 2005, India supplied 22% of the world's generic drugs and a significant proportion of the vaccines made for the developing world.[10]

With the growth of the Indian pharmaceutical industry in the post 1970s, Indian generic manufacturers developed cheaper versions of various patented drugs and moved aggressively into the global market once the international patents expired.[11] As the Indian generic manufacturing industry expanded rapidly during this time, it became a

[7] *Supra* note 1 at 743.
[8] *Supra* note 2 at 17.
[9] *Ibid*. at 4.
[10] Cheri Grace, "A Briefing Paper for DFID: Update on China and India and Access to Medicines," (London: DFID Health Resource Centre, 2005) 8.
[11] Nilesh Zacharias & Sandeep Farias, "Patents and the Indian Pharmaceutical Industry," Business Briefing: Pharmagenerics (2003) 2.

major international supplier of drugs to countries where these products could be marketed legally because they had not been patented locally – usually developing countries.[12] With overall production of $7.3 billion (finished product domestic consumption plus exports), Indian firms produce approximately 1.5% of the global pharmaceutical market of $480 billion.

In 2004, India's drug prices were among the lowest in the world, even in purchasing power parity (PPP) terms. In a study comparing the prices between India and other countries where patent protection exists, the evidence indicates that in some cases drugs are up to 41 times more expensive in countries with patent protection.[13] For example, a study by an International Monetary Fund (IMF) economist reported that drug prices in Malaysia, where patent protection exists, were from 20 percent to 760 percent higher than in India.[14]

There are also benefits associated with the Indian generic manufacturing industry that extend beyond the price of the generic drug itself. In addition to direct supply, Indian generic drugs have an important indirect effect on the competitiveness of the marketplace for ARV drugs. Competition from generic drugs has been credited with reducing the cost of ARVs for a single patient from as much as $15,000 USD per year to

[12] John H. Barton, "TRIPS and the Global Pharmaceutical Market," 23:3 Health Affairs (Stanford: Project Hope, 2004) 147.
[13] K. Balasubramaniam, "Access to Medicines and Public Policy Under TRIPS," Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability, eds. Christophe Bellmann, Graham Dutfield and Ricardo Melendez-Ortiz (London: Earthscan, 2003) 137.
[14] *Ibid*.

as little as $150 USD per year.[15] This downward trend of ARV prices has occurred all throughout the world. In Brazil, ARV prices came down by 82% within 5 years after Brazil initiated local generic production – based primarily on API supply from India – and provided free universal HIV treatment to Brazilians who needed it.[16] Another meaningful indicator of this phenomenon would be the effects of "generic entry" on the prices of drugs coming off patent expiry.

Several studies on data from the U.S. market show considerably significant and rapid price decreases with each "generic entry" upon patent expiry. For instance, one study shows an average generic/branded price ratio of 0.59 after patent expiry with just one generic manufacturer, and 0.17 with twenty such manufacturers.[17] This lower price point, whether direct or indirect, is crucial for many developing countries which may not have the domestic markets to sustain generic manufacturing on an economic scale. What is more often the case is that many developing countries simply lack the domestic capacity, technology or knowledge to manufacture essential medicines such as ARVs.

The Indian pharmaceutical industry has traditionally been an important supplier domestically and to the less regulated markets of Africa, Asia and Latin America. Today, India is a major supplier of finished products, including vaccines and ARVs, to

[15] *Supra* note 8 at 1.
[16] *Supra* note 10 at 15.
[17] Jayashree Watal, "Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?" Science, Technology and Innovation Discussion Paper No. 8 (Cambridge: Harvard Center for International Development, 2000) 3.

both the developed and developing world.[18] Indian generics had ushered in a "golden age" of access to affordable drugs, especially ARVs. However, with the adoption of TRIPS and a more stringent intellectual property regime, the Indian generic manufacturing industry's ability to provide affordable generic drugs has been severely limited. With India's adoption of the World Trade Organization's (WTO) Trade-Related Intellectual Property Rights (TRIPS) Agreement and the subsequent amendments to the 1970 IPA, the generic manufacturing industry was placed in a period of transition that threatened access to treatment.

With the introduction of product patents on all drugs invented after January 1, 2005, Indian generic companies could no longer "reverse engineer" any drug that was patented elsewhere in the world. With a lack of product-related research and development (the focus of the Indian generic industry was on process-related research and development) much of the Indian generic industry was consolidated into a smaller number of firms. To compensate for its loss of revenue, many Indian pharmaceutical firms expanded their generic drug exports either as suppliers or through joint venture agreements with foreign firms, usually in developed countries.[19] More and more Indian firms have increased their emphasis on exporting to the more profitable regulated markets, as evidenced by the large concentration of U.S. Food and Drug Administration (FDA)-approved manufacturing plants in India - more than any other

[18] *Supra* note 10 at 14.
[19] *Supra* note 2 at 17.

country besides the U.S. itself.[20] However, even with this trend towards producing drugs for developed countries and "first world diseases," there is still flexibility within the present intellectual property regime to ensure access to treatment in developing countries.

Utilizing the Flexibilities within the TRIPS Agreement: Essential for Effective Access to Treatment

Article 31(f) of the TRIPS Agreement provides little flexibility for the production of generic drugs by stipulating that compulsory licenses are only granted in instances where production is predominantly for the supply of the domestic market of the member authorizing its use. However, a temporary waiver could be granted to permit countries to produce patented drugs under compulsory license and export them to countries with no manufacturing capacity.[21] Section 92(a) of the 2005 IPA covers compulsory licensing of pharmaceuticals for export purposes. Under this provision, the Indian government had to meet several requirements in order to grant a compulsory license for export, including establishing that the importing country lacks the sufficient manufacturing capacity to produce the drug in question (least developed countries are assumed to lack the manufacturing capacity to produce pharmaceuticals that they wish

[20] *Supra* note 10 at 7-8.
[21] Sudip Chaudhuri, "TRIPS and Changes in Pharmaceutical Patent Regime in India," Working Paper No. 535 (Calcutta: Indian Institute of Management, 2005) at 36.

to import).[22] Further, the exported generic drugs must be inventoried, clearly labelled/marked as produced for export under a compulsory license, and only be for the amount necessary to meet the needs of the importing member.[23] It is important to note that while provisions exist for national governments to use instruments like compulsory licensing, it may not be politically and/or economically feasible to exercise such tools. The United Nations Development Programme's (UNDP) 2001 Human Development Report found that pressure from Europe and the United States makes many developing countries fear that they will lose foreign direct investment if they legislate for or use compulsory licenses.[24] Given the importance of bilateral and international trade relationships in today's globalized world, countries like India are all but forced to limit their use of compulsory licensing outside of national emergencies.

The same barriers exist with another instrument – parallel importation – in which drugs are produced genuinely under the protection of a patent, placed into circulation in one market, and then imported into a second market without the authorization of the owner. Parallel imports, or gray-market imports, allows national governments to obtain patented drugs offered on the world market by importing from countries where the drug is sold at a lower price.[25] Patented medicines are often sold at different prices in different countries, and parallel importation allows a country to shop around for the

[22] *Supra* note 8 at 6.
[23] *Ibid*.
[24] *Supra* note 9 at 35.
[25] Tido von Schoen Angerer, David Wilson, Nathan Ford and Toby Kasper, "Access and Activism: The Ethics of Antiretroviral Therapy in Developing Countries," 15:5 AIDS 2001 (London: Lippincott, Williams & Wilkins, 2001) S82.

lowest price. By permitting pharmacists, hospitals and insurance services to procure drugs from cheaper international sources, prices of brand-name drugs are directly reduced and savings are presumably passed on to patients in some degree. The underlying justification of allowing parallel imports is that since the innovator has been rewarded through the first sale of the product, its patent rights have been "exhausted" and hence it should have no say over the subsequent re-sale.[26] Therefore, the ability of a right-holder to exclude parallel importation legally from a particular market depends on the importing nation's treatment of exhaustion of intellectual property rights. Under a national exhaustion scheme, exclusive rights end upon first sale within a country but IPR owners may exclude parallel imports from other countries. Under an international exhaustion scheme, rights are exhausted upon first sale anywhere, and parallel imports cannot be excluded.[27] Since intellectual property rights are generally recognized on a territorial basis, each nation has established its own policy covering parallel imports. Article 6 of TRIPS (as clarified by the *Doha Declaration*) preserves the territorial prerogative to regulate parallel trade by allowing each country the freedom to establish its own regime for exhaustion.[28] India's amended *Patents Act*, however, provides no qualification about the exhaustion of patent rights. Instead, Section 107A (b) of the 2005 IPA states that the "importation of patented products by any person from a person who is duly authorised by the patentee to sell or distribute the product shall not be

[26] *Supra* note 21 at 17.
[27] Keith E. Maskus, "Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries," Final Report to World Intellectual Property Organization (Colorado: University of Colorado at Boulder, 2001) 3.
[28] *Ibid*. at 4.

considered as an infringement of patent rights." This provision does permit parallel imports in certain cases, though the phrase "duly authorised by the patentee" is uncertain and usually causes delays in utilizing parallel imports. Given the difficulties associated with compulsory licensing and parallel importation, perhaps the most effective method of controlling patent monopolies lies in patent opposition mechanisms.

Indian Patent Act Today

When India adopted TRIPS in 1995, the country was given a ten-year window to reform its intellectual property regime, culminating in the *2005 (Amendments) Indian Patent Act* (2005 IPA). The amendments implemented a number of changes to India's patent system including, most notably, product patents. Under the 2005 IPA, inventors are now able to patent the pharmaceutical products that they develop, and prevent generic manufacturers from producing or selling these drugs without a license for the duration of the patent (usually 20 years).[29] Two categories of generic products remain legal in the Indian market: generic copies of products already off-patent in regulated markets, and generic versions of products patented before 1995. It is important to note that these two categories comprise over 90% of the products on the Indian market, including

[29] Sorcha O'Carroll, "Importing Indian Generic Drugs Following TRIPS: Case Studies from Zambia and Kenya," Online: Accessed on 7 July 2008, <http://www.law.utoronto.ca> 1.

many first-line ARV drugs.[30] While many of the ARVs currently produced in India were developed prior to 1995, and therefore will escape this legislation, it has significant implications for the availability and affordability of any drugs produced after that date. Generic versions of products patented after 2005 are generally considered illegal and not allowed in the Indian market. These new patent monopolies in India could prevent the generic production of newer, more expensive combinations of ARVs ("second-line treatment") that are needed for PLHAs that become resistant to "first-line" treatment. Though patent-protected ARV drugs are relatively few in number, they still represent a very large percentage of health and treatment budgets. For example, of the 14 ARV drugs on the Brazilian National AIDS Program, three new single-source products accounted for 63% of the total program costs in 2003.[31] The provisions in the 2005 IPA have clearly spelled out the status of generic versions of drugs invented before 1995 and after 2005. What about drugs that are invented and/or patented within the ten-year transition window?

Drugs patented between 1995 and 2005 (during the ten-year TRIPS implementation period) were placed in a "mailbox" and would be reviewed for patent approval in 2005. If a patent had been granted for the drug in another WTO member country, then its owners could be granted Exclusive Marketing Rights (EMR) until a decision is made on the patent application. EMRs give the owner the exclusive right to sell or distribute the

[30] Cheri Grace, "The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines," (London: DFID Health Systems Resource Centre, 2004) 31.
[31] *Ibid* at 19.

product in India for a period of five years, or whenever the patent application is accepted or rejected, whichever comes first. EMRs offer rights very similar to that of patents, and in many ways, contain even stronger monopoly provisions. This is because they are easier to obtain, and do not have to go through the same rigorous examination and opposition process that a patent does. Under s. 11A (7) of the 2005 IPA, a product "in the mailbox" can continue to be commercialized even if the branded original has been granted patent protection, provided that the domestic generic manufacturers pay a "reasonable royalty" to the patent holders. However, the patent-holder shall only be entitled to receive reasonable royalties from such enterprises which: have made a significant investment, were producing and marketing the concerned product prior to January 1, 2005, and continues to manufacture the product covered by the patent.[32] If a manufacturer is able to meet these requirements, a pharmaceutical company/patent owner would be unable to bring an infringement claim against the generic company, but only demand reasonable royalties. Notwithstanding this provision, the amendments made in the 2005 IPA generally strengthened the protection of intellectual property rights, especially with regards to pharmaceutical products. What are the implications of this for Access to Treatment?

With the 2005 Amendments to the IPA, proponents of TRIPS argued that intellectual property protection would allow local Indian companies to increase foreign investment, receive a transfer of technology and focus R&D on local diseases, thereby enhancing

[32] *The Patents (Amendment) Act, 2005*, The Gazette of India, Part II, Section 1, (2005) s. 11A (7).

access to treatment. However, the evidence has shown otherwise, with Indian generic manufacturers increasingly turning their attention towards more lucrative foreign markets and the diseases of developed countries. According to the World Health Organization (WHO), out of $56 billion spent globally on medical R&D in 1994, only 0.2% was on pneumonia, diarrheal maladies and tuberculosis, which accounts for 18% of global illness. Enhanced IP protection has changed industry structures and transformed the types of competition, and this has consequently led to a change in prices, quality levels and physical availability.[33] Overall, the evidence shows that the implementation of stringent patent rights in developing countries has had a negative impact on access to treatment, especially for PLHAs.

Drugs in this class have little therapeutic competition with older drugs that essentially become ineffective due to viral resistance.[34] With new waves of ARV drugs being produced to combat resistance, access to proper treatment will only worsen as these new drugs are subject to patent protection and the monopoly pricing power associated with it. There are, however, some safeguards within the IPA 2005 (such as compulsory licensing) that prevent complete patent monopolies in order to ensure a minimum level of access to treatment.

[33] *Supra* note 10 at 30.
[34] *Ibid*. at 20.

METHODOLOGIES EMPLOYED

The methodology employed for the research can be divided in to two stages:

- Literature Review on the subject area.
- Individual consultation with experts from academia, policy makers and other civil society organizations.

The methodology employed for writing can be divided in the following stages:

Fundamental Scholarship-The research will essentially be empirical and multidisciplinary in nature. Though the research will focus on legal rules and ethical principles, it will also explicate issues in bioethics, medicine and health, and human rights principles. The research will proceed from the intellectual perspective that law is problematic rather than certain, that its causes and effects, rather than its formal rules, invite scrutiny. Further, the research will be designed to secure a deeper understanding

of law as a social phenomenon, including research on the historical, philosophical, linguistic, economic, social or political implications of law.

Doctrinal – Doctrinal methodology will be employed for the purpose of International and National case law, and Regulations and Statute analysis.

Ethics Scholarship-The fundamental purpose of this paper is exploration of ethical implications in developing countries with regard to access to medicines in these countries. Hence, ethics scholarship will be employed throughout the paper.

Comparative – Drawing from standards of theological and legal discourse on patenting from various developing countries, this research also proposes to comparatively evaluate the fundamental research questions.

Policy Scholarship-The fundamental aim of this paper is law and policy reform in developing countries; hence policy scholarship will be employed to influence policy makers in developing countries.

Empirical research undertaken

- **Literature Review on the subject area.**

After a preliminary reading of the WTO law, a thorough research was done for existing literature on the subject. The IDRC library search and Westlaw were the main search engines used. Thereafter a bibliography was written. Please find a copy of the bibliography attached as ANNEXURE 1.

After a bibliography was in place, an effort was made towards assembling all the articles, reports, monographs and books for literature review. Most of the literature was available online/IDRC library. However, Ms. Christine from the IDRC was particularly helpful in getting me most of the article through inter-library loan.

After a first reading of the articles and reports in the bibliography, the main research questions were formulated. The main research question was:

Do the current compulsory licensing provisions in Indian Patent Law inhibit or promote access to medicines?

Thereafter, broad research framework was created to answer the research question. The framework consists of the following questions:

1. Detailed study of the nature, scope and procedural elements of functioning of the Patent legislations in India

2. Draw the underlying linkages between the patent framework and its implications for access to essential medicines and track developments on the issue through national and international case law.

3. Explore the legal provision (Compulsory Licensing) and its implementation in Brazil, Thailand, United States and Canada. (For Comparative Perspective).The provision will be explored in detail in India.

4. Explore the feasibility of compulsory licensing as a tool to facilitate access to essential medicines within the current patent regime in India.

- **Individual consultation with experts from academia, policy makers and other civil society organizations.**

The first step toward the empirical research was identification of various stakeholders in India to be interviewed. Eight stakeholders were identified after thorough research on the subject via internet search, literature review and contacting experts on the subject.

The eight stakeholders were:

1. Academics
2. Lawyers/Patent Attorneys

3. NGOs
4. Health care workers
5. Pharmaceutical Companies
6. Policy Makers
7. International Bodies
8. Generic Pharmaceutical companies

Based on the literature review, research question, research framework and identified experts, the following questions were drafted for the purpose of the interview.

- Is the Indian Patent Act well equipped to ensure access to medicines or is there need for amendments to the legislations?

- Will amending the WTO rules governing the exportation of medicines under compulsory licence make the use of compulsory licensing more administratively friendly?

- The argument that patent protection is essential to stimulate research and development, although quite shaky with respect to many fields of technology, is very strong with respect to pharmaceutical products. Comments/ Solutions?

- Does limiting patentability on innovation have benefits vis-à-vis access to medicines?

- Does TRIP prevent the use of compulsory licensing? Are the "flexibility" provided by TRIPS useful for Nation States? If yes, why is the use of Compulsory licensing so tough in India and if not, then should there be amendments in TRIPS/International Treaties?

- Is Lack of Government Will a reason for non-implementation of Compulsory Licensing or is it purely administrative challenges?

- Obstacles to using TRIPS-related flexibilities exist in the legislation of many developing countries and the lack of clarity about options for import and export of generic drugs are reasons for non-availability of drugs .Comments?

- Pressure form the US has actively opposed developing country efforts to implement compulsory licensing? Comments/Solution?

- Why were countries like Thailand and Brazil able to implement Compulsory Licensing while India was not?

- How effective has the use of compulsory licensing been in Brazil and Thailand?

- Canada's recent Compulsory Licensing agreement with Rwanda attracted a lot of criticism. Comments?

However, different set of questionnaire were used for different set of experts/stakeholder according to their experience and expertise.

The diagrammatical representation of the above mentioned research design is Annexed as ANNEXURE 2

There after 40 experts, NGO's etc were identified and contacted. A list of experts contacted and in India and interviewed is annexed as ANNEXURE 3. Several interviews were conducted.

SUCCESSES AND PROBLEMS ENCOUNTERED IN DATA COLLECTION ACTIVITIES

Field-research consisted of data collection with three major stakeholder groups: policy-makers, NGOs and academia. There are two NGOs in India currently working on patent law vis-à-vis access to medicines. Experts from both the NGOs were interviewed. Five policy makers associated with right to heath and TRIPS and WTO were interviewed. Eight academics working/teaching the subject were also interviewed.

However, the health care workers were unaware of the patent law and its implication. After speaking to two doctors, it was decided not to pursue this group. Therefore, no more health workers were interviewed. Two HIV/AIDS Networks were also interviewed. They were also unaware of intellectual property rights law and its implication on access to drugs though they had some knowledge about the pre- and post opposition[35] provisions of the patent law.

[35] With the adoption of TRIPS, it was imperative that member countries implement a proper procedure to scrutinize the thousands of patent applications submitted to patent offices every year. The 1970 IPA provided a detailed pre-grant opposition procedure to avoid wrongful claims by scrutinizing claims before a patent was granted. Over a period not exceeding 18 months, the complete specifications of the

Unfortunately, contacts with the pharmaceutical companies could not be established. A few pharma companies like Dr. Reddy's were unwilling to talk on the subject.

Therefore it was decided to interview patent lawyers litigating on behalf of the industry instead since they represent the industry clients and their interests. Contacts are being established with a few lawyers.

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product were to be made open for public inspection, and any interested person could oppose the grant of the patent on certain specified grounds. However, Section 25 of the 2005 IPA has diluted these provisions into a primarily post-grant opposition procedure. There are 11 grounds on which a patent can be opposed, but this can only be done within one year after the patent has already been granted. India's pre-grant opposition procedure is restricted to only two grounds: 1) non-compliance with patentability requirements (including novelty, inventive step and industrial applicability), and 2) non-disclosure or wrongful disclosure of genetic resources or traditional knowledge. With limited pre-grant opposition mechanisms, there exists the possibility that patents could be granted without extensive examination and scrutiny by the public. Once an application satisfies all the requirements of the 2005 IPA, a patent is granted expeditiously and published in the official gazette. It is only then that the patent is opened up for public inspection, whereas this process previously took place before the granting of the patent. Even with the limitations of the current patent opposition procedure in India, there have been a number of successful cases that have been pivotal to enhancing access to treatment in India.

Most of the interviews proved to be very informative and valuable. However, a few interviews were disappointing due to lack of knowledge and interest exhibited by some of the policy makers and experts.

After the first five interviews itself, some research questions were amended significantly to make the study effective and beneficial.

FINDINGS:

The finding of the study have been summarised in a tabular format as under:

1.

Non-Governmental Organisations				
Does TRIPS prevent the use of compulsory licensing? Are the "flexibility" provided by TRIPS useful for Nation States?	**The argument that patent protection is essential to stimulate research and development, although quite shaky with respect to many fields of technology, is very strong with respect to pharmaceutical products. Comments?**	**Is the Indian Patent Act well equipped to ensure access to medicines or is there need for amendments to the legislations? Does it provide for right to health?**	**How effective has the use of compulsory licensing been in Brazil and Thailand? Which country has the most efficient Compulsory licensing provision in their legislations?**	**Can an effective CL provision remedy most of the problems related to access and drug pricing?**
Yes it does. They can be utilised by the Nation States.	**There is a need to create incentives. 80% of the**	**The Indian Patent Act is the most progressive**	**Very effective. It had enabled better negotiation and reduction in prices.**	**It is a stop gap measure but certainly not the only measure.**

India has implemented these flexibilities.	pharmaceutical market is in the developed countries.	and health friendly law. However the CL provision is ambiguous and needs streamlining.		
There are flexibilities. However they can be dominantly used only for domestic purpose. Also they are insufficient as only countries with manufacturing capacity can use them. What about other countries?	The CIPH report clearly proves that the patents system as an incentive for R&D has failed to deliver.	Even though the Indian patent law includes some flexibility, it is ambiguous and the law needs to be amended for clarity and predictability.	Very effective.	No. India does not have a good chapter on Compulsory Licensing. The spirit of section 83 is not reflected in section 84. It is a very useful instrument but cannot be used in its present form.

Why were countries like Thailand and	Pressure form the US has actively opposed developing	Does limiting patentability on innovation have	Do you think there is	Obstacles to using TRIPS-related

Brazil able to implement Compulsory Licensing while India was not? Is there a lack of Government will?	country efforts to implement compulsory licensing? Comments/Solution?	benefits vis-à-vis access to medicines?	lack of Government will to implement CL?	flexibilities exist in the legislation of many developing countries.
Because India has a fewer Patents. The drugs patented in Thailand were in the public domain in India. However the temporary injunction issued by Delhi High Court in the recent Roche Vs. Cipla case can be termed as Compulsory Licensing.	Yes India has received tremendous pressure and so has Thailand	Absolutely. India has been at the forefront. For instance, in the recent Novartis case, the Madras High Court upheld a narrow patentability criterion.	Viewing CL as a last resort is the wrong perspective, especially for health technologies.	There are some unnecessary obstacles in most of the legislations. For instance, the three year lock in period is not required.
The need to use Compulsory licensing did not arise in India. However, there will definitely be patents on a lot of	Definitely and it is visible in the Thailand case.	Definitely because as soon as the patentability criteria is limited the number of patent granted	There is lack of Government will.	There are three major obstacles. 1. The three year lock in period should go 2. There should be a time limit to

drugs in the future and then CL provision will be useful.		decreases, thereby decreasing the monopoly.		dispose off a CL application. 3. There is no clear cut limitation on the power the Courts.

2.

POLICY MAKERS			
Does TRIP prevent the use of compulsory licensing? Are the "flexibility" provided by TRIPS useful for Nation States? If yes, why is the use of Compulsory licensing not implemented in India and if not, then should there be amendments in TRIPS/International Treaties?	Is the Indian Patent Act well equipped to ensure access to medicines or is there need for amendments to the legislations? Does it provide for right to health?	Pressure form the US has actively opposed developing country efforts to implement compulsory licensing? Comments?	Why were countries like Thailand and Brazil able to implement Compulsory Licensing while India was not? Is there a lack of Government will?

The main objective of the TRIPS amendment was to introduce flexibilities and India has implemented all the flexibilities in the Indian Act.	**The Indian Act is considered to be a model Act and countries like Philippines are amending their Acts based on Indian Law. There are enough flexibility and the Act guarantees right to Health.**	**It is difficult to say whether there is an arm twisting. No such thing has been documented so far.**	**India has not used the provision yet because the drug prices in India are low and the drugs are affordable. Only during the Avian Flu pandemic did the government think of using it. If a need to use the Compulsory Licensing provision arises in the future, the Government of India will not hesitate.**
The TRIPS allows the use of CL and the flexibilities are very useful.	**The Act is well equipped to address the issue of access and patents.**	**There is definitely a commercial pressure. It was seen in the case of Thailand but it is also argued that Thailand was not transparent in its procedures.**	**India has not used the provision because there not been a need yet. The Patent At has very narrow criteria for patentability. Till 2005 there was no product patent therefore most of the drugs are affordable. This is an important tool and should not be wasted. India has shown wisdom by not using it.**
Yes. TRIPS does allow the use of Compulsory	**The Indian Patents Act has made some efforts to address the**	**These are early days so one can't really assess the effectiveness as there are**	**As far as the use of CL in India is concerned, we did not really need to**

Licensing. There were certain ambiguities until the DOHA round. It is absolutely unambiguous as far as the Pharma sector is concerned.	**problem of access to drugs. However, there is some ambiguity in the CL provision. There are lot of subjective element included. For instance, the word "reasonable" has been used several times but it is not clear what kind of compensation should be given to the rights holders which are not really conducive to the functioning of CL system.**	**very few cases. However, there was a lot of pressure on the Thai Government. It was basically an agenda of the Pharma majors which is being pushed through multilateral process. Every country is negotiating for its own interest and so is the USA.**	**use the system. There is not a lack of government will but it has to be the last resort as the first step should be an effort use of Voluntary Licensing.** **India will be less inclined to use the CL provisions and ultimately it will depend on the ground realities.**
Yes there are flexibilities and they have all been implemented in the Indian Law.	**Indian has is one of the best Acts and it allows access to medicines.**	**No evidence to suggest pressure.**	**No Lack of government will. If need be, India will use the provision.**

Can an effective CL provision remedy most of the problems related to access and drug pricing?	Obstacles to using TRIPS-related flexibilities exist in the legislation of many developing countries.	
Not necessarily.	Yes. There are shortcomings in the legislations of many developing countries. For eg: Sri Lanka is bound by the Free Trade Agreement.	
As far as patent law is concerned, it is in place. However, implementation should be done in the right spirit.	There are not many Obstacles in the Patent Act. The three year period is for general cases. In case of emergency, the process can be expedited.	
The CL system has a lot of pre-conditions, the fore-most being the ability of the countries to use the system which in turn is dependent on availability of viable Pharma Sector.	Yes there are certain obstacles. The main problem is that most of the developing and LDC do have a generic manufacturing capacity and therefore they cannot take advantage of the CL provision. Only few countries like India and Brazil have these capacities. Just having these provisions is not enough; there have to domestic stakeholders to use the provision.	

Not necessarily. There are many factors which implicate the access issue.	----------	

3.

ACADEMIA and OTHER EXPERTS			
Does TRIP prevent the use of compulsory licensing? Are the "flexibility" provided by TRIPS useful for Nation States? If yes, why is the use of Compulsory licensing not implemented in India and if not, then should there be amendments in TRIPS/International Treaties?	The argument that patent protection is essential to stimulate research and development, although quite shaky with respect to many fields of technology, is very strong with respect to pharmaceutical products. Comments/ Solutions?	Is the Indian Patent Act well equipped to ensure access to medicines or is there need for amendments to the legislations? Does it provide for right to health? Pressure form the US has actively opposed developing country efforts to implement compulsory licensing? Comments?	Is there a lack of Government will?
TRIPS provides flexibilities but it is unfortunate that some of the flexibilities have not	In fact, many of the tropical diseases are critical from socio-economic perspective but the patent system has not	There is a provision in the Act, though not exactly right to health.	Yes, there is a lack of Government will. A competitive environment should be provided.

been incorporated in the Indian Law. For instance, Article 31 (b) should have been incorporated in the Law.	**provided an environment of incentive.**		
The flexibilities are extremely useful.	**Patents do have importance in the Pharma sector. Mansfield's study suggested that patents provide important incentives. However, he was later criticised for his methodology of empirical study. Patent system is working well, as it is able to give new drugs to the society.**	**The Indian Patent Act is very complex but can ensure access.**	**There has not been a need so far. In case of a demand, the Government will implement it.**
Yes and No. There are flexibilities but most of the ones existing in pre-TRIPS legislation have been taken away. For instance, the grounds on which Compulsory Licensing can be issued have undergone a change. Having flexibilities is not enough	**Many studies have shown that many products were developed in the past without patent being the incentive. Product patent is a wasteful incentive for drug development which only encourages little progress and incremental innovation.**	**Section 3d of the Indian Patent provides very narrow criteria for patentability which has saved many drugs form monopoly abuse. There are certain issues like the patenting of micro-organisms which impinges on biotechnology inventions or definition of chemical entity/pharmaceutical**	**Policy makers pride themselves on not using CL provision and consider their actions to be wise. But, even in distress, the Government refuses to declare emergency.**

because how much of these flexibilities can be used by the Nation States independent of other Nations is an important issues. Developing countries may find it difficult to use the flexibilities.		**substance which need to be addressed.**	
Yes.	**There is no justification for this argument in pharma and enough counter examples have been shown in the discourse since. Patents are likely to inhibit research, reduce access, etc. Reduced period of patenting/prize schemes/increased royalty/pooled patent schemes etc are some solutions**	**IP Act is generally okay. However efficacy definition in Section 3 d should not have been left open. It should have said no patents on salts, esters, etc irrespective of efficacy and new use. In general any new obstacles in registering generics early that have since surfaced should have been removed. CL – 3 year provision after granting patent could be removed. And make CL issue more "automatic". It needs to explicitly proscribe data exclusivity for drugs before 1995. And if at all data exclusivity for patented drugs, then**	**There is definitely a lack of government will to implement this provision. Also till now no CL applications filed in India by govt or private parties. Yes CLs could have been made 'automatic' for HIV drugs, and other drugs for life-threatening diseases.**

		data excl. period should be made co-terminus with patent period, after taking into account any TRIPS related objections. . In general any new obstacles in registering generics early that have since surfaced should be removed. Do you mean extending patents by issuing patents on new use/dosage forms? If so, yes they definitely limit access.	
Yes, there is flexibilities and TRIPS provides for Cl.	**Patent does stimulate R&D but what kind of research is recording R&D is important to investigate.**	**There has been considerable pressure from EU and the USA. The EU pressure is not on record. But what it has said is that providing company's right on drugs is going to deter them from investing back in new medicines. There has been lot of bad publicity in the US press about the Thailand case.**	**There can be severe sanction if there is political will to implement/use the provision.**

TRIPS allow for CL. Article 31 talks about non-voluntary licensing.	There is lack of evidence to suggest incentive.	There has been a lot of bilateral pressure. CL is a more political issue than a legal one.	There has been lack of political will in invoking a public health clause which is due to a poor public health record. There is an absolute misinterpretation of this provision which amounts to injustice to the negotiations to trips.

Canada's recent Compulsory Licensing agreement with Rwanda attracted a lot of criticism. Comments?	Can an effective CL provision remedy most of the problems related to access and drug pricing?	Obstacles to using TRIPS-related flexibilities exist in the legislation of many developing countries. Comments?	How effective has the use of compulsory licensing been in Brazil and Thailand?
TRIPS provide for export and it is a special procedure which can very be cumbersome.	Yes it can and especially if Article 31(b) of TRIPS is implemented.	Yes. There are shortcomings in the legislations of many developing countries. For eg: Sri Lanka is bound by the Free Trade	It has very been effective in Brazil. Though Thailand has implemented the provision, due to the US pressure, they might invoke it.

		Agreement.	
----------	**No. Because even if the drugs are available the health infrastructure in most of the countries is awful.**	**Yes, there is pressure but there is no evidence to suggest this. Pressure from the EU/Japan also exists.**	**It is a bit early to assess.**
----------	**Not at all. There are certain subject areas which need to be made unpatentable. Role of public funded R&D is immense and this role should be broadened. Drug innovation must continue but an alternative to patents us exists as well.**	**There are certain issues like the patenting of micro-organisms or definition of chemical entity/pharmaceutical substance which need to be addressed.**	**There has been a good deterrent.**
No idea –have not been following.	**Yes in theory and if actually implemented and CL issuance made less tiresome. Price regulation may still be required.**	**There are many reasons – parallel importing restrictions are indeed an obstacle.**	**No personal knowledge but seems to be doing well. However Brazil pharma industry is now virtually in the hands of foreigners.**
Yes. It has attracted a lot of criticism in	**No. CL is a very weak law. In fact**	**India does not have the best law but it has a**	**It has been effective but the true test of this provision**

a different ways because Canada allows the 30th August declaration. But the law is seen as not being effective. There are too many obstacles for it to work well.	**pre-grant opposition is a more effective way to ensure access in developing countries.**	**competent CL chapter when compared to other countries.**	**will be seen, when this provision is used by more countries especially after 2005.**
The way TRIPS was negotiated was very sad. The Council devised a law which is complex and unworkable. It's a flawed system.	**CL is a good law in theory but a difficult one when implemented. The issue cannot be solved by use of any of the IP provisions. We have to look beyond the IP framework.**	**The Indian Act is not an ideal Act and it could be further strengthened. The three year lock-in period should be deleted and there should be adequate time to apply for a CL provision. The CL application procedure should be simplified.**	**It has provided some deterrence.**

PRELIMINARY ANALYSIS

Each of the questions used of the interview will be briefly analysed from the stakeholder perspective:

> *Does TRIP prevent the use of compulsory licensing? Are the "flexibility" provided by TRIPS useful for Nation States?*

All the stakeholders recognised that TRIPS does provide for flexibilities and provides for the use of Compulsory Licensing. What was really contentious was the amount of flexibility that exists. The policy makers felt that there was enough flexibility that existed in TRIPS and they were very well accommodated within the Indian Patent Act. However, some of the members of academia and experts from the NGOs felt that the flexibility was not enough. It was procedurally cumbersome and there was lack of Government will to use it.

The argument that patent protection is essential to stimulate research and development, although quite shaky with respect to many fields of technology, is very strong with respect to pharmaceutical products. Comments?

While most experts felt that the patent system as an incentive has failed to deliver, other held to the importance of patents in the Pharma sector. One of the experts was of the opinion that the product patent regime has only encouraged incremental innovation as opposed in radical innovation. Further, another expert felt that 80% of the R&D investment was taking place in only developed countries. It is therefore, important to have markets for these products.

Pressure form the US has actively opposed developing country efforts to implement compulsory licensing. Comments?

Al the stakeholders agreed that there was some US pressure on developing countries. However, the policy makers were more reluctant to admit it, whereas the NGOs/Academia were more candid about their perspective on this issue. Some academia also felt that there was considerable EU/Japan pressure.

Thailand was one of the most recent cases quoted by many stakeholders as an example of the US pressure.

Is the Indian Patent Act well equipped to ensure access to medicines or is there need for amendments to the legislations? Does it provide for right to health?

There were various views on this question. One expert form an NGO stated that the Indian Patent law is the best law amongst the developing countries while there other expert stated that the Indian Law needs to be substantially amended and he pointed out three clear weaknesses of the Act.

Most of the academia felt that, though there is no direct provision of right to health, it does allow for access to medicines. For instance, the patentability criteria in the Act is very narrow and therefore patenting which limited.

Why were countries like Thailand and Brazil able to implement Compulsory Licensing while India was not? Is there a lack of Government will?

All the stakeholders across the board believed that the provision was not implemented in India because the need to use the provision had not arisen yet. For instance, Compulsory Licensing issued for most of the drugs in Thailand and Brazil were not patented in India. Therefore, they were both accessible and affordable. India introduced the product patent regime only in 2005.Therefore, most of the drugs patented before 2005 are off patent.

However, while all the policy makers felt that there was no lack of Government will and if the opportunity came by, the government would use the provision. While the NGO s and academia felt that there was lack of Government will to use Compulsory Licensing due to bilateral pressures.

The Ministry of Health declared in one of his responses on the CL, it will be used as the last resort. While most of the academia felt that it was imprudent to keep CL as a last resort , one of them felt that voluntary licensing is in fact the first option and therefore, CL was clearly a last resort.

Can an effective CL provision remedy most of the problems related to access and drug pricing?

While Prof. Keayla describes Compulsory Licensing as the "soul of Patent Law", other stakeholders felt that compulsory licensing was an inadequate provision to address the issue of access. Most of them were of the opinion that the Compulsory Licensing chapter in the India Act was not a robust one. For instance, Prof. Keayla was of the opinion that most of the TRIPS flexibilities were not incorporated in the Indian Act. If Article 31 b is implemented, the Compulsory Licensing can remedy most of the problems related to access.

An expert form an NGO felt that it was a stop gap measure but not the only strong measure. In fact, the other experts highlighted some of the weakness of the CL provision in the India law. He along with many were particularly concerned with the three year lock-in period in the Act. While one of the policy makers felt that the three years lock-in period was only for the general cases, in case of emergency the three year lock-in period did not apply.

Some of the academia were of the opinion that the pre- and post grant provisions were definitely more efficient than the CL provision.

One of the members of the academia felt that even if CL is used to its full potential, price regulation will needs to be done. CL as a standalone instrument is not enough to guaranteed affordability and access.

CONCLUDING REMARKS

With the passing of the original 1970 IPA, it was clear that the policy of the Indian government was geared towards the protection of public health and the expansion of the Indian generic manufacturing industry. The evidence shows that this strategy was hugely successful in increasing the number of generic drugs available, lowering prices of ARV drugs (either directly or indirectly through the marketplace) and enhancing access to treatment, especially for developing countries that lacked the manufacturing capacity to produce their own generic drugs. However, with India's admission into the WTO and the adoption of TRIPS, the country's pioneering intellectual property regime was harmonized with that of the rest of the developed world. Product patents were now allowed, and large multinational pharmaceutical corporations were able to monopolize ownership of some drugs, thus driving prices up. The Indian generic manufacturing industry is now in a phase of transition, and there needs to be a new strategy for ensuring access to treatment in the post-TRIPS world. The TRIPS Agreement itself contains flexible mechanisms for balancing access to treatment with the preservation of intellectual property rights, such as compulsory licensing, parallel importation and patent opposition procedures.

Section 84 of the 2005 IPA provides for compulsory licenses as a way to prevent the abuse of patents for a monopoly. Three years after the grant of a patent, any person can apply to the Controller alleging that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or that the invention is not available at a reasonable price, and ask that the Controller grant a compulsory license.[36] Under this provision, the Indian government has considerable leeway and flexibility to issue compulsory licenses based on a desired policy objective. For example, if the policy objective is to lower drug prices, it can be tackled by making the sale of patented inventions on unreasonable terms a ground for compulsory licenses.[37] Additionally, anytime after the sealing of a patent, an application for compulsory license can also be made under Section 92. Under Section 92(c), there is a certain procedure that must be followed in order to obtain a compulsory license, though this may be circumvented in cases of emergency, extreme urgency or public non-commercial use, including public health crises relating to Acquired Immune Deficiency Syndrome (AIDS), human immunodeficiency virus (HIV), tuberculoses and other epidemics.[38]

Though the compulsory licensing provision has been there in most of the Patent Legislations in the world, the Doha Declaration reinforced the existence of TRIPS

[36] *Supra* note 8 at 8.
[37] Jayashree Watal, "Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?" Science, Technology and Innovation Discussion Paper No. 8 (Cambridge: Harvard Center for International Development, 2000) 3.
[38] Sudip Chaudhuri, "TRIPS and Changes in Pharmaceutical Patent Regime in India," Working Paper No. 535 (Calcutta: Indian Institute of Management, 2005) 32.

flexibilities further. Compulsory licensing is seen as one of the most potent provision against abuse of monopoly rights.

FURURE COURSE OF ACTION.

It is very clear form the empirical research that the policy makers have a very different perspective on the issue of access to drugs, as apposed to the academia and the NGO sector. There is a clear discontent amongst some of the NGOs and the academia regarding the functioning /perspective of the Government on the right to access issues.

A research paper for one of the Intellectual Property Rights peer review journal will be written based on this research and perspectives shared by the stakeholders on the issue. The paper will look at some of the weaknesses of the Act pointed out by the stakeholders and critically analyse those provisions vis-à-vis access to medicines in India.

The paper will also look at the cases of CL use in Thailand and Brazil and critically scrutinize the effectiveness of this provision in each of these countries. The Thailand case will be used as the main case study.

Since the patents Act was amended only in 2005 to incorporate the product patent regime, there has not been a crucial state of affairs of access to drugs in India so far.

However, there is an apprehension that the situation may arise anytime soon and therefore Compulsory Licensing will be an important instrument for access. Therefore, this paper will evaluate the provision of CL in the Indian Act and see whether it can be used without problems by the Government, if the need arises. It will further recommend amendments based on expert opinions and critical analysis of the literature review.

Compulsory Licensing: Potent law in India?

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Context dictates goals. Goals dictate projects. Projects dictate actions. Actions dictate results.

Compulsory Licensing in India: Achieving Clarity.