

NATCO PHARMA LTD. V. BAYER CORPORATION AND THE COMPULSORY LICENSING REGIME IN INDIA

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The access versus profit debate is a worldwide phenomenon in the pharmaceutical industry and India is no exception. In recent times however, India's increasingly visible, pro-access stance has developed new teeth. In a spate of patent cases, the judiciary has made it clear that public interest is of prime importance and India will not tolerate the exploitation of its masses by drug giants looking to reap benefits. It was in this vein that the IPAB rendered its decision in Natco v. Bayer. Unfortunately however, the base created by the ruling remains weak at best. Not only does it fail to address crucial issues that could shape the future of Indian law in this area, but it also fails to consider the logical corollaries of its reasoning in some aspects. This note seeks to critically analyse the judgment in this light and explore the way forward. It argues that the decision's overall interpretation of law, though sound in the factual matrix of this case, is problematic in the larger picture. The note concludes by outlining the possible effects of the decision on India's pharma-patent regime and setting out the lessons to be learnt by the drug manufacturers.

I. INTRODUCTION

The compulsory licensing debate in relation to pharmaceuticals has been a talking point for a long time now.¹ So when, on March 4, 2013, the Intellectual Property Appellate Board ('IPAB') dismissed the appeal filed by Bayer Corporation ('Bayer') and confirmed the compulsory license given to Natco Pharma Ltd. ('Natco') for the production of Bayer's patented kidney-cancer drug Nexavar ('the drug'), it marked a momentous occasion in Indian

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¹ See Sara M. Ford, *Compulsory Licensing Provisions under the TRIPS Agreement: Balancing Pills and Patents*, 15(4) AMERICAN UNIVERSITY INTERNATIONAL LAW REVIEW 941, 953 (2000) (Discussing the long-standing conflict between the right to access life-saving medication and the profit-driven agendas of pharmaceutical companies in restricting such access); See also, Eric Bond and Kamal Saggi, *Compulsory Licensing, Price Controls, And Access To Patented Foreign Products*, 7 (The Department of Economics, Vanderbilt University, Working Paper No. 12-W05, 2012), available at <http://www.vanderbilt.edu/econ/wparchive/workpaper/vu12-w05.pdf> (Last visited on May 12, 2013) (Discussing the effects of compulsory licensing on prices, welfare and the decision of pharmaceutical companies to work their patents in a foreign market).

pharmaceutical patent history.² Even as the spotlight has been focussed on compulsory licensing regimes post the adoption of the Doha Declaration,³ Part II of the paper examines how developing nations such as India have been engaged in a long-drawn battle with big pharmaceutical manufacturers to increase access to essential drugs. Against this backdrop, the decision in *Bayer Corporation v. Natco Pharma Ltd.* (*Natco v. Bayer*),⁴ which is analyzed in Part III, sheds new light on issues arising out of this debate, giving a brief glimpse of what the future of compulsory licensing in India could look like.

Part IV of this paper undertakes a critical analysis of the ruling in *Natco v. Bayer* and its possible implications on the law and practice of compulsory licensing in India. I argue that even though the landmark decision reasonably addresses questions in the specific facts of the case, in the larger picture, it fails to answer many crucial questions that will shape the contours of the compulsory licensing regime in India. Restricting itself to the narrow factual matrix before it, the decision successfully shirks responsibility for propounding broader principles of pharmaceutical patent law that could have far-reaching ramifications. In addition, it examines the issue of compulsory licensing in the broader framework of the Agreement on the Trade-Related Aspects of Intellectual Property Rights ('TRIPS'). Finally, the paper outlines the potential effects of the decision and implores the exercise of caution in respect of compulsory licensing.

II. THE BACKGROUND STORY: DRUG GIANTS V. THE THIRD WORLD

The idea of granting patent protection to pharmaceuticals, especially essential drugs, has always been a contested one. The inherent tussle between profit-driven drug companies and welfare oriented governments seeking to ensure cheaper access to essential medicines has frequently occupied the global centrestage.⁵ Even though Article 7 of the TRIPS specifically provides that one of its objectives is to ensure that information sharing can help both manufacturers and consumers, pharmaceutical companies have continued to

² *Bayer Corporation v. Natco Pharma Ltd.*, Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

³ The Doha Declaration on the TRIPS Agreement and Public Health, 2001 (Adopted on November 14, 2001).

⁴ *Bayer Corporation v. Natco Pharma Ltd.*, Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁵ Reuters, *Analysis: India Cancer Ruling Opens Doors for Cheaper Drugs*, March 13, 2012, available at <http://www.reuters.com/article/2012/03/13/us-india-drugs-idUSBRE82C01N20120313> (Last visited on May 12, 2013).

denounce the practice of compulsory licensing worldwide.⁶ The crux of this debate, therefore, lies in balancing the two competing claims.

On one side are the pharmaceutical giants, supported by much of the developed world, who demand increased patent protection under stricter intellectual property rights regimes, citing it to be the “bedrock of their business”.⁷ They contend that increased usage of compulsory licenses will disincentivize research and development (‘R&D’) and use TRIPS provisions to supplement their demand for longer patent protection.⁸ Owing to high R&D costs, they argue that it is inevitable that the prices of drugs, especially path-breaking essential ones like Glivec,⁹ will skyrocket. As a result, the argument proceeds, having shorter patent periods by granting compulsory licenses is not just inequitable but also stifles innovation in the long-term.¹⁰ However, critics point out that even assuming that the prices offered by drug companies are not solely profit-driven,¹¹ these allegations no longer hold water. It has been proven that the biggest driving factor for innovation is, in fact, markets.¹² Thus, given that drug companies’ point of focus is on developing the most saleable drugs rather than the most needed ones, longer patents will only serve to enhance their prof-

⁶ Divya Murthy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health*, 17(6) AMERICAN UNIVERSITY INTERNATIONAL LAW REVIEW 1299, 1310-1314 (2002); TRIPS, Art.7 provides as follows: Objectives - The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

⁷ David W. Opderbeck, *Patents, Essential Medicines, and the Innovation Game*, 58(2) VANDERBILT LAW REVIEW 501, 519 (2005).

⁸ Patent requirements of TRIPS can be found in Arts. 27–34, which form a comprehensive code for all aspects of patent regimes, including provisions for compulsory licensing. World Intellectual Property Organization, *The Impact of the International Patent System on Developing Countries: A Study by Getachew Mengistie*, A/39/13/Add. 1, August 15, 2003, available at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=17555 (Last visited on May 12, 2013).

⁹ Glivec is Novartis’ cancer drug, the patent battle for which recently concluded with the Indian Supreme Court rejecting the patent application. See Reuters, *Novartis Loses Landmark India Patent Case on Glivec*, April 2, 2013, available at <http://in.reuters.com/article/2013/04/01/india-drugs-patent-novartis-glivec-idINDEE93000920130401> (Last visited on May 12, 2013).

¹⁰ Sara M. Ford, *Compulsory Licensing Provisions under the TRIPS Agreement: Balancing Pills and Patents*, 15(4) AMERICAN UNIVERSITY INTERNATIONAL LAW REVIEW 941, 953 (2000).

¹¹ The most common criticism of drug companies is that they are driven solely by profit incentives. Even in instances where R&D costs are not an issue, they continue to exploit markets in developing nations with high prices. See F.M. Scherer and Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, 4 (Commission on Macroeconomics and Health, World Health Organization, Working Paper No. WG4: 1, 2001).

¹² See, e.g., Els Torreale ET AL, *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 359 THE LANCET 2188 (2002), available at <http://download.thelancet.com/pdfs/journals/lancet/PIIS0140673602090967.pdf?id=f1b40765af4fa604:-36a4b4c9:13fb74521b9:7fc71373176410307> (Last visited on July 6, 2013); See also, Kellogg School of Management, *The Innovation Gap in Pharmaceutical Drug Discovery & New Models for R&D Success*, March 12, 2007, available at <http://www.kellogg.northwestern.edu/biotech/faculty/articles/NewRDModel.pdf> (Last visited on July 7, 2013).

its.¹³ In fact, studies have shown that barring a few exceptional circumstances, there is *no link* between compulsory licensing and sluggish innovation rates or a decline in R&D.¹⁴ Moreover, as a previous instance involving the United States has established, developed countries can be hypocritical about their stance, themselves using the threat of compulsory licenses in times of need.¹⁵ In recent times, there have even been instances of drug makers voluntarily agreeing to provide otherwise expensive, life-saving drugs at a cheap price.¹⁶ Coupled with other factors, this only goes to illustrate that the objections raised by pharmaceutical makers are in fact largely baseless and driven by ulterior motives. Nevertheless, they have continued to refute the falsity of such allegations, and have made it difficult to completely disregard their interests owing to their immense economic prowess.¹⁷

On the opposite side, these drug giants are countered by developing nations who want to shorten patent life and want flexibility to grant compulsory licenses in order to ensure greater access to essential medicines.¹⁸ According to them, high levels of income inequality coupled with poor infrastructure make it extremely difficult for the State to provide essential medicines at affordable prices in large quantities.¹⁹ At the same time, the gap in the access to such life-saving medication continues to be alarming. Statistics from the World Health Organisation reveal that the average availability of essential medicines across the world is an abysmal 51.8 per cent in public sector health facilities.²⁰ Developing countries are, as a result, advocates for allowing government autonomy in the endowment of compulsory licenses,²¹ although they

¹³ The Wall Street Journal, *Should Patents on Pharmaceuticals Be Extended to Encourage Innovation*, January 23, 2012, available at <http://online.wsj.com/article/SB10001424052970204542404577156993191655000.html> (Last visited on May 12, 2013).

¹⁴ Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKLEY TECHNOLOGY LAW JOURNAL 853 (2003).

¹⁵ Murthy, *supra* note 6, 1314-1315.

¹⁶ Reuters, *Roche to Sell Cheaper Cancer Drugs in India*, March 23, 2012, available at <http://www.reuters.com/article/2012/03/23/us-roche-india-cancer-idUSBRE82M0AQ20120323> (Last visited on May 12, 2013).

¹⁷ The economic power of pharmaceutical companies stems primarily from two factors – their backing by powerful governments and the dire need of their investments, products and advanced technologies in the developing nations.

¹⁸ Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the 'Doha' Solution*, 16-18 (The Law School, The University of Chicago, John M. Olin Law and Economics Working Paper No. 140, 2002), available at http://www.law.uchicago.edu/files/files/140.Sykes_TRIPs_.pdf (Last visited on May 12, 2013).

¹⁹ Sean Flynn ET AL, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 JOURNAL OF LAW, MEDICINE AND ETHICS 184, 188-190 (2009).

²⁰ MDG Gap Task Force Report (2012), *The Global Partnership for Development: Making Rhetoric a Reality*, 62, available at http://www.who.int/medicines/mdg/mdg8report2012_en.pdf (Last visited on July 7, 2013).

²¹ J. Watal, *Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?* (Center for International Development, Harvard University, Science, Technology and Innovation Discussion Paper No. 8, 2000).

are often coerced into submission by developed countries through threats such as trade sanctions and blacklisting.²²

One of the commonly proposed solutions to boost access to unaffordable life-saving medication is compulsory licensing, although its success remains tentative. Typically granted to ensure that patented inventions are reasonably worked to the benefit of the public, compulsory licenses constitute a severe incursion into the patentee's exclusive field of operation.²³ Compulsory licenses take the form of an authorization given to a third party to use the patent without the patentee's consent. The classic rationale for allowing compulsory licensing is that public welfare, and particularly health, in the immediate term outweighs the long-term objective of encouraging innovation.²⁴ While this does not, in any manner, indicate an absolute sacrifice of innovation, the pressing nature of public health can necessitate a compromise, placing innovation at a lower priority. Pharmaceutical companies, supported by developed nations, argue precisely against such a compromise.²⁵ They claim that greater patent protection equals better innovation and by making such a compromise, their incentive to innovate gets adversely affected. However, as already mentioned above, this presumption no longer holds true.²⁶ Evidence shows that the level of pharmaceutical patent protection, especially in developing nations, is irrelevant in spurring innovation.²⁷ The suitability of compulsory licenses is not therefore, affected by such concerns. Nevertheless, since the enactment of the TRIPS, different developing nations have adopted different strategies to deal with this power struggle.²⁸ While some, like Brazil, have managed to use the threat of compulsory licensing effectively to make pharmaceutical companies bow before them,²⁹ others like Thailand and Egypt have been at the receiving end of the ire of nations such as the United States.³⁰ In fact, signatories of TRIPS

²² The Washington Post, *African AIDS Victims Losers of a Drug War: U.S. Policy Keeps Prices Prohibitive*, December 4, 1999, available at <http://www.washingtonpost.com/wp-srv/WPcap/1999-12/04/007r-120499-idx.html> (Last visited on May 12, 2013).

²³ Sonia Baldia & Martin Aldeman, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 VANDERBILT JOURNAL OF TRANSNATIONAL LAW 507, 524 (1996).

²⁴ Sara Germano, *Compulsory Licensing Of Pharmaceuticals In Southeast Asia: Paving The Way For Greater Use Of The Trips Flexibility In Low-And Middle-Income Countries*, 76(1) UMKC LAW REVIEW 273, 279-80 (2007).

²⁵ Sykes, *supra* note 18.

²⁶ See *supra* text accompanying note 12.

²⁷ Opderbeck, *supra* note 7.

²⁸ TRIPS came into force on January 1, 1996. It was followed by the Doha Declaration on November 14, 2001 which specifically sought to address concerns regarding this issue.

²⁹ For a detailed account of how Brazil used this threat effectively, see Tina Rosenberg, *Look at Brazil*, The New York Times January 28, 2001, available at <http://www.nytimes.com/2001/01/28/magazine/look-at-brazil.html?pagewanted=all&src=pm> (Last visited on May 12, 2013).

³⁰ See Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5(1) YALE JOURNAL OF HEALTH POLICY, LAW & ETHICS 193 (2005) (For a narration of Thailand's and Egypt's fate).

have not been able to arrive at a mutually acceptable middle ground till date, although scholars have tried to develop many potential models of cooperation.³¹

The IPAB's path-breaking decision in *Natco v. Bayer* comes against this background. By virtue of being the first ever compulsory license to be granted by India, it is expected, *inter alia*, to bring about a windfall for other license-seekers.³² In many other spheres however, it seems to have left a lot to the imagination. What does this mean for the future of patent rights in India? How does this impact the global scenario and what could be its possible effects? In order to answer these questions, the next section broadly outlines the salient features of the decision and analyses its impact.

III. THE DECISION IN NATCO V. BAYER

Natco's application for a compulsory license for Nexavar³³ was filed before the Controller General of Patents ('the Controller') in 2011, under §84(1) of the Indian Patents Act, 1970 ('the Act').³⁴ In a judgment delivered on March 9, 2012, the Controller granted the license to Natco, against which Bayer appealed to the IPAB. In the interim, Bayer sought a stay on the Controller's decision but this was denied by the IPAB.³⁵ Even though the IPAB's decision was largely the same as that of the Controller, they differed slightly on some aspects. Referring to the Report of the Justice N. Rajagopala Ayyangar Committee, TRIPS and the Code of Federal Regulations of the United States, the IPAB approached the dispute from a public health perspective in the context of the

³¹ Eric Bond & Kamal Saggi, *Compulsory Licensing, Price Controls, And Access To Patented Foreign Products*, 7 (The Department of Economics, Vanderbilt University, Working Paper No. 12-W05, 2012), available at <http://www.vanderbilt.edu/econ/wparchive/workpaper/vu12-w05.pdf> (Last visited on May 12, 2013).

³² India Knowledge@Wharton, *Sparring Over Sorafenib: How Will Natco's Move against Bayer Affect Pharma Licensing?*, April 19, 2012, available at <http://knowledge.wharton.upenn.edu/india/article.cfm?articleid=4681> (Last visited on May 12, 2013).

³³ Chemically known as 'Sorafenib Tosylate', the drug is used for the treatment of advanced stage liver and kidney cancer. By stopping the growth of new blood vessels and impacting other cellular growth mechanisms, the drug can extend the life of a patient, the duration being between 6 months and 5 years.

³⁴ The Indian Patents Act, 1970, §84(1) reads as follows:

84. *Compulsory licences*.—(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:

- (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
- (b) that the patented invention is not available to the public at a reasonably affordable price, or
- (c) that the patented invention is not worked in the territory of India.

³⁵ Reuters, *Bayer's Plea for Stay on Nexavar Generic in India Dismissed*, September 17, 2012, available at <http://in.reuters.com/article/2012/09/17/india-bayer-natco-idINL3E8KH5F320120917> (Last visited on May 12, 2013).

right to life under Article 21 of the Constitution of India, 1950³⁶ and flagged the major issues based on the three-pronged test laid out in §84(1) of the Act.³⁷

Dealing first with the technical and procedural hurdles, the IPAB dismissed Bayer's contention that they had not been heard or given notice before arriving at a *prima facie* determination under §87(1) of the Act.³⁸ Glossing over the issue in a short paragraph, the IPAB clarified that the principle of *audi alteram partem* would come into play only after the Controller decided, on a *prima facie* satisfaction, that the case needed to be heard. Therefore, the question of serving notice for making the *prima facie* determination did not arise at all.

Next, they addressed the question of Natco's attempts to obtain a voluntary license. They disagreed with Bayer's contention that Natco had not made reasonable efforts to negotiate the terms of a potential license, categorically stating that once Natco's request was rejected as per §84(6)(iv), there was no obligation to make further attempts to do so. Although this finding of the IPAB seems to have been reasonable with respect to the particular facts of this case, its application elsewhere could be problematic. The order itself recognises that even though the Controller had found the language of the letter sent by Natco to be harsh, the IPAB did not believe there was any need for niceties.³⁹ This line of reasoning not only seems to lower the obligation to attempt to obtain a voluntary license but also significantly impacts the nature of communication that could be construed as an 'attempt'. It could allow compulsory license applicants to successfully employ the threat of a potential compulsory license as a bargaining chip for obtaining a voluntary license on favourable terms. On the flip side, this will force patent holders to make reasonable and concerted

³⁶ Art. 21 of the Constitution of India, 1950 protects the right to life, which has been subjected to wide judicial interpretation. See Constitution of India, 1950, Art.47 (In the specific context of public health).

³⁷ Reference was also made to the Paris Convention for the Protection of Industrial Property, 1883 and the Doha declaration on the TRIPS Agreement and Public Health, 2001. In fact, the IPAB outlined the following four markers to be kept in mind while dealing with this issue:

- (a) Patents are not granted for an import monopoly of the patented article,
- (b) The grant of a patent shall not impede protection of public health,
- (c) The grant of a patent must balance the rights and obligations and finally,
- (d) It must make the benefits of the patented invention available at a reasonably affordable price to the public.

³⁸ §87 deals with the procedure for dealing with applications for compulsory licenses and revocation of licensed patents. §87(1) reads as follows:

87. *Procedure for dealing with applications under sections 84 and 85.*—(1) Where the Controller is satisfied, upon consideration of an application under section 84, or section 85, that a *prima facie* case has been made out for the making of an order, he shall direct the applicant to serve copies of the application upon the patentee and any other person appearing from the register to be interested in the patent in respect of which the application is made, and shall publish the application in the official journal.

³⁹ See Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 16 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

efforts to engage in negotiations with voluntary license seekers, rather than summarily rejecting such requests without serious consideration.

On the last technical objection of Natco's failure to file evidence for its claim, the IPAB opined that there was no such specific requirement to do so under the Act. In fact, it went so far as to say that even if some evidence had not been filed, the objection should have been raised before the Controller and that this, in itself, would not be a ground for allowing the appeal.⁴⁰ This holding of the IPAB is particularly interesting because it creates ambiguity with respect to how instances where the Controller's decision is based on incomplete facts should be treated in appeal. For instance, can the IPAB call for further evidence at the appellate stage or is it required to set aside the order for insufficient evidence? If the order is set aside, will it be open to the applicant to file a fresh application with complete data?

Moving to the substantive questions, the IPAB began, *first*, by examining the role of CIPLA in the dispute. CIPLA had been selling a generic version of Nexavar for the much lower price of Rs. 30,000/- per month (to Bayer's Rs. 2,80,428/- per month) since 2010 and a patent infringement suit filed by Bayer was pending against them. Given these facts, Natco contended that Bayer should not be permitted to include CIPLA's sales made in the total sales of the drug in India since Bayer alone was responsible for satisfying the reasonable requirements of the public under §84(1)(a). Bayer countered by pointing towards the injustice that would be caused if CIPLA's sales were not taken into account for this purpose. Bayer argued that because CIPLA was selling a version of the same drug, if consumers purchased CIPLA's drug, they would obviously not be required to purchase Bayer's product. Consequently, owing to the low pricing of CIPLA's drug, Bayer's market would get affected and it would be unable to fulfill the condition of satisfying the "reasonable requirements of the public". This in turn would become a legitimate ground for a compulsory license to be issued in respect of Bayer's patented drug, thereby further prejudicing Bayer's interests.⁴¹ The IPAB concluded that the requirement had to be met by Bayer alone and that it could not rely on CIPLA's sales especially since it was contesting CIPLA's market presence in a separate litigation.⁴² The objective of granting a patent is to increase public access to the patented product.⁴³ Consequently, the *quid pro quo* for patent protection is the patentee's obligation

⁴⁰ See Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶¶ 17-18 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁴¹ See Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶¶ 25-26 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁴² See Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 29 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁴³ The Indian Patents Act, 1970, §83(1)(g).

to make the patented product available to the public at affordable prices. The IPAB opined that since the patentee alone was getting the benefit of the patent, the burden of ensuring reasonable access also had to be met solely by the beneficiary i.e., the patentee and/or his licensee(s).⁴⁴ Therefore, it held that CIPLA's presence was irrelevant for the purpose of determining the extent of Bayer's compliance with the law.

On the basis of the law as it exists today, this decision is legally sound. However, from a policy perspective, this could have some serious repercussions for India's patent regime governing pharmaceuticals because it puts patentees in a precarious position. Admittedly, the IPAB could not have ruled on this aspect in the instant case, since CIPLA was not a party. Even so, consideration of this aspect is crucial from the viewpoint of future cases where the facts may present themselves in a different manner.

As Bayer contended, if a hypothetical party A infringes a patent by selling the patented product at lower prices than the patentee and captures its market, the latter will be adversely affected at two levels. *First*, it will be forced to lower its own prices, which could then impact its recovery of R&D costs. Admittedly, this may not always be the case, especially in instances where India is not the primary market for the drug. However, even if this were untrue, being coerced into reducing prices is not likely to go down well with drug companies and could discourage them from further investing in the Indian market.⁴⁵ Additionally, it is important to note that while this scenario only accounts for R&D from foreign drug corporations and not from publicly funded sources, an increasing amount of investment in the drugs and pharmaceuticals sector now comes from such corporations. In fact, in 2013, the drug sector has risen to be the 5th largest FDI-attracting sector in India.⁴⁶ And with 100 per cent FDI being allowed in the pharmaceutical sector,⁴⁷ this investment is only set to increase in the future. Therefore, policies that dampen investment prospects could retard important prospects of future growth.⁴⁸ Further, if A's product continues to be

⁴⁴ See Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶¶ 28-29 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁴⁵ McKinsey & Co., *India Pharma 2020 – Propelling Access and Acceptance, Realising True Potential*, available at <http://online.wsj.com/public/resources/documents/McKinseyPharma2020ExecutiveSummary.pdf> (Last visited on July 7, 2013) (Indicating that dampening of investments could slow down the massive potential for growth of the Indian pharmaceutical industry by 2020).

⁴⁶ DEPARTMENT OF INDUSTRIAL POLICY AND PROMOTION, FACT SHEET ON FOREIGN DIRECT INVESTMENT, April, 2013, available at http://dipp.nic.in/English/Publications/FDI_Statistics/2013/india_FDI_April2013.pdf (Last visited on July 7, 2013).

⁴⁷ DEPARTMENT OF INDUSTRIAL POLICY AND PROMOTION, CONSOLIDATED FDI POLICY, April 5, 2013, available at http://dipp.nic.in/English/Policies/FDI_Circular_01_2013.pdf (Last visited on July 7, 2013).

⁴⁸ See KPMG, *The Indian Pharmaceutical Industry: Collaboration for Growth*, 28, available at <http://www.in.kpmg.com/pdf/Indian%20pharma%20outlook.pdf> (Last visited on July 7, 2013).

priced lower than the patentee's, then it will lead to an overall reduction in the patentee's market share, leaving it vulnerable to compulsory licenses on the ground of insufficient working in the market in question. Additionally, it will have to expend resources to fight a patent infringement suit against A. Together this will create a wholly unfavourable environment for patent-seekers and could dent India's chances of attracting foreign drug makers to set up shops in India. It could also impact the availability of cutting-edge medication in India in the long term, if manufacturers feel that Indian patent laws provide insufficient protection.⁴⁹ On the other hand, in the short term at least, it will provide the much needed impetus to smaller, domestic pharmaceutical manufacturers to increase their outreach. This in turn will advance the public interest by increasing the availability of cheaper, indigenous versions of generic drugs, which has always been one of India's strong points.⁵⁰ Additionally, it will also assuage concerns of smaller players and allow them to tap the enormous potential for generic drugs.⁵¹ However, since this was largely beyond the scope of the IPAB's current order, only future decisions will tell how these aspects shape up.

Secondly, in dealing with the question of whether the reasonable requirements of the public were being met by Bayer, including whether the drug was publicly available at a reasonably affordable price, the IPAB once again chose to adopt the public interest lens. Dismissing Bayer's contentions, it opined that the sole consideration in granting compulsory licenses was whether the patented product was available to the public at a price that was reasonably affordable for them.⁵² Bayer argued that it had instituted an effective Patient Assistance Program ('PAP') subsequent to the application which should be taken into account. However, this was overruled by the IPAB on the ground that philanthropic proposals would not count for the purposes of satisfying the requirements of §84.⁵³ But the IPAB did point out that there was no absolute bar on considering occurrences subsequent to the application.⁵⁴ Thus, if the PAP had met the reasonable requirements of the public, it could have been considered. Since that was not the case, it would not count. All other considerations such as nature of the drug, need for differential pricing etc. were overlooked and the IPAB categorically stated that Bayer had not fulfilled the requirements

⁴⁹ Kiran Mazumdar Shaw, *Glivec Lesson for Pharma: Patented Drugs must be Priced Smartly*, April 3, 2013, available at http://articles.economictimes.indiatimes.com/2013-04-03/news/38248707_1_patent-protection-glivec-indian-patent-act (Last visited on May 12, 2013).

⁵⁰ KPMG, *supra* note 48, at 17-19.

⁵¹ *Id.*, at 5-6.

⁵² See *Bayer Corporation v. Natco Pharma Ltd.*, Order No. 45/2013, ¶ 40 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁵³ See *Bayer Corporation v. Natco Pharma Ltd.*, Order No. 45/2013, ¶ 42-44 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁵⁴ See *Bayer Corporation v. Natco Pharma Ltd.*, Order No. 45/2013, ¶ 42-43 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

in §84(1)(a) by any stretch of imagination. Further, the IPAB reiterated that the patent holder's position was irrelevant in the consideration of compulsory licenses, and the affordability of the patented product for the public was the sole factor in the determination of a compulsory license application.⁵⁵

This part of the decision is especially important not just for potential compulsory license applicants but also for future patent seekers. On one hand, this raises important questions about how exactly 'reasonable affordability' is to be defined from a public perspective. The usage of an ambiguous standard like this could increase the scope for subjectivity. On the other hand however, even without precise definitions, the emphasis on the public perspective is heartening. It illustrates yet again that the focal point of Indian pharmaceutical patent law seems to be on ensuring affordable access to the largest numbers and that the judiciary's primary consideration is that of public interest. The IPAB has sent out a clear message that it will not allow drug companies to wriggle out of compulsory licenses without actually working their patent to the advantage of the public. Indian patents are based on a *quid pro quo* and the IPAB seems unwilling to compromise on this aspect.⁵⁶ In fact, even the Supreme Court seems to be viewing these issues in a similar vein.⁵⁷ From a foreign viewpoint therefore, this is a notable assertion of India's stance and it represents a clear victory for patients and general manufacturers alike.

Thirdly, on the issue of the 'working' of the drug in Indian territory, the IPAB refused to accept Bayer's plea that it was not feasible to manufacture the drug in India and that importation was the only option. Differing slightly from the opinion of the Controller, the IPAB held that the word 'worked' could have a flexible meaning based on the specific facts. However, it pointed out that any contentions regarding the non-feasibility of local 'working' had to be proven, not merely stated. In the instant case, they agreed with the Controller that Bayer had failed to demonstrate why it could not 'work' the drug locally. Therefore, it was held to have failed the test of §84(1) in this regard.

This part of the ruling is remarkable for three reasons. *Firstly*, it imposes an evidentiary burden on the patentee to prove that it cannot meet the requirement of §84(1) by local manufacture. This creates some ambiguity with respect to the extent and manner in which the Court will examine such evidence, since the Act does not deal with these aspects for compulsory license cases. *Secondly*, it demonstrates how the IPAB has cleverly tried to avoid a potential challenge at the World Trade Organization ('WTO') for the violation

⁵⁵ See Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 39-40 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁵⁶ See *supra* text accompanying notes 43-44.

⁵⁷ BBC News, *Novartis: India Rejects Patent Plea for Cancer Drug Glivec*, April 1, 2013, available at <http://www.bbc.co.uk/news/business-21991179> (Last visited on May 12, 2013).

of the TRIPS. Article 27.1 of TRIPS clearly provides that “...patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.” Even while acknowledging this limitation, the IPAB has attempted to evade a legal violation by giving it a different interpretation. They read the TRIPS provision to mean that the requirement of non-discrimination applies only to the final step of revocation of patent, and not to the intermediate measure of compulsory licensing.⁵⁸ Consequently, they opine that compulsory licensing for lack of local manufacture is perfectly legal.⁵⁹ However, the IPAB’s interpretation may not hold water in light of the complex maze of legal provisions that exist in this regard, which is examined in detail later.⁶⁰ Thirdly and most importantly, the opinion contradicts its own stance by conceding that in certain cases, patents may be granted purely for import purposes.⁶¹ While the IPAB has not outlined specific instances where this could occur, its finding assumes significance in light of the broader orientation of the Act. As acknowledged in the decision itself, one of the foremost considerations in pharmaceutical patent cases is that patents are *not* granted to sustain the import monopoly of the manufacturer.⁶² Therefore, if in any given case a patentee is allowed to ‘work’ its patent entirely by importation, it will be against the objectives of the Act itself. By acknowledging such a possibility without elaborating any further, the IPAB may have unknowingly opened a can of worms.

Lastly, in order to meet the ends of justice, the IPAB modified the royalty rate payable by Natco in respect of the license and increased it by 1 per cent to 7 per cent. Although it acknowledged the UNDP recommendation to award a maximum possible royalty of 6 per cent, the IPAB also took note of the disparate profit margins of Bayer (about 14 per cent) and distributors of Nexavar (about 30 percent). Therefore, placing reliance on §90(2), it increased the royalty rate so as to allow Bayer to derive a reasonable advantage from its patent.⁶³

⁵⁸ See Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 52 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁵⁹ See Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 52 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁶⁰ See discussion *infra* Part IV.C.

⁶¹ See Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 52 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁶² See Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 22 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁶³ See Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 54 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

Overall therefore, the IPAB upheld Natco's compulsory license, dismissing Bayer's appeal and modifying only the royalty rate.

IV. THE LARGER PICTURE: WHAT THIS COULD MEAN FOR THE INDIAN PHARMACEUTICAL PATENT REGIME

Even as this order seems to have opened the doors for easier compulsory licensing, its ramifications are not restricted to Indian shores. Domestically as well as internationally, this decision will have a wide-ranging impact on investments in the pharmaceutical industry, research and development costs, trade relations and a variety of other interrelated matters.⁶⁴ This section presents an overview of the potential effects of the decision.

A. INCREASE IN COMPETITION AND EVENTUAL GROWTH OF A HEALTHIER ENVIRONMENT

The decision in *Natco v. Bayer*⁶⁵ has sufficiently indicated the leanings of the IPAB and will serve to encourage other manufacturers to apply for compulsory licenses.⁶⁶ The most obvious impact of the decision therefore, is expected to be the increase in the applications for compulsory licenses. This in turn is likely to have a two-fold effect. One, it will increase competition in the pharmaceutical industry and lead to lowering of drug prices, thereby providing some respite in the form of cheaper access to essential medicines.⁶⁷ In fact, the role of CIPLA in *Natco v. Bayer* is noteworthy in this regard. It illustrates the large trade-off i.e., of revenue from drug sales against the expenses of fighting a patent infringement suit, which local manufacturers are willing to make to cater to the market for life-saving medication. If such practices are not penalised, they may not augur too well for the reputation and strength of the Indian patent regime as a whole. Nevertheless, it is definitely a positive sign for patients.

More importantly however, after a certain period of time, it could also have the counter-intuitive effect of actually reducing applications for compulsory licenses. This would stem from the fact that the threat of a compulsory

⁶⁴ Maricel Estavillo, *India Grants First Compulsory License, For Bayer Cancer Drug*, March 12, 2012, available at <http://www.ip-watch.org/2012/03/12/india-grants-first-compulsory-license-for-bayer-cancer-drug/> (Last visited on May 12, 2013).

⁶⁵ *Bayer Corporation v. Natco Pharma Ltd.*, Order No. 45/2013, ¶ 40 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁶⁶ India Knowledge@Wharton, *supra* note 32.

⁶⁷ Alberto do Amaral, *Compulsory Licensing and Access to Medicine in Developing Countries*, 3 (SELA (Seminario en Latinoamérica de Teoría Constitucional y Política) Paper No. 47, Yale Law School, 2005), available at http://digitalcommons.law.yale.edu/yls_sela/47/ (Last visited on May 12, 2013).

license may coerce drug majors to be more open to permit voluntary licensing.⁶⁸ In addition to greater market competition, voluntary licenses would have the benefit of increasing efficiency and lessening the gestation period for affordable access to essential medicines by reducing the need for state intervention. At the same time, pharmaceutical companies will be able to dictate their own terms to a larger extent, thereby retaining some control over the process.⁶⁹ Overall therefore, this will promote a healthy environment in which all stakeholders will be put in advantageous positions.

B. SATURATION OF THE MARKET AND PATENT 'THICKETS'

A converse, negative effect of an increase in compulsory licensing could emerge from a parallel increase in the number of patents filed. Often, one of the terms of a compulsory license is for the imitation to have a packaging that is distinct from the original.⁷⁰ This includes colour, shape, dosage etc. If *Natco v. Bayer* triggers the threat of a profusion of compulsory licenses, pharmaceutical companies may resort to filing patent 'thickets' in anticipation.⁷¹ Patent 'thickets' are clusters of patents with overlapping claims, such that it becomes a challenge to enter that field without infringing some patent.⁷² As a result, companies wanting to obtain a license face the herculean task of identifying whom they should approach and whose patent they might be potentially infringing.⁷³

After *Novartis AG v. Union of India*⁷⁴ ('Novartis case'), the likelihood of patent thickets becoming prevalent in India is slim.⁷⁵ Nevertheless, if that were to happen, it would lead to a situation similar to that of the United States, where the market has become overcrowded with "patents for new

⁶⁸ Germano, *supra* note 24.

⁶⁹ Kevin E. Noonan, *The Anatomy of a Compulsory License: Natco Pharma Ltd. v. Bayer Corp. (Indian Patent Office)*, March 15, 2012, available at <http://www.patentdocs.org/2012/03/the-anatomy-of-a-compulsory-license-natco-pharma-ltd-v-bayer-corp-indian-patent-office.html> (Last visited on May 12, 2013).

⁷⁰ *Natco Pharma Ltd. v. Bayer Corporation*, Compulsory License Application No. 1/2011 (Controller of Patents, Mumbai), 56, available at http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf (Last visited on May 12, 2013).

⁷¹ Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, INNOVATION POLICY AND THE ECONOMY 1, 119 (2001), available at <http://faculty.haas.berkeley.edu/shapiro/thicket.pdf> (Last visited on May 12, 2013).

⁷² Claire Howell, *The Hargreaves Review: Digital Opportunity: A Review of Intellectual Property and Growth*, 1 JOURNAL OF BUSINESS LAW 71, 77 (2012).

⁷³ Ian Hargreaves, *Digital Opportunity: A Review of Intellectual Property and Growth*, May, 2011, available at <http://www.ipo.gov.uk/ipreview-finalreport.pdf> (Last visited on May 12, 2013).

⁷⁴ (2013) 6 SCC 1.

⁷⁵ Anand Grover, *Novartis Case: Supreme Court's Historic Decision on Section 3(d)*, THE TIMES OF INDIA April 2, 2013, available at http://articles.timesofindia.indiatimes.com/2013-04-02/india/38217259_1_therapeutic-efficacy-chennai-patent-office-patent-oppositions (Last visited on August 10, 2013).

dosages and new usages rather than new drugs”.⁷⁶ Consequently, other companies would be discouraged from filing for compulsory licenses owing to the saturation of the market with generic variations of the same drug. Therefore, competition would be affected and prices would continue to be unaffordable.⁷⁷ If such a situation were to arise, solutions such as patent pools could be explored.⁷⁸ However, the key point to remember is that such a possibility begs the need for cautious usage of compulsory licenses in exceptional circumstances.

C. THE ‘LOCAL WORKING’ REQUIREMENT AND INTERNATIONAL RAMIFICATIONS

§84(1)(c) provides that a compulsory license may be granted if the patent is not being “worked in the territory of India” and this provision has often been touted as the cornerstone of the Indian compulsory licensing regime.⁷⁹ As aforementioned, in *Natco v. Bayer*, the IPAB left the interpretation of this phrase flexible, even as it tried to skirt issues relating to the legal consistency of its decision with international instruments such as the TRIPS.⁸⁰ However, the international law foundations of this requirement remain nebulous. Article 5(A)(1) of the Paris Convention for the Protection of Industrial Property, 1883 (‘Paris Convention’)⁸¹ clearly states that importation by the patentee alone cannot result in a forfeiture of the patent. Further, although Article 5(A)(2) of the Paris Convention explicitly permits the grant of compulsory licenses on the ground of lack of ‘local working’, Article 27.1 of TRIPS prohibits discrimination of patent rights on the basis of the place of invention. To complicate matters further, Article 2.2 of TRIPS states that obligations under the Paris Convention remain unaffected.

Against this backdrop, the ruling in *Natco v. Bayer* is significant because it provides an interesting spin on the interpretation of these provisions. Even though the IPAB order itself does not provide details of the legal maze of provisions in international instruments, it relies on the detailed discussion in the Controller’s decision.⁸² The Controller, after considering all the relevant provisions of TRIPS and the Paris Convention, chose to read them harmoniously.

⁷⁶ *Prescription Drugs: India Values Their Compulsory Licensing Provision - Should The United States Follow In India’s Footsteps?*, 29(1) HOUSTON JOURNAL OF INTERNATIONAL LAW 191, 217 (2007).

⁷⁷ *Id.*

⁷⁸ Joel D’Silva, *Pools, Thickets and Open Source Nanotechnology*, 31(6) EUROPEAN INTELLECTUAL PROPERTY REVIEW 300, 303 (2009).

⁷⁹ Shamnad Basheer & Mrinalini Kochupillai, *The ‘Compulsory License’ Regime in India: Past, Present and Future*, Japanese Patent Office, 36 (2005).

⁸⁰ *Id.*, 9.

⁸¹ The Paris Convention for the Protection of Industrial Property, 1883, Art. 5(A)(1).

⁸² *Natco Pharma Ltd. v. Bayer Corporation*, Compulsory License Application No. 1/2011 (Controller of Patents, Mumbai), 39-45, available at http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf (Last visited on May 12, 2013).

In doing so, he drew a distinction between the revocation of the patent and something less harsh such as a compulsory license. Using Article 5(A)(2) of the Paris Convention to fortify his reasoning, the Controller then opined that a reasonable fetter in the form of a compulsory license was within the purview of the TRIPS and the Paris Convention.⁸³ However, it is notable that he also ruled that the term ‘working’ could not amount to importation in any circumstance,⁸⁴ a conclusion which the IPAB differed with.⁸⁵

Keeping this in mind, there is one pertinent aspect which comes to the fore. It concerns the scope and application of the phrase “*patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced*” employed in Article 27.1 of TRIPS. As per the IPAB’s ruling, reading the phrase with provisions of the Paris Convention, it merely amounts to a prohibition on the revocation of the patent.⁸⁶ They opined that since the interpretation of the requirement for working can vary from case to case, mere importation can only imply that the manufacturer’s patent cannot be revoked. However, a compulsory license can still be granted without amounting to discrimination.⁸⁷ This however begs the question of why TRIPS uses this term in the first place. If the real intention behind this provision was merely to avoid revocation of patents on the basis of lack of local working while giving leeway for compulsory licensing on the same ground, the provision could have explicitly said so. However, the term used is broader and mandates that patent rights should be enjoyable in the manner specified. Coupled with the inherent ambiguity in Article 31 of TRIPS,⁸⁸

⁸³ Natco Pharma Ltd. v. Bayer Corporation, Compulsory License Application No. 1/2011 (Controller of Patents, Mumbai), 41-42, available at http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf (Last visited on May 12, 2013).

⁸⁴ Natco Pharma Ltd. v. Bayer Corporation, Compulsory License Application No. 1/2011 (Controller of Patents, Mumbai), 43, available at http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf (Last visited on May 12, 2013).

⁸⁵ See Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 52 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁸⁶ See Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 52 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁸⁷ See Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 52 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

⁸⁸ Art. 31 of TRIPS provides as follows:

Article 31: *Other Use Without Authorization of the Right Holder*.—Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or

this represents yet another instance where the balance between the interests of various stakeholders remains precarious.⁸⁹

More importantly, a plain meaning interpretation of the provision makes it clear that what is prohibited is the placing of restrictions on the exclusivity of patent rights, based on where the product is manufactured.⁹⁰ In fact, the interpretation given by the WTO seems to suggest that Article 31 of TRIPS, which allows for compulsory licensing exceptions, is to be interpreted subject to the conditions in Article 27.1.⁹¹ However, a compulsory license on the ground of importation clearly violates this directive as it would amount to discrimination on the basis of place of manufacture. This puts the IPAB's interpretation on unstable ground. Nevertheless, since the IPAB's ruling largely circumvents the nuances of this issue, the field remains open and will require clarification in the future.

In a slightly different vein, the IPAB's order represents an authoritative confirmation of the stance that developing nations have advocated since the Uruguay Round.⁹² Even though scholarly opinion has swayed on both sides

other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.

⁸⁹ Ford, *supra* note 10, 960-62.

⁹⁰ BENNION ON STATUTORY INTERPRETATION 548 (5th ed., 2008) (The plain meaning rule dictates that in instances where the informed interpretation of a particular statute leaves no room for doubt about the correct grammatical meaning intended by the legislature, that is the correct legal meaning of the statute).

⁹¹ WORLD TRADE ORGANISATION, WTO ANALYTICAL INDEX: GUIDE TO WTO LAW AND PRACTICE, VOL. II Art. 27, ¶¶ 184-85 (3rd ed., 2012), available at http://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_02_e.htm#article31 (Last visited on May 12, 2013).

⁹² J.H. Reichman, *The TRIPS Component of the GATT's Uruguay Round: Competitive Prospects for Intellectual Property Owners in an Integrated World Market*, 4 FORDHAM INTELLECTUAL PROPERTY, MEDIA AND ENTERTAINMENT LAW JOURNAL 171, 207 (1999).

on occasion,⁹³ the WTO, dominated by developed nations, has been adamant about disallowing such discrimination.⁹⁴ Even though the IPAB's decision may make India vulnerable to a WTO challenge, it represents a rare act of assertion on its part.⁹⁵ In fact, a similar provision in the Brazilian Code was taken to the WTO by the United States, but was later abandoned due to other reasons.⁹⁶ Therefore, one major impact of this could be to encourage other developing countries to follow suit and refuse to surrender to Western interests by incorporating such provisions. This in turn could have both positive and negative effects as outlined below.

First, it may force greater compliance with Articles 7⁹⁷ and 66.2⁹⁸ of TRIPS by ensuring that transfer of technology occurs as a direct consequence of more compulsory licenses.⁹⁹ While developed nations would definitely be unhappy with such a development, they may have no option but to yield if the developing world stands its ground. This will not only lead to

⁹³ In favour of a local working requirement, see Bryan Mercurio & Mitali Tyagi, *Treaty Interpretation in WTO Dispute Settlement: The Outstanding Question of the Legality of Local Working Requirements*, 19(2) MINNESOTA JOURNAL OF INTERNATIONAL LAW 275 (2010) (Arguing that working requirements are consistent with the TRIPS Agreement); For the Contrary position, see Enrico Bonadio, *Compulsory Licensing of Patents: The Bayer-Natco Case*, 34(10) EUROPEAN INTELLECTUAL PROPERTY REVIEW 719, 724-25 (2012).

⁹⁴ See World Trade Organization, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, March 17, 2000, available at http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf (Last visited on May 12, 2013).

⁹⁵ Enrico Bonadio, *Compulsory Licensing of Patents: The Bayer-Natco Case*, 34(10) EUROPEAN INTELLECTUAL PROPERTY REVIEW 719, 724 (2012).

⁹⁶ *Id.*, 723.

⁹⁷ Art. 7 of TRIPS provides as follows:

Article 7: *Objectives*.—The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

⁹⁸ Art. 66 of TRIPS provides as follows:

Article 66: *Least-Developed Country Members*.—

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.
2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

⁹⁹ Naomi A. Bass, *Implications Of The Trips Agreement For Developing Countries: Pharmaceutical Patent Laws In Brazil And South Africa In The 21st Century*, 34 THE GEORGE WASHINGTON INTERNATIONAL LAW REVIEW 191, 204 (2002) (Examining the impact of TRIPS on pharmaceutical patent laws of developing countries and arguing that they should retain compulsory licensing provisions).

greater development of local research outfits but will also mean greater employment opportunities for citizens, thereby leading to a general increase in social welfare.¹⁰⁰ But the *second* effect could be negative. Renowned scholar Coleen Chien's hypothesis is that delinking compulsory licensing and innovation rates rests on the assumption that the licensing is unpredictable and does not affect an 'important' market.¹⁰¹ However, if a majority of the developing nations stand together to impose local working requirements, the basis for those assumptions may well be eroded.¹⁰² This would then imply that the spread of compulsory licenses could lead to a decline in R&D in the long run. To avoid this last consequence therefore, it is vital for competing interests to be balanced reasonably. Instead of making indiscriminate use of compulsory licenses, developing countries must be careful to resort to such means only in the most critical situations, with the legal definition of such a critical situation being made clear and unambiguous.¹⁰³

D. DWINDLING OF FOREIGN DIRECT INVESTMENT

One of the foremost concerns of the developing nations in general, with regard to an increased usage of compulsory licensing, has been the anticipated decrease in Foreign Direct Investment ('FDI'). Developed nations like the United States have, in the past, resorted to using instruments such as Bilateral Free Trade Agreements to negotiate better patent regimes for themselves.¹⁰⁴ In fact, the United States has been quite vocal about its disappointment with the decision in *Natco v. Bayer*¹⁰⁵ and has argued that the decision will discourage new investments.¹⁰⁶ Additionally, as previous experiences of nations such as South Africa and Argentina among others have shown, many

¹⁰⁰ Frederick M. Abbott, *Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health*, 27–28 (International Center for Trade & Sustainable Development, Issue Paper No. 24, 2009), available at <http://ictsd.org/downloads/2009/07/innovation-and-technology-transfer-to-address-climate-change.pdf> (Last visited on May 12, 2013).

¹⁰¹ See Chien, *supra* note 14. See also, Amaral, *supra* note 67, 11.

¹⁰² *Id.* While any one developing nation may not individually qualify as an 'important' market, if majority of them come together to oppose the tyranny of drug companies, they could collectively represent perhaps one of the most important markets. This is especially applicable for diseases such as AIDS which are more prevalent in developing nations than developed ones.

¹⁰³ Robert C. Bird, *Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effects*, 37(2) JOURNAL OF MEDICINE, LAW AND ETHICS 209, 211–15 (2009).

¹⁰⁴ C. M. Correa, *Implications of Bilateral Free Trade Agreements on Access to Medicines*, 84(5) BULLETIN OF THE WORLD HEALTH ORGANIZATION 399 (2006).

¹⁰⁵ *Bayer Corporation v. Natco Pharma Ltd.*, Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

¹⁰⁶ Amiti Sen, *US Protests Patent Issuance to Natco to Sell Copied Versions of Nexaver*, THE ECONOMIC TIMES March 27, 2012, available at http://articles.economictimes.indiatimes.com/2012-03-27/news/31245102_1_compulsory-licence-patent-owner-indian-patent-office (Last visited on May 12, 2013).

developing nations cannot afford to irk the developed countries of the world.¹⁰⁷ India, like other developing nations, must keep in mind the fact that its greatest strength lies in its continued importance to the developed world in many spheres. In any case, a coalition of like-minded nations in similar positions will be able to negotiate better with both western governments as well as pharmaceutical companies.¹⁰⁸ Therefore, even as India makes bold steps forward, it should take adequate measures to ensure that its investment prospects are not adversely affected.

E. LESSONS FOR PHARMACEUTICAL COMPANIES

As the surge of opinions on the impact of *Natco v. Bayer*¹⁰⁹ will demonstrate, there is a lot that drug giants can take away from this ruling. Even as they protest against the imposition of rules such as the local working requirement, it seems likely that developing nations such as India will retain such provisions in order to protect their interests. Therefore, as scholars suggest, companies would be better off in the long run by accounting for such requirements rather than trying to preserve their intellectual property rights and incurring huge litigation costs.¹¹⁰ This way they would be able to ensure rewards from long term investment plans.¹¹¹ Additionally, it may make sense for drug manufacturers to sacrifice a small percentage of their profits by lowering prices and increasing distribution, in exchange of getting rid of the threat of compulsory licensing.¹¹² Finally, in order to maintain control, patentees would also be better off acknowledging that voluntary licenses are not a bad option and will provide greater room for negotiation and profit-making.¹¹³

V. CONCLUSION

The compulsory licensing of patents in India can be traced back to Act V of 1888, which sought to consolidate the law relating to patents, in order to bring it at par with the latest developments in English law.¹¹⁴ In reality however, it was not until the new Indian Patents Act was brought into force in 1970 that significant changes came about. Aimed at encouraging new scientific

¹⁰⁷ See H. L. Bentolila, *Lessons from the United States Trade Policies to Convert a 'Pirate': The Case of Pharmaceutical Patents in Argentina*, 5(1) *YALE JOURNAL OF LAW AND TECHNOLOGY* 59 (2003).

¹⁰⁸ Germano, *supra* note 24, 293.

¹⁰⁹ *Bayer Corporation v. Natco Pharma Ltd.*, Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

¹¹⁰ Reuters, *supra* note 35.

¹¹¹ See Amaral, *supra* note 67, 10.

¹¹² See Noonan, *supra* note 69.

¹¹³ See Watal, *supra* note 21.

¹¹⁴ The Inventions and Designs Act, 1888.

research and technology along with advancements in the industry,¹¹⁵ the new Act introduced sweeping changes to the law, including an entire chapter dedicated to the regulation and grant of compulsory licenses.¹¹⁶ Since then, the provisions for compulsory licensing of patents have existed in our statute books, without being invoked until *Natco v. Bayer*¹¹⁷.

It is for this reason that the world stood with bated breath as the IPAB pronounced its decision. In some aspects however, it appears that the order has failed to rise to the challenge that was posed before it. No doubt it has changed the face of compulsory licensing. But it has failed to deal with issues in a comprehensive manner so as to outline broader principles for the future. Most importantly, its interpretation of the local working requirement under §84 of the Act has raised many eyebrows. And the repercussions extend beyond the narrow scope of intellectual property rights and compulsory licensing in the pharmaceutical industry.

In a similar vein, the recent ruling of the Supreme Court in the *Novartis* case¹¹⁸ has created global ripples.¹¹⁹ In refusing *Novartis*' application for its cancer-drug *Glivec*, the Court delivered a landmark decision which outlines significant issues not just for India's patent regime, but also for its socio-economic needs.¹²⁰ Thus, even as the world grapples with the watershed decision in *Natco v. Bayer*, there are deeper questions that have come to the fore. Coupled with the ruling in the *Novartis* case, it seems as though India today stands at an important crossroads in determining its future, not just in the narrow context of IPR but also in terms of the place that India will occupy in the new world order. Will the Indian legislature and judiciary pander to the interests of the developed world and put short-term economic interests over long-term policy goals? Or will we muster the courage to stand our ground and proclaim India's arrival as a global force to be reckoned with? The future holds all the answers.

¹¹⁵ *Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries*, (1979) 2 SCC 511; AIR 1982 SC 1444 (Concerning a case of revocation of patent and discussing in detail, the history of Patent Law in India and the scheme of the Patents Act of 1970).

¹¹⁶ The Indian Patents Act, 1970, Chapter XVI. The original chapter was subsequently replaced by a more detailed version in the Patents (Amendment) Act, 2002.

¹¹⁷ *Bayer Corporation v. Natco Pharma Ltd.*, Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.htm> (Last visited on May 12, 2013).

¹¹⁸ *Novartis AG v. Union of India*, (2013) 6 SCC 1.

¹¹⁹ The Editorial Board, *India's Novartis Decision*, THE NEW YORK TIMES April 4, 2013, available at <http://www.nytimes.com/2013/04/05/opinion/the-supreme-court-in-india-clarifies-law-in-novartis-decision.html> (Last visited on July 7, 2013); Reuters, *Novartis Loses Landmark India Cancer Drug Patent Case*, April 1, 2013, available at <http://uk.reuters.com/article/2013/04/01/uk-india-novartis-patent-idUKBRE93002F20130401> (Last visited on July 7, 2013).

¹²⁰ Sudip Chaudhuri, *The Larger Implications of the Novartis-Glivec Judgment*, 48(17) ECONOMIC AND POLITICAL WEEKLY 10 (2013).

