

Compulsory Licensing under Section 92A: Issues and Concerns

Harshita Mathur†

National Law Institute University, Bhadbhada Road, Barkheri Kalan, Bhopal 462 002, India

Received 8 May 2008

As the patents laws continually soar in dynamic transition, burning controversy that rages up is compulsory licensing under Section 92A of the Indian Patents Act enabling exportation of patented drugs. This dissertation is a research-based factual analysis of patents as a real barrier to the accessibility to drugs and the extent to which compulsory licensing remodels the situation, in reference to the latest legal development- *Natco v Pfizer* which has hauled the key provisions before the legal eye for severe scrutiny. This paper is an endeavour to analyse the issue of patents v patients in the light of a possible outcome of this potentially landmark case.

Keywords: Patents, TRIPS, compulsory licensing, Section 92A, arbitrage, R & D

“That he, the Inventor, ought to be both compensated and rewarded...will not be denied...it would be a gross immorality of the law to set everybody free to see(or use) a person’s work without his consent, and without giving him an equivalent.”

John Stuart Mill (1848)

Grant of compulsory licenses has been riddled with technical and legal roadblocks as far as the Indian experience goes. Regardless of the current TRIPS mandated international patent laws, compulsory licensing provisions have been the source of inexorable rancor among the patentees. The genesis of the predicament can be mapped out as one sets to dovetail the conflicting dual concerns characterizing the labyrinth— the promotion of vital research by the pharmaceutical companies and access to drugs.¹ So far Compulsory Licenses (CLs) have been granted in very few cases for exportation (Section 92A of the Indian Patents Act). The case of *Natco v Pfizer* therefore assumes great importance. In such a situation, it is requisite that one ventures into its true

import and implications it has on access to drugs through this route, the country’s economy, new Indian patent regime and international community that awaits implementation of a globally harmonized patent system in India.

The discourse that follows is predominantly premised on the verity that compulsory licensing provisions were needed to bring in a certain degree of equity in the system by making products, particularly, pharmaceuticals accessible and affordable to large population in developing countries. Whether it is adequate or even useful to address these issues is the point of debate. Whether the exclusivity offered to the patent holder is the real barrier to accessibility to drugs and whether implementation of the compulsory license system as framed under TRIPS and national patent laws are truly adequate and beneficial also need to be discussed. One way to understand the ramifications would be to understand and analyse the recent case of by *Natco Pharma v Pfizer*. The DOHA Declaration of 2001 also adds a new dimension to the whole issue.

TRIPS, Doha Rounds and ‘Paragraph 6’ Decision

Prior to 1994, i.e., until the signing of the General Agreement on Tariffs and Trade (GATT), intellectual property laws and international trade policies were essentially separate entities with very little technical or legal nexus between them.² Further in 2001, the Inter-Ministerial Conference of the World Trade Organization (WTO) officially initiated the Doha Agenda with a declaration that acknowledged the

†Ms Harshita Mathur is pursuing fourth year of the LLB (Hons) course at the National Law Institute University, Bhopal, and has completed on-line certificate course in ‘Intellectual Property Rights and Informative Technology in the Internet Age’ conducted by the Indian Law Institute, Delhi. She has interned in various prestigious law firms and is a responsible Member of the Gender Justice Cell, Centre for Advanced Research in Environmental Studies Cell and the Cell for Advanced Studies in Corporate Law.
E mail: hmr088@gmail.com

need to recognize a sovereign nation's right to protect public health of its people, even at the expense of not honouring intellectual property right.³ Pursuant to this, many national systems incorporated additional provisions enabling compulsory licensing.⁴ Compulsory licenses⁵ were granted in the past under some national laws, but they failed to deliver the essential medicines to the ailing populations in those countries. According to the World Health Organization (WHO) estimates, about one third of the world's population lacks access to essential medicines.⁶ Even with a compulsory license, many countries with severe health epidemics do not have the means or capacity to manufacture drugs as TRIPS required that the manufacture resulting from compulsory licensing must be predominantly for the domestic market. Recognizing this shortcoming, the WTO met again in 2003 at the Fifth Ministerial Conference in Cancun and adopted a decision on a 'temporary solution' in the form of an interim waiver to the Article 31(f) restriction thereby extending compulsory licensing provisions by temporarily removing limitations on exports of drugs under a compulsory license to countries that could not manufacture drugs themselves.⁷

CLs for export have been granted since 2005⁸, the first being the one granted by Canada. The case of *Natco v Pfizer* in India has put the key provisions of the Indian Patents (Amendment) Act, 2005 extending compulsory licensing to exportation of drugs, under the scanner. Until this interim waiver was not placed in law, the general procedure of licensing followed was as typified in Section 84 of the Indian patents Act. The new 'Paragraph 6' decision of the Doha declaration entered the statute books of Indian Patent Regime in the form of Section 92A⁹ in the year 2005.

Canada-Rwanda Case: First 'Doha- Style' Case

In 2004, Canada became the first country to implement the 2003 decision. Bill C-9, An Act to amend the Patent Act and Food and Drug Act (*The Jean Chrétien Pledge to Africa*), enabled compulsory licenses for the export of generic versions of patented drugs to countries with calamitous public health tribulations¹⁰ and if the Natco lawsuit succeeds, India would be the second country to follow this path. Though, Canadian company Apotex had agreed in 2004 to produce a fixed-dose combination of the three HIV/AIDS drugs, *zidovudine*, *lamivudine*, *nevirapine* later to be known as *TriAvir*, after all attempts at procuring voluntary licenses and CLs failed. Nine

Canadian patents were related to the drugs. However, when in 2007, Rwanda signaled its willingness to exploit the mechanism, Apotex qualified for the much awaited break. After the circulation of Rwandan request by the WTO, Apotex filed for and on 19 September 2007 obtained a two-year-compulsory license on the nine Canadian patents for manufacturing 15.6 million tablets and exporting them to Rwanda.¹¹

No matter what the consequent verdict on the *Natco v Pfizer* case is, the new law has the potential to be used for the benefit of patients in developing countries through an appropriate judicial analysis.

Section 92A under the Lens: *Natco Pharma Ltd v Pfizer/Roche*

The ball was set rolling on 15 September 2007 when a Hyderabad-based generics manufacturer *Natco Pharma Ltd* filed an application for a CL before the Controller General of Patents. Reportedly, Natco had a licence from Nepal to import Erlotinib, patented in India by Swiss firm Roche under the brand name *Tarceva*, and Sunitinib, patented by US firm Pfizer Inc under the name *Sutent*. Natco Pharma manufactures generics and contends that the generic versions¹² can be manufactured at one-fifth the cost of the patented drug of the innovators. Since Nepal is a least developed country, it does not need to establish that it has insufficient manufacturing capacity¹³ and hence it is legally permissible to obtain a compulsory license to override the patents for public health reasons (relying on Section 92A & Article 31 of the TRIPS Agreement). The outcome of this application is eagerly awaited by the Indian drug makers, innovative companies (patent holders) and patients.

Significance of the Case and the Critical Questions Raised

Natco's lawsuit, if successful may not single-handedly change the patent regime world over, but it will prove to be an important precedent and will help to define the modalities of operating this provision including legal and administrative procedure adopted in this case. Furthermore, compliance with TRIPS is not just aligning the national laws through legislation; it does have a sizeable impact on the world economy and trade relations of the specific member state. India, according to the aid group Médecins Sans Frontières (MSF)¹⁴, is the main supplier of essential medicines to poor countries. Unlike other countries, India has been a leader in the supply of generic drugs and hence could be a major beneficiary if the least developing

countries offer new markets even for patented drugs under the DOHA Declaration.¹⁵ Many of the Indian pharmaceutical companies are approved by the World Health Organization and some by the US FDA to export generic versions of many off-patent drugs including many new fixed-dose combinations. In fact, after it proved unable to secure the export of TriAvir from Canada in the Canada-Rwanda case, MSF sourced the drug from India.¹⁶ Thereby opening a fresh opportunity for Indian companies. If similar compulsory licenses are granted, the broader ramifications on the global patent systems would be a matter of deep anxiety and apprehension to the innovating companies.¹⁷

Should the decision in the near future by the Delhi high Court be favourable to Natco, overriding the said patents, the research-based industry may claim that compulsory licenses provisions together with the Doha Declaration have been pushed beyond the remit and ambit of true health emergencies. However, on the other hand, the international patient advocacy groups, governmental organizations and inter-governmental organizations like WHO fancy that the ostensible 'monopoly pricing power' available through the patent system would be diluted to a great extent.

Fundamentals Revisited: A Research-based Analysis Ostensible 'Monopoly Pricing Power' and Therapeutic Competition

Some widely held assumptions give rise to acerbic criticisms against patents. The first and foremost is the one of alleged monopolies that patents generate and which the atypical compulsory licensing for export seeks to dilute. The effect of patents in pharmaceuticals does appear to grant monopolies but if the technicalities of this form of IPR are explored in the light of empirical and experiential considerations, patents do not, in effect, bestow monopoly pricing powers due to the availability of off - patent substitutes in many cases. Indeed, as a result of therapeutic competition many of the patented drugs in use today face competition from 2 to 10 close substitute drugs to treat the same conditions.¹⁸ In addition considering the long gestation period required for developing a new product, effective exclusivity offered through the patent system is much shorter than the 20 years of protection available under TRIPS.¹⁹ Whether the availability of substitute products, some of them even non-patented or patent expired would be an argument against the grant of compulsory licences in such cases is to be considered.

Nationally Enforceable, Limited Monopolistic Rights and Cost-Constraints

Furthermore, rights in patents are not eternal but are only limited monopolistic rights. The true value of a patent is determined by the availability of equivalent non-patented products during the life time of the patent and the nature of generic competition in that therapeutic area. In addition many patents are never filed in least developed countries and therefore are no barriers to their being exploited without a licence.²⁰ Costs, market opportunities, maintenance fees etc, are some of the reasons for innovators not to file patent applications across large numbers of countries. The maintenance fee goes on increasing in some countries till the end of the patent life and consequently the costs could mount dramatically over the years.²¹ Studies suggest that, patents can not be said to cause inaccessibility to the essential drugs in 'many' developing countries as in 98.6% of the time they do not exist.²² In view of the above, the argument that patents are a possible barrier to accessibility to essential drugs can not be said to be true in all cases.

The 'Myth' of Price Reductions

Contrary to the proposition that copycat versions are cheaper as compared to the drugs traded by the multinational patentees, data accumulated by the Médecins Sans Frontières and analysed by Hudson Institute says that in some cases, prices of drugs (antiretrovirals in the survey) in low income countries from the originator are comparable or even below than the prices offered by generic companies.²³ Thus, while the compulsory licensing may enable better accessibility, they do not necessarily reduce drugs prices. For that reason, if India chooses to override patents on the sole ground that generics will allow more access and availability to patients in LDCs such as in Nepal, the reason will be India's ability to produce these drugs and supply which the LDC may not be capable of doing, apart from humanitarian considerations.²⁴

Compulsory License: An Accomplice to Arbitrage and Counterfeiting

What's more, the drug patent wars have undeniably reached new battle fronts. The question now relates to the world markets as the Indian economy integrates and establishes its niche internationally. Despite tremendous efforts to create a diplomatic compulsory licensing system, TRIPS in its current construction has not fully addressed the allied concepts of counterfeit drugs and arbitrage that are made easier to

breed through compulsory licensing. Although a single act to permit exportation to a least developing country by a growing small-scale pharmaceutical company would not do much to the global bottom-lines of patent holders, should Natco's case stand, the lawsuit can open floodgates for Indian and foreign generic companies which could start flooding to substantial parts of world markets. Fastened to the above is the threat of arbitrage. Arbitrage occurs when a non-counterfeit drug is imported to a market where they are priced low as a result of a license etc. and re-exported to a market where it is priced higher without the consent of the patent holder (parallel imports). TRIPS does not currently mandate its members to adopt any specific measures to prevent arbitrage as a pre-condition to compulsory licensing.²⁵ However, they are only expected to take 'reasonable measures'²⁶ in this regard. Markets around the world are being flooded with 'parallel imports' and 'gray market' goods.²⁷ The central apprehension is that once compulsory license to export are granted it will put in place a proper and defined legal route under which these drugs will be traded at prices pegged at any rate lower than that of patented drug. How these drugs are circulated and rerouted will depend upon the legal status of the importing jurisdictions. In such a case, compulsory licensing with no clear standards against arbitrage will increase the probability that consumers in developed countries will inadvertently purchase substitutes in an effort to purchase cheaper drugs.²⁸ The risk of arbitrage is amply illustrated in the international developments through cases like the *Glaxo Group Ltd v Dowellhurst Ltd*²⁹ case. Watching through international enlargements, it can also be pointed out that a recent EU Council regulation was directed at preventing diversion of lower-price AIDS drugs from Africa into the EU through unique labeling, differential coloration, and enhanced legal barriers.³⁰ Similar rules should apply before any license is granted under the paragraph 6 provisions under WTO stipulations.

Almost certainly, the general consensus asserts that arbitrage chips away at already-existing efforts to provide affordable drugs through differential pricing and kills the incentives for R& D in pharmaceuticals. Therefore, in the light of these considerations, it is essential that providing of drugs through the CL route should be carefully monitored and controlled to ensure that only quality drugs move in those markets.

India in the Global Race of Technology

Above and beyond, it is to be realised that India's pharmaceutical industry even during the process patent era had developed innovative technologies rather than just reverse engineering. For this reason, it is germane to appreciate that western pharmaceutical companies aren't the only ones who stand to lose. Several domestic Indian companies, including *Ranbaxy*, *Dr Reddy's* and *Nicholas Piramal*, are pursuing original research and development—and in some areas, already compete head-to-head with their Western counterparts.³¹ Already, the core issue with the top global R&D based drug companies, namely declining productivity of their in-house R&D and patent expirations of numerous blockbuster drugs, increasing legal and regulatory constraints, more exacting clinical trial requirements and product safety issues are adding to woes.³² While aggressive innovation for new drugs as well as new approaches to drug discovery are happening selectively worldwide and the top-most Indian companies are also attempting to join the fray. Once Section 92A is employed, it might open the Pandora's Box since even drugs from innovative companies in India may be subjected to compulsory licenses particularly for exports to LDCs.

Non-Viability at the International Level

Additionally, Section 92A is said to have anticipated bettering access to medicines among countries that lack manufacturing capabilities. The question that begs an answer is—'will there be enough producers/exporters in case compulsory licensing is adopted and used by many LDCs and others with no technological capabilities? The studies suggest that this may not thrive as illustrated through its under-use in the immediately preceding years. *Amir Attaran*, an immunologist and lawyer, makes this argument based on history of compulsory licenses.³³ As granting of a compulsory license is profoundly characterized by international politics, in view of foreign investments and respect towards international IPRs regime, many companies maybe averse to investments in countries where CLs are rampant. Together with this, when mulled over through a long term perspective, there is no guarantee that the prices for such exports will actually be lower while retaining the same quality and standards as the scale of production for a single national market may not be sufficiently high to achieve economy of scales and costs of setting up of dedicated manufacturing

facility could be critically expensive.¹⁹ What's more to be witnessed, is that national governments world-over will issue a license under sections similar to 92A only when its domestic demand for drugs has been met. Not many developed countries in the world today have that capacity, India perhaps being an exception. Realistically, there is no rock-solid evidence that under prevailing conditions, many countries will use this measure to assist another country that lacks manufacturing capacity.

Recouping the R & D Costs and 'Aggressive Marketing'

Lastly, the success of patents and other intellectual property systems of reward to the innovator rests on the marketability of the products. It is natural that industries which invest in R&D would expect to reap substantial financial gains from their investments and pharmaceuticals industry is no exception. To achieve this 'aggressive marketing' at high costs are often resorted to by companies.³⁴ To ensure adequate market share for the new products against available substitute generic drugs, the new drugs need to be much superior in efficacy and/or be safer.

Exploring Legal Minutiae- Law Procedure Examined

The Patentees' Right to Hearing

The progress of the suit hit a roadblock when the hearing of the patent holder in respect of grant of compulsory license was objected to. This development needs examination. Both under the common law and statutory law, the Controller should grant them a hearing. Even 'Natural-justice' under the fundamental common-law principles obliges him to allow patentees to be heard before any decision adverse to their interests is taken. Secondly, patent is a tradeoff between private and public benefit³⁵ and as 'adequate remuneration' remains highly subjective being based on the controller's discretion; patent holders can not be denied the right to hearing as royalty considerations have great economic significance to the patent holder and it will be unfair to decide without even hearing the stakeholder.. The argument relating to right to hearing is further bolstered as India must grant patentee and applicant a level playing field.

Issue of 'Adequate Remuneration'

The issue of what is an adequate remuneration also needs to be considered. Firstly, TRIPS requires countries utilizing compulsory licensing to pay 'adequate remuneration' without specifying a method

of calculation.³⁶ If the reward system is not adequate to recoup an innovator's investment in the high cost, long gestation R&D activity, that will be a serious disincentive for furtherance of much needed drug discovery and development programmes.

Secondly, it is pertinent to state that Indian law requires the Controller to reflect on 'nature of the invention,' 'the expenditure incurred by the patentee in making the invention,' and other factors in determining adequate remuneration³⁷ but that is limited to the case of ordinary compulsory licenses granted under Section 84. There is no reason why the same should not be extended to cases falling within Section 92A. Therefore, Act should also be amended to include Section 92A in the application of Section 90 and 'adequate remuneration' should be given according to its worth, a conclusive definition and a formula for calculation.

Presently also, Controller would need access to information in the patentees' sole possession to determine what amounted to 'adequate remuneration' for the compulsory license³⁸ and it would only be a redundant supposition that the same can be ascertained without hearing the patentee.

More Determinate terms in Compulsory Licensing Provisions

On its face, the compulsory licensing provisions contain a number of vague terms that are intended to broaden the scope of terms like public health, essential drugs etc. The lack of specificity was perhaps intended to give least developed countries flexibility to decide for themselves grounds on which they could grant compulsory licenses and that nations can minimize delay in accessing essential drugs. In reality, it can create more controversy because any nation can, in theory, declare a public health emergency for questionable reasons to assign compulsory licensing for any patented drug.³⁹ Also, with respect to adequate remuneration, the term 'economic value' has been left undefined. In the light of lack of judicial enunciations in patent law, legislators are required to amend letter of the law so that interests of the subjects do not suffer.

Measures Against Counterfeiting and Arbitrage to be a Precondition for Granting a License

As already stated²⁰, the concepts of arbitrage and counterfeiting of drugs are safeguarded in TRIPS in a very broad-spectrum. The provisions are widely worded and again, 'Reasonable measures' should be allotted a more specific and concrete meaning and

lucid standards together with stringent legal barriers²⁶ to arbitrage should be incorporated in the national law. The status of the importing jurisdiction as regards its legal position to put off arbitrage and thwart counterfeiting should be assessed. Such measures should be made a precondition to the issue of a compulsory license and unless the importing country is equipped and geared up to control circulation of drugs manufactured under licenses, no compulsory license should be issued. Clarifying these ambiguities will not only improve efficiency in utilizing compulsory licenses but may also encourage nations to issue compulsory licenses without concerns of innovators' backlash.

Quite perceptibly, the procedure categorically demands attention. Studies show that if compulsory licensing under Section 92 A becomes an accepted mechanism, it would persuade a lot more generic companies to pursue it in view of a new revenue models available to them. In addition generic companies applying for compulsory licences may continue to launch next generation products through the compulsory licence route quoting essentiality criterion. For example, Natco Pharma itself is reportedly planning to launch their version of Celzentry, a second-line drug of Pfizer against HIV/AIDS.⁴⁰

TRIPS must Develop a Definitive Process

Further, compulsory licenses should not be understood to be an undeviating solution to the malady as it was only an interim waiver ; it was an intended temporary measure with expediency in mind and not a permanent one. Thus the implementation of the compulsory licence has to be terminated the moment the terms under which the licences have been granted are no longer valid. Hence provision is not conducive to long term planning for any company. That may be one of the reasons why so few have been granted so far. Just one in three years and reportedly 23 countries have already agreed not to resort to them. It's time that TRIPS and the new Doha rounds as and when they are completed come with a more definitive process to be followed in these circumstances. What are yet to be effectively pursued are the government-patent-holders' partnership programmes which have time and again delivered effective access to medicines and practice of 'differential pricing' or price-tiering must receive global approval and implementation so that an undefined provision like that of compulsory licensing is not resorted to.

Requisite Standardization of National Legislations

Procedures for issuing a CL vary among countries. In Indonesia, government use has to be authorized by presidential decree. In Malaysia, the Minister of Domestic Trade and Consumer Affairs has the authority to do so, while in Thailand 'any ministry, bureau or department of the government' has this authority. Thus, the national legislations are decisive of the degree to which the conditions for grant of a CL will be strict or lenient. TRIPS does not specify at what level a CL/government-use can or should be authorized & needs to incorporate more workable provisions. An illustrative instance can be traced in the Canada-Rwanda case itself. The Canadian legislation permitted a maximum of two-year term for a CL, not enough to recoup the investment for producing a generic drug. Various pre-grant flexibilities can play a complementary role in safeguarding access to medicines. In addition, role of competition law could be explored further.⁴¹

Global Scenario Future Predictions

The recently revamped rules of compulsory licensing have triggered a spate of challenges to economists and pharma-intellectuals worldwide. As it continues to grow since 2003, when Zimbabwe issued a CL⁴² for all the AIDS/HIV related medicines, there has been a paradigm shift in the implementation of a TRIPS compliant patent laws in many countries. Malaysia, Zambia, Indonesia, Taiwan , China, Canada, Brazil, United States, Cambodia etc., out of which many used the exceptional case of 'government use (GU)', were the other countries to join the bandwagon. Analyses show that the trend has caught up swiftly among the developing countries i.e., Thailand, Brazil, etc. In Canada, CLs have shown tremendous growth from 1970 to 1978, 142 CLs were issued on 47 prescription drugs. Prices of generic versions were 20-60% below the original price, depending on the number of competitors.⁴³ In 2006-07, Thailand⁴⁴ issued CLs for drugs including three for cancer and in South America, the Brazilian government issued one for non-commercial use of the patented *ARV Sustiva (efavirenz)*. In March 2007, the Italian Competition Authority ordered Merck & Co Inc to provide free licences for the manufacture and sale in Italy of the active ingredient *finasteride* of treatment of prostate hypertrophy.

As CLs are picking up at the international picture it has become a 'credible threat' to the patents holders. It may entail dismal consequences as it will make the

exercise a highly commercialized affair, as countries may resort to it only to procure drugs at a lower rate. Thailand being a great case study to elucidate upon what could be the possible implications of compulsory licensing, it could be noted that initially Thailand imported consignment of generic *efavirenz* from India whereas in the meanwhile the national companies started preparations for local production.⁴¹ Similarly, countries may maneuver to build their manufacturing capabilities and then misuse the mace of CLs to thrive against competitors.

Also, it can spell trouble for IP- reliant sectors, particularly, biotechnology firms which are often valued on the basis of the strength of their patent portfolio.⁴⁵ Although there is no biologics CL case as yet, it might become prominent as a result of India's new biopharmaceuticals strategy of producing branded generics. If developing countries continue their attitude to CLs as it stands now it can be easily foreseen that they may 'turn multinationals away' as cautioned by Prasanna Kumar Ghosh, former advisor to government on Biotech. This is not unfounded as when Thailand issued 3 CLs in 2006-07, one of the affected companies withdrew seven pending applications for registration thus effectively withholding them from the Thai market.⁴⁶

Weighed against the other developing countries, India is not yet disposed to scare off investors and use CLs sporadically. If one peruses the Indian experiences in this respect, it should be marked that India has no precedential enunciations over the matter. Even when 'bird flu' created a potential emergency in 2006, India refrained from giving a CL; instead it placed an order for *Tamiflu* with Roche, the original manufacturer.⁴⁵ Also in the present case, India is not in favour of issuing a CL unless there is an epidemic which impacts a large chunk of the population, and needs immediate solution.⁴⁷ Thus seen through above narration, it is easily discernible that India as a developing nation has so far been respectful towards the international patents regime and patentees' rights.

Conclusion

As is reflected by the enormity this verdict is to assume, no prudent IPR legalist would choose to stay oblivious to the commotion caused in the legal circuits as compulsory licensing under Section 92A does the rounds. The examination of the wavering possibilities between which the judgment floats exposes the need for changes in the presently worded

provisions so that both at the interpretation and implementation stages there will be more clarity and equity. The overall implications of the DOHA Declaration and the subsequent rules framed by the TRIPS Council for the utilization of the provisions under Para 6 on the Indian pharmaceutical industry as an instrument for growth of the industry are still not clear. So far the impact has been minimal, but these are early days. Going by the experience of Indian Patents Act 1970, which had provisions for compulsory licences as well as licences of right (for pharmaceuticals), the present provisions, if they are not amended to make them user-friendly and practical are unlikely to be a major factor for either India as a supplier or for the recipients (patients in India, other developing and least developed countries).

Should Natco's case stand, it will entail severe repercussions world over as India will make significant changes in its approaches to meet the increasing demands for better access to life saving drugs which are still under patent protection. One of the findings of this paper is that that patents are not the only barriers to fair accessibility to drugs and present provisions for the issue of compulsory licenses are certainly not the answer to the problems faced by large populations in need of drugs, patented or off-patent in the poor countries of the world. At the same time the role of patents as system of reward for offer a major stimulus to continued R & D in pharmaceuticals cannot be minimized. The paper is in consonance with the proposition that IPRs protection systems are commercial instruments meant for promoting research and innovation and no efforts should be made including wide interpretations of CL provisions to reduce the impact that IPR protection on new drug discovery and development.

References

- 1 Outterson Kevin, Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets, *Yale Journal of Health Policy Law & Ethics*, (5) (2005)193-194. The study clearly highlights that the key in evaluating policy trend of TRIPS is Article 7 which envisages balancing of these two competing interests.
- 2 Santoro Michael A, Human rights and human needs: diverse moral principles justifying third world access to affordable HIV/AIDS drugs, *North Carolina Journal of International Law and Commercial Regulation*, 31 (4) (2006) 923, 925.
- 3 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. WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, para. 4 (14 Nov 2001).

- 4 India too did the same. Under Indian Law, Chapter XVI of the Patents Act deals with compulsory licenses. This chapter is drafted along the lines of Article 31 of the TRIPS Agreement.
- 5 Compulsory licensing allows a government to produce, import, sell and use generic products before expiry of the patent by licensing a company, government agency or other party the right to use a patent without the consent of the patent holder. The objective of granting compulsory licenses is to prevent the abuse of monopoly granted by the patent, and to safeguard the public welfare and health care issues prevailing in the nations. In the present context, the exercise is sought to obtain permission to manufacture the generic versions of a patented drug.
- 6 Brundtland Gro Harlem, *Director-General of World Health Organization*: in opening address to the World Health Assembly, May 2001.
- 7 Principally, those on the UN's list of least-developed countries and certain other countries having per-capita incomes of less than US \$745 a year.
- 8 The first compulsory licenses for export were issued by Canada and Rwanda. The licences enabled Canada's manufacturer *Apotex* to manufacture and export copies of the anti-AIDS drug *TriAvir*, patented by *GlaxoSmithKline*, to Rwanda. Indian Natco Pharma's application is the second time this provision has come under review.
- 9 Section 92A reads as:
 - (1) Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.
 - (2) The Controller, shall on receipt of an application in the prescribed manner, grant a compulsory license solely for the manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.
- 10 Canada is first to grant WTO compulsory licence for export of generic drug, Boscariol John W, Silva Orlando E, Potter Simon, Swick Brenda C and Nador Anita, <http://www.mondaq.com/article.asp?articleid=58946> (6 June 2008).
- 11 Four of these patents were owned by the Glaxo Group, two by the Wellcome Foundation, two by Shire Biochem and one by Boehringer Ingelheim and Dr Karl Thomae GmbH. P Hestermeyer, 'Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines' ASIL (American Society of International Law) Insight, *International Economic Law Edition*, 10 December 2007, 11(28) (2007), <http://www.asil.org/insights/2007/12/insights071210.html> (6 June 2008).
- 12 Generics are drugs which are produced and distributed without patent protection. A generic usually contains the same active ingredients as the original formulation. In most cases, it is considered bioequivalent to the brand name counterpart with respect to pharmacokinetic and pharmacodynamic properties. By extension, therefore, generics are assumed to be identical in dose, strength, route of administration, safety, efficacy, and intended use.
- 13 '*Roche v Natco: India's First 'Doha Style' Compulsory License?*' <http://spicyipindia.blogspot.com/2008/01/roche-vs-natco-indias-first-doha-style.html> (29 March 2008).
- 14 *Médecins Sans Frontières* or '*Doctors without borders*' (as referred to in US) is a secular international humanitarian aid organization which was created in 1971. It provides emergency medical assistance to war-torn regions and to populations in danger in developing countries due to endemic diseases or otherwise.
- 15 Silverman Ed, India to consider issuing compulsory licenses, 21 February 2008, <http://www.pharmalot.com/2008/02/india-to-consider-issuing-compulsory-licenses> (30 March 2008).
- 16 Joseph Reji K, Rwanda to import of patented medicines under compulsory license, 26 July 2007, <http://www.essentialdrugs.org/indiadrug/archive/200707/msg00035.php> (9 June 2008).
- 17 Bate Roger, Patent Absurdity, *Wall Street Journal*, 13 March 2008, http://www.aei.org/publications/filter..pubID.27639/pub_detail.asp (30 March 2008).
- 18 Cool K and Dierickx I, Rivalry, strategic groups and firm profitability- an analysis of the US pharmaceutical Industry, *Strategic Management Journal*, 14 (1993) 47-59 and Afuah A, *Technical progress and product market success in pharmaceuticals: The case of cholesterol ethical drugs*, POPI Working Paper, Chapter I- Medicines Innovation, p.14, Massachusetts Institute of Technology, Cambridge, MA USA, 1992.
- 19 Sykes Richard, *New medicines: The practice of medicines and public policy*, The Nuffield Trust, The Stationery Office, London, 2000.
- 20 Noehrenberg Eric, The realities of TRIPS, patents and access to medicines in developing countries, in *The Intellectual Property Debate, Perspectives From Law, Economics and Political Economy*, edited by Meir Perez Pugatch (Edward Elgar Publishing, UK), 2006, p.172.
- 21 Hawkins Douglas, Studies on the cost of patenting, *University of Baltimore Intellectual Property Law Journal*, 1997 cited in Noehrenberg Eric, The Realities of TRIPS, Patents and Access to Medicines in Developing Countries, *The Intellectual Property Debate, Perspectives from law, Economics and Political Economy*, edited by Meir Perez Pugatch (Edward Elgar Publishing, UK), 2006, p.172.
- 22 Attaran Amir, How Patents and Economic Policies affect the access to essential medicines in developing countries?' *Health Affairs*, 23(3) (2004) 159.
- 23 Adelman Carol C, Jeremiah Norris, Jean Weicher S, *Myths and realities on prices of AIDS drugs*, Report, Hudson Institute, 2004, <http://www.hudson.org/files/publications/AdelmanARVWhitePaper.pdf>. (31 May 2008).
- 24 The reason for the proposition being that, if, in future these generics are priced above or at par with the originators products they would neither increase accessibility nor contest with the originators with respect to price. It will be clear exploitation of obvious loopholes of the law resulting in extermination of the rights of the patent-holders for the sake of short term revenue gains in favor of generics manufacturers.
- 25 Kim Do Hyung, *Research Guide on TRIPS and Compulsory Licensing: Access to Innovative Pharmaceuticals for Least Developed Countries*, February 2007 in *Globallex* http://www.nyulawglobal.org/globallex/TRIPS_Compulsory_Licensing.htm (5 May 2008).

- 26 Reasonable measures under TRIPS are very widely-worded general requirements, which mandate that—(a)drugs made under compulsory licenses be designated by distinctive packing, colors and shapes to detect acts of arbitrage and identify the source of production or export and (b) members who import and export pharmaceutical products under a compulsory license to send notice of the details of the transaction, such as name of the drug, name and address of the manufacturer, name and address of the importer, quantity, and duration etc.
- 27 Sever Mark J, Jr., Protecting your brands from parallel imports, <http://www.archerip.com/protecting-your-brands-from-parallel-imports/> (7 April 2008).
- 28 Hilboldt Jim, Counterfeit Medicines outside the United States: Challenges and Responses, 878 PLI/Pat 869 (2006) in Research Guide on TRIPS and Compulsory Licensing: Access to Innovative Pharmaceuticals for Least Developed Countries, Kim Do Hyung, http://www.nyulawglobal.org/globalex/TRIPS_Compulsory_Licensing.htm (5 May 2008).
- 29 *Glaxo Group Ltd v Dowelhurst Ltd* [2004] E.T.M.R. 39 (31 July 2003), In this recent case, reportedly, low cost AIDS drugs intended as charitable donations for Africa were being diverted and allegedly found their way back to the UK.
- 30 Outterson Kevin and Kesselheim Aaron S, Market-based licensing for HPV vaccines in developing countries, <http://content.healthaffairs.org/cgi/content/full/27/1/130?ck=nck> (7 April 2008).
- 31 Silverman Ed, India to consider issuing compulsory licenses, <http://www.pharmalot.com/2008/02/india-to-consider-issuing-compulsory-licenses> (30 March 2008).
- 32 Subramanian K V, Imperatives for the Indian pharmaceutical industry in a changing world, <http://www.expresspharmaonline.com/20080131/indianpharmain202004.shtml> (13 April 2008).
- 33 Attaran Amir, Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution, *Emory International Law Review*, 17(2003) 734.
- 34 View drawn from, *The Truth About Drug Companies*, Marcia Angell, *New York Review Books*, 15 July 2004.
- 35 Goren David, Pharmaceutical Innovation & Intellectual Property Rights A Global Public Good, *The Intellectual Property Debate, Perspectives from Law, Economics and Political Economy*, edited by Meir Perez Pugatch (Edward ElgarPublishing, UK), 2006, p.172.
- 36 Mercurio Bryan C, TRIPS, patents, and access to life-saving drugs in the developing world, *Marquette Intellectual Property Law Review*, 8(2) (2004) 211, 242-44 (Reasoning that the ambiguous provision for 'adequate remuneration' invites future disputes).
- 37 Relevant section being Section 90 of the Indian Patents Act, Section 90 reads as—
- Terms and conditions of compulsory licences:
- (1) In settling the terms and conditions of a licence under Section 84, the Controller shall endeavor to secure—
- (i) that the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors.
- 38 *Natco v Roche/Pfizer*: Hearing on the right to hearing, 21 March 2008, <http://spicyipindia.blogspot.com/2008/03/natco-vs-rochepfizer-hearing-on-right.html> (1 May 2008).
- 39 Gupta Vishal, A Mathematical Approach to Benefit-Detriment Analysis as a Solution to Compulsory Licensing of Pharmaceuticals Under the TRIPS Agreement', 13 *Cardozo Journal of International & Comparative Law*, 13 (2) (2005) 631, 647.
- 40 Unnikrishnan C H, Natco to now take on Pfizer over HIV drug, 8April 2008, <http://www.livemint.com/2008/04/08001147/Natco-to-now-take-on-Pfizer-ov.html> (01 May 2008).
- 41 'Briefing Note on Access to Medicines', World Health Organization, Western pacific region, Regional office for South- East Asia, February 2008, p.2, 5.
- 42 *Varichem Pharmaceuticals Ltd*, was authorized to produce ARVs or HIV/AIDS-related medicines during the emergency period and the medicines produced under the licence were to be subject to price controls.
- 43 Lexchin J, Pharmaceuticals, patents, and politics: Canada and Bill C-22, *International Journal of Health Survey*, 23(1) (1993) p.147-160.
- 44 Thailand issued its first CL in November 2006, for *efavirenz*. In January 2007, two more compulsory licenses were issued, for *lopinavir/ritonavir* and for a cardiovascular drug, *clopidogrel*.
- 45 Jayaraman K S, Biotech patents and the future of compulsory licensing, 22 May 2008, <http://spicyipindia.blogspot.com/2008/05/ks-jayaraman-on-biotech-patents-and.html> (2 June 2008).
- 46 Though later these may have been resumed but the immediate effect was withdrawal of marketing of these drugs, 'Briefing Note on Access to Medicines', World Health Organization, Western pacific region, Regional office for South- East Asia, February 2008, p. 2.
- 47 We are not in favour of CL unless there is an extraordinary problem. There is no point in going in for CL unless there is an epidemic which impacts a large chunk of the population, and needs immediate solution,- A senior official of Department of Industrial Policy and Promotion (DIPP) Silverman Ed.). Govt. may use compulsory licensing for drug companies only in emergency, *The Economic Times*, April 03, 2008, http://economictimes.indiatimes.com/News/News_By_Industry/Healthcare__Biotech/Healthcare/Govt_may_use_compulsory_licensing_for_drug_companies_only_in_emergency/articleshow/2921237.cms (9 June 2008).