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INDIA'S PHARMACEUTICAL INNOVATION POLICY: DEVELOPING STRATEGIES FOR DEVELOPING COUNTRY NEEDS

SWARAJ PAUL BAROOAH*

India's insistence on flexibilities in pharmaceutical patent policies during TRIPS negotiations and the subsequent legislative implementation of TRIPS flexibilities led to India receiving attention in the pharmaceutical policy world early on. However, it is India's actual usage of these flexibilities in the recent past – to prevent evergreening and to grant compulsory licenses – that has made nearly all parties interested in the effects of using flexibilities in the TRIPS Agreement sit up and take notice. India's robust generics industry, burgeoning population and growing economy, contrasted with its significant poverty levels, make it a difficult country to ignore for countries on both sides of the rich-poor spectrum. With the (belated) fear that other developing countries may begin to take note of how they too can successfully implement such flexibilities, the newest wave of occidental pressure has come on stronger than ever. After examining the position and significance of pharmaceutical patents for the developing world, this article examines the specific developments that have led to this wave of pressure. Regardless of the increased access to medicines that these developments have brought about, India's status as an influential state is on shaky ground if it is not in compliance with its international obligations under TRIPS. Drawing the conclusion that India is well within its rights under TRIPS, this paper goes on to explain the significance of India's stance in the context of the tension a developing country faces between policy requirements and political pressures. Finally, the paper concludes by recognizing the difficult balance between incentivizing the creation of new medicines and ensuring maximum possible access to medicines that pharmaceutical innovation policy requires in the global context and recommends looking beyond just the patent system for pharmaceutical innovation.

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I. INTRODUCTION

“Despite being a member of the World Trade Organization, and an important global trading partner, India has systematically failed to interpret and apply its intellectual property laws in a manner consistent with recognized global standards.”¹

- Ron Waldron, Chief IP Counsel, Pfizer Inc.

Waldron’s testimony before a subcommittee of the United States (US) House of Representatives is representative (if not one of the prime catalysts) of a recent wave² of occidental pressure on India to modify its pharmaceutical patent regime

¹ TESTIMONY BEFORE THE HOUSE COMMITTEE ON WAYS AND MEANS, SUBCOMMITTEE ON TRADE, March 13, 2013, *available at*: http://waysandmeans.house.gov/uploadedfiles/pfizer_testimony31313.pdf (last visited December 28, 2013).

² At the time of adoption of TRIPS, India’s creative use and adoption of TRIPS flexibilities resulted in the first wave of pressure which questioned the legitimacy of such

as India's regime is disturbing the price regimes that Big Pharma have set up³. Along with this denouncement, the recent past has been witness to a variety of other pressure mechanisms directed at the "raising" of India's patent standards. These mechanisms include actions taken by large pharmaceutical companies,⁴ letters from both houses of the US Congress,⁵ and various reports.⁶ Some of this pressure has been directed at introducing provisions that India lacks in its current legal framework – such as patent linkage and data exclusivity provisions. There have also been several bilateral and multilateral treaties in negotiation that seek to raise the floor of global patent harmonization so as to ensure a higher minimum standard of intellectual property rights protection in India. Most of these measures are reactions to certain recent developments in India's pharmaceutical landscape. These developments include the *Novartis* case,⁷ the *Natco* case,⁸ the revocation of the Sunitinib patent,⁹ and several news reports of three more compulsory licenses

implementation of TRIPS terms. See George K. Foster, *Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and its Aftermath*, 3 UCLA J. INT'L L. & FOREIGN AFF. 283, 311 (1998). The more recent wave of pressure has come in several different forms. See text accompanying footnotes 4, 5 and 6.

³ "For example, in 2000, when only patented antiretroviral drugs for human immunodeficiency virus (HIV) infection were widely available, they cost approximately \$10,000 per person per year, even in very poor countries. Today, these same medicines cost \$150 or less if they are purchased from Indian generics companies." See Amy Kapczynski, *Engineered in India – Patent Law 2.0*, 369 N. ENGL. J. MED. 497 (2013). A more recent example was seen in India when the compulsory license granted to Natco brought down the price of Nexavar from Rs 2,80,000 per month to Rs 8,800 per month. See R. Sivaraman, *Natco Pharma wins cancer drug case*, THE HINDU (March 4, 2013).

⁴ For example, in response to a recent landmark case decided by the Supreme Court of India, Novartis stated, "This decision discourages innovative drug discovery essential to advancing medical science for patients". Statement available at: <http://www.novartis.com/newsroom/product-related-info-center/glivec.shtml> (last visited December 23, 2013).

⁵ On 18 June 2013, 170 Members of Congress (lower house) encapsulated concerns regarding India's patent regime in a letter to President Obama's office. On 20 June 2013, 40 US Senators (upper house) voiced similar concerns in a letter to John Kerry, Secretary, US Department of State.

⁶ For example, The USTR 2013 Special 301 Report, the US Chamber of Commerce's GIPC IP Index 2013 [hereinafter GIPC Report], the Report of the Commission on the Theft of American Intellectual Property, etc. For more on these reports, see Swaraj Paul Barooah, *Part II: Pfizer's Testimony leads the way as US pressure on India increases*, SPICYIP (June 27, 2013), available at: <http://spicyipindia.blogspot.in/2013/06/part-ii-pfizers-testimony-leads-way-as.html> (last visited December 24, 2013).

⁷ *Novartis A.G. v. Union of India & Ors*, Civil Appeal Nos. 2706-2716 of 2013 arising out of SLP (C) Nos. 20539-20549 of 2009 [hereinafter *Novartis*].

⁸ *Bayer v. Union of India & Others*, OA/35/2012/PT/MUM, available at: <http://www.ipab.tn.nic.in/045-2013.htm> (last visited July 25, 2013) [hereinafter *Natco*].

⁹ *Sugen v. Cipla*, OA/5/2013/PT/DEL, available at: <http://www.ipab.tn.nic.in/107-2013.htm> (last visited July 25, 2013) [hereinafter *Sunitinib*].

on cancer medications.¹⁰

Though at first glance these reactions appear to be situation-specific, the fact that the path India's pharmaceutical patent regime takes has global implications is not lost on any of the stakeholders involved. Aside from its burgeoning domestic market,¹¹ India is the world's third largest producer of drugs by volume¹² (behind the US and Japan) and the one of the world's largest exporter of generic drugs.¹³ India is thus seen as a leader in the developing world with respect to pharmaceutical products. With growth and innovation drying up,¹⁴ pharmaceutical

¹⁰ Health Ministry recommends compulsory licensing of three anti-cancer drugs, PHARMABIZ.COM (May 3, 2013), available at: <http://www.pharmabiz.com/NewsDetails.aspx?aid=75138&sid=1> (last visited July 21, 2013).

¹¹ High disease burdens, economic growth leading to higher levels of disposable income, improvements in healthcare infrastructure and improved healthcare financing are drivers of growth in the domestic market. See PRICE WATERHOUSE COOPERS, INDIA PHARMA INC.: GEARING UP FOR THE NEXT LEVEL OF GROWTH, available at: http://www.pwc.in/en_IN/in/assets/pdfs/pharma/pharma-summit-report-31-10-12.pdf (last visited December 24, 2013).

¹² MINISTRY OF EXTERNAL AFFAIRS, GOV'T OF INDIA, PHARMACEUTICALS, available at: <http://www.indiainbusiness.nic.in/industry-infrastructure/industrial-sectors/drug-pharma.htm> (last visited July 25, 2013).

¹³ Nageshwar Patnaik, *India tops exporting generic medicines*, THE ECON. TIMES, March 7, 2010, available at: http://articles.economicstimes.indiatimes.com/2010-03-07/news/28443868_1_generic-medicines-india-tops-pharmaceutical-industry (last visited July 25, 2013). See also: "Dubbed the pharmacy of the developing world, India has steadily provided much-needed generic medicines to international markets, at very competitive prices, during the past decade. Of the 312 medicines on the World Health Organization (WHO) List of Prequalified Medicines at the end of 2012, 231 (74%) were generic, of which 200 (87%) were manufactured in India", WHO Prequalifications of Medicines Programme, *Annual Report 2012 Globalizing Quality* 13(35), available at: http://apps.who.int/prequal/info_general/documents/WHO_PQP_Annual_report_2012web.pdf (last visited December 24, 2013).

¹⁴ Despite unprecedented levels of investment in pharmaceutical research, the number of new drugs remains low. This may point to a limitation with the current R&D model for pharmaceutical innovation. See Bernard Munos, *Lessons from 60 years of pharmaceutical innovation*, 8 NATURE REVIEWS DRUG DISCOVERY 959 (December 1, 2009), available at <http://www.nature.com/nrd/journal/v8/n12/execsumm/nrd2961.html> (last visited October 4, 2013). See also Pamolli et al., *The productivity crisis in pharmaceutical R&D*, 10 NATURE REVIEWS DRUG DISCOVERY 428 (June 1, 2011), available at: <http://www.nature.com/nrd/journal/v10/n6/abs/nrd3405.html> (last visited October 11, 2013). Further, potentially up to a \$50 billion drug market will be up for grabs for generics since several blockbuster patents will be expiring in the next 5 years. See Jayati Ghose, *Pharma Inc. prepares to scale patent cliff, eyes \$50 billion market*, THE FINANCIAL EXPRESS, (October 3, 2013), available at: <http://www.financialexpress.com/news/pharma-inc-prepares-to-scale-patent-cliff-eyes-50bn-market/1177414> (last visited October 4, 2013)

companies are re-examining their strategies for growth in terms of products¹⁵ as well as markets.¹⁶ Many of the aforementioned measures thus seek to address, the production and export of India's generic drugs, as well as the potential export of patent policy trends.

A. India – Dawdler, Outlier or Leader?

India's current pharmaceutical ambience is the result of pharmaceutical policy experimentation that started a few decades ago. The patent system introduced by the British in 1865 led to India having some of the highest drug prices in the world.¹⁷ Concerned by this, as well as by the predominance of foreign pharmaceutical firms, the Patents Act, 1970 was passed. It drastically reduced the scope of patents that could be granted on pharmaceuticals. Product patents were not allowed while process patents were granted to a limited extent.¹⁸ This led to the creation of a robust domestic generics industry that could quickly reverse engineer original formulations as well as develop new processes for drug production.¹⁹ As the generics industry in India became more competitive, drug prices fell until they were some of the lowest in the world. This continued till 1995, when India joined the WTO, which involved accepting the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).²⁰

However, the acceptance of TRIPS was not necessarily a signal of India's (nor any other country's) desire to harmonize standards for pharmaceutical patents. In fact, many countries had already shown a dislike for strong intellectual property (IP) provisions at the World Intellectual Property Organization (WIPO). The signing of the TRIPS Agreement was a result of a desire to be part of the World

¹⁵ See Elie Doigin, *Big Pharma moves from 'blockbusters' to 'niche busters'*, 16 NATURE MEDICINE 837 (2010), available at: <http://www.nature.com/nm/journal/v16/n8/full/nm0810-837a.html> (last visited October 11, 2013).

¹⁶ See Deena Beasley, *Analysis: Big Pharma emerging mkts tactics shift as growth slows*, REUTERS (January 17, 2013), available at: <http://www.reuters.com/article/2013/01/17/us-pharma-emergingmarkets-idUSBRE90G17A20130117> (last visited December 24, 2013).

¹⁷ STAFF OF S. COMM. ON THE JUDICIARY, SUBCOMM. ON ANTITRUST & MONOPOLY, 87TH CONG. 1ST SESS., REP. NO.448 41 (1961) (showing India with the highest prices of the seventeen countries surveyed, which included the United States); Amy Kapczynski, *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CAL. L. REV 1571 (2009) [hereinafter Kapczynski–*Harmonization*].

¹⁸ See SUDIP CHAUDHURI, *THE WTO AND INDIA'S PHARMACEUTICALS INDUSTRY: PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES* 1, 29 (2005)

¹⁹ *Id.*

²⁰ See Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27.1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

Trade Organization (WTO), the creation of which had been catalyzed by the lack of a formal global trade system (apart from the ad-hoc General Agreement on Tariffs and Trade (GATT)). With the spread of globalization, countries were rushing to join this international trade organization. However, in order to join, countries needed to accept its four constituent agreements in full – the Multilateral Agreements on Trade in Goods, General Agreement on Trade in Services, TRIPS and the Dispute Settlement Understanding. Of these, the TRIPS Agreement appeared to be incongruous to the spirit of the WTO, since governments granting exclusion rights did not seem to fit in with the concept of free trade. The ‘one-size-fits-all’ approach it adopted, and the favoring of private privileges over diffusion of knowledge²¹ were two of the primary criticisms²² TRIPS faced right from the start. The lack of any actual evidence in support of these IP policies, combined with the fact that many developed nations started allowing strong IP protection only after undergoing a ‘copy-and-learn’ model themselves,²³ gave little credibility to one-size-fits-all approach. However, since the TRIPS Agreement was packaged together with the other WTO Agreements, countries had little choice but to accept it.

Since TRIPS required massive changes in many countries, there were also certain flexibilities included in the Agreement so as to allow Member States some policy space to tailor TRIPS norms to their domestic realities. This included providing a 10-year window from 1995 to 2005 to developing countries for making the necessary changes to their respective IP regimes. Although Art. 65 of the TRIPS Agreement allowed for a transition period, only 13 countries used this provision. Of these 13, only 6 used the complete period.

Simultaneously, the global “access to medicines” movement became much larger during this period, with extensive global mobilization for the public health concerns of developing countries. This trend resulted in the 2001 Doha Declaration, which recognized and reaffirmed nations’ rights to protect public

²¹ The probable imbalance that could occur was observed much before the TRIPS Agreement even came into being. *See e.g.* N. RAJJAGOPALA AYYANGAR, GOVERNMENT OF INDIA, REPORT ON THE REVISION OF THE PATENTS LAW (1959).

²² *See* SUSAN K SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 11 (2003) [hereinafter SUSAN SELL].

²³ The “copy-and-learn” model was seen in the practice of permitting the copying of foreign technology by limiting the grant of exclusion rights until local companies slowly developed capacity for not just copying but also innovating. Exclusion rights were only actively encouraged after the local companies developed innovative capacity. *See* ELLEN 'T HOEN, THE GLOBAL POLITICS OF PHARMACEUTICAL MONOPOLY POWER, 9 (2009), available at: <http://www.msface.org/content/global-politics-pharmaceutical-monopoly-power> (last visited December 24, 2013) [hereinafter HOEN]. *See also, infra* note 32.

health.²⁴

The access to medicines movement gave birth to a well-coordinated network of scholars, activists, and community-based organizations that were highly motivated, increasingly sophisticated and “remarkably aware of esoteric patent law developments”.²⁵ This gave India the time and opportunity to make up for any possible knowledge bias that existed at the time of the signing of TRIPS and, to make full use of TRIPS flexibilities.²⁶ Additionally, the circumstances in India during this time period included a strong generic industry that could provide access to medicines at comparatively low prices. Despite this, however, much of the Indian population still could not afford healthcare. India’s policy decisions on pharmaceuticals were thus still based primarily on providing access to its own population.

This meant that when countries implemented the TRIPS Agreement into domestic legislation, India was one of the few countries that was creative and generous in its use of the permitted flexibilities.²⁷ Much of the policy that is currently criticized stems from the existence of these flexibilities. India’s ability to influence approaches to pharmaceutical innovation policy has thus come about due to its extensive use of TRIPS flexibilities. This use, combined with its strong generics industry, has turned India into a voice that cannot be ignored on the world stage. The recent patent developments in India have set in motion what could be the beginning of a new approach to pharmaceutical innovation. For this to happen though, other strong voices in the developing world will need to espouse a similar creative yet hardliner approach to ensuring a strict balance between increasing access and encouraging innovation. In addition to continued research and empirical evidence on these imbalances, this will also require great political willpower as moving away from the occidentally supported views is not an easy task. In essence, a new narrative of pharmaceutical innovation will need to be brought about. However, if other countries do not take up a similar stance quickly, India is still relatively well positioned to continue its current approach due to the strong local generics industry which will ensure that regardless of Big Pharma’s direct investments into India, there is access to medicines in India. Thus whether

²⁴ The Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2 (2001) [hereinafter Doha declaration].

²⁵ See Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 YALE L.J. 804 (2008) [hereinafter Kapczynski–*Knowledge Mobilization*].

²⁶ Jean O. Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?* (Nat’l Bureau of Econ. Research, Working Paper No. w6366, 1998); Santanu Mukherjee, *The Journey of Indian Patent Law Towards TRIPS Compliance*, 35 INT’L REV. INTELL. PROP. & COMPETITION L. 125, 127-128 (2004).

²⁷ Kapczynski–*Harmonization*, *supra* note 17.

India's recent activities have made it an outlier or a leader will be determined in the coming few years.

This article will look into the question of how innovation and access to medicines is affected by the exporting or importing, as the case may be, of pharmaceutical patent policies to and from India. Part II will examine the narrative that has led to pharmaceutical patents becoming the dominant method of pharmaceutical innovation. This involves a look at how the TRIPS Agreement came to be the primary international IP legislation. Following this, Part III will examine the recent developments that were cited above as reasons for the sudden escalation of pressure – in particular, the *Novartis* case, which centered on the anti-evergreening provision, as it has received the most amount of global attention. Apart from this, Pfizer's rejected Sutinib patent, India's first compulsory license case (Nexavar), and the three compulsory licenses currently being processed will be discussed. Part IV then places these developments within the context of the TRIPS framework to determine their legitimacy and to examine whether these are policies that other countries could adopt. Relying on the determination that India's patent policies are in fact in compliance with India's TRIPS obligations, Part V examines the international political tensions that exist in the implementation of atypical policy measures, regardless of whether the policy a country wants to implement is legitimate and appropriate for its domestic circumstances. These tensions are placed in the broader perspective of India's role in changing approaches to pharmaceutical innovation policy. In light of some of the issues highlighted in the article, Part VI concludes with some recommendations for the path forward.

II. THE POSITION AND SIGNIFICANCE OF PHARMACEUTICAL PATENTS

This part of the article seeks to provide the relevant background information necessary to examine the developments that have occurred and the significance of India's current stance. The first section will lay out the current role and relevance of TRIPS in determining the legitimacy of pharmaceutical patents as innovation policy. This will be followed by an overview of the usefulness of patents as an incentive for innovation in the pharmaceutical sector. This contextual background provides an understanding as to the choices that India and other countries have before them while stepping forward in the field of pharmaceutical innovation and access to medicines.

A. *A Brief History of TRIPS*

The TRIPS Agreement, with 159 Member State signatories, is currently the determinative international framework governing intellectual property law. Historically, IP laws were made by nations for themselves and by themselves. The 1883 Paris Convention for the Protection of Industrial Patents (covering patents,

trademarks, and industrial designs), which was the first international IP convention, did not create new substantial law nor impose new laws on its Member States. Rather, it reflected a consensus among Member States that they could legislate their own IP laws, but had to extend those rights and privileges to nationals of other Member States as well.²⁸ The 1970s saw the formation of the World Intellectual Property Organization, which is a specialized agency of the United Nations. Created under the aegis of WIPO, the Patent Cooperation Treaty (PCT)²⁹ was one of the first tangible steps towards international harmonization of domestic laws. However, two clashing interests soon revealed themselves. On one hand, developing countries were beginning to demand more access to technology; on the other hand, industry interests in developed countries started demanding that stronger rules be laid down for the protection of IP rights. These diametrically opposing interests led to a stalemate at WIPO and no new reforms could be made.³⁰ Soon, however, WIPO was bypassed through the means of a new agreement – the TRIPS Agreement, which came as part of a “package deal” along with the rest of the WTO covered agreements. While purporting to be bringing about reform for the development of all countries, it turned out to be extremely controversial. As mentioned previously,³¹ there was no empirical evidence that the “one size fits all” approach and the favoring of private privilege over diffusion were optimal approaches.³² To the contrary, many developed nations started strengthening their own patent system only after the development of their domestic industries.³³

One of the central driving forces of the TRIPS Agreement was the US-based Intellectual Property Commission (IPC). This was a private coalition of 12 members who were the heads of a handful of US multinational companies.³⁴ The

²⁸ For applicable “national treatment” and “most favourable nation” clauses. *See* Paris Convention for the Protection of Industrial Property, art. 2-3, 19 (July 14, 1967), 21 U.S.T. 1583, 828 U.N.T.S. 305, as referenced in TRIPS art(s). 3-5. *See also*, SUSAN SELL, *supra* note 22, at 11.

²⁹ While the Patent Cooperation Treaty did not establish a ‘Universal Patent’, it did provide a more efficient means of securing patents in different countries.

³⁰ FREDERICK ABBOTT *ET AL.*, *INTERNATIONAL INTELLECTUAL PROPERTY IN AN INTEGRATED WORLD ECONOMY*, 5 (2d ed., 2011) [hereinafter ABBOTT *ET AL.*].

³¹ SUSAN SELL, *supra* note 22.

³² Jerome H. Reichman *et al.*, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 DUKE L.J. 85, 94–99, 103–08 (2007) [hereinafter Reichman *et al.*].

³³ France (until 1960), Switzerland (until 1977), Italy (until 1978), Sweden (until 1978) and Spain (until 1992); *See* HOEN, *supra* note 23, at 9, *available at*: <http://www.msfacecess.org/content/global-politics-pharmaceutical-monopoly-power> (last visited December 24, 2013).

³⁴ These included CEOs of companies like Pfizer, Du-Pont, CBS, Bristol Myers,

IPC systematically organized support for a stronger global IP regime, and presented a proposal based on industrialized countries' existing laws to the GATT Secretariat in 1988. In the midst of the boom of international trade and the consequent need for international trade laws, the IPC contributed heavily to the creation of TRIPS by successfully linking the issues of trade and intellectual property in the minds of State negotiators. Its intense lobbying eventually led to the acceptance of exclusion rights as a part of the free trade agenda under the WTO.³⁵ Leading the movement right from the start, therefore, were the representatives of the interests of rights holder-based industries. Although there were a variety of factors that can be correlated to the eventual signing of the TRIPS agreement in its current form, one that is often overlooked is this starting point. Having set the starting point for negotiations so heavily tilted in one direction, even assuming all parties had equal bargaining power, it would still be a monumental task to create a neutral, balanced result. All States, however, did not have equal bargaining power. While it remains true that it was technically voluntary for States to sign on to the WTO and thus TRIPS, as is often true in the political arena, there were several implicit and explicit consequences to this "choice". One of the main reasons that States had for accepting TRIPS rules concerning patentable subject matter was their strong desire to join the world trading system established by the WTO, while other reasons included economic arm-twisting stemming from market access concerns such as threats of removing countries from the list of Generalized System of Preferences (GSP).³⁶

Unlike other WTO agreements, the TRIPS Agreement was proscriptive rather than restrictive. One of the main points of departure from former treaties was the introduction of global minimum standards for IP protection. It called for the introduction of a minimum of 20 years of patent protection "without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced".³⁷ This is significant because nearly 50 countries did not provide for patenting of pharmaceuticals prior to the TRIPS Agreement.³⁸ Aside from implementing minimum standards for protection of

Johnson & Johnson, General Motors, IBM and Hewlett-Packard. *See* HOEN, *supra* note 23, at 10.

³⁵ HOEN, *supra* note 23, at 11.

³⁶ Kent Jones, *Green Room Politics and the WTO's Crisis of Representation*, 9 PROGRESS DEV. STUD. 349 (2009). *See also*, SUSAN SELL, *supra* note 22, at 75.

³⁷ Art. 27, TRIPS Agreement.

³⁸ *See* CARLOS CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES 11 (2000) (*citing* UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT, THE TRIPS AGREEMENT AND DEVELOPING COUNTRIES, 1996), *available at*: <http://apps.who.int/medicinedocs/pdf/h2963e/h2963e.pdf>. *See also*, PRNewswire, *Pfizer: WTO Doha Declaration Reaffirms Values*

intellectual property, TRIPS also put some safeguards into place. Article 8³⁹ recognizes a Member's right to legislative enactments of measures necessary to protect public health and nutrition. This forms the principle underlying provisions of TRIPS, by which Member States can use compulsory licenses, parallel imports and the other flexibilities of the Agreement. However, the Agreement restricted the issuance of compulsory licenses by restricting exclusive licenses⁴⁰ and sharply restraining the conditions for and of such licenses.⁴¹ Subsequent bilateral trade agreements have made these TRIPS flexibilities more difficult to use as well.⁴² Most developing countries were already dependent on pharmaceutical firms from developed countries, and these extended patent requirements worsened this dependency by cutting off a vital source of generic and domestically manufactured drugs, which were rendered illegitimate by the patent regime. Therefore, the primary challenge for developing countries seeking to improve their access to medicines was to determine the scope and interpretation of the 'flexibilities' found in the Agreement.

C. *The Narrative of Patent theory in Innovation Policy*

Patents are legal entitlements granted by the State, in the form of certain time-limited exclusion rights, over the information behind products (or processes) that are deemed to be novel, non-obvious and have utility, in exchange for the

of *Intellectual Property Protection* (November 14, 2001), available at: <http://ww1.aegis.org/news/pr/2001/PR011126.html> (last visited December 28, 2013).

³⁹ Art. 8 of the TRIPS Agreement states:

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

⁴⁰ This marked a change in policy for a number of developing countries, which had previously reserved the right to issue exclusive compulsory licenses. This was usually used to license the product out to a third party in case the government felt that foreign patent holders were merely filing patents to block usage of the patented object, or to promote importation of that product from the patent holder.

⁴¹ Art. 31, TRIPS Agreement.

⁴² Pedro Roffe & Christoph Spennemann, *The impact of FTAs on public health policies and TRIPS flexibilities*, 1(1/2) INT'L J. INTELL. PROP. MGMT. 75 (2006), available at: <http://www.ictsd.org/downloads/2008/08/roffe-spennemann.pdf> (last visited December 24, 2013).

disclosure of the working of such products or process. The economic objective of the patent system is to incentivize the creation of innovative products and processes; this objective is achieved by granting, to the patent holder, the right to exclude others from selling or use a patented product or process,⁴³ to prevent the appropriation of economically valuable information (without compensation) by competitors. This would reduce the ability of the patent holder to commercialize his/her patent, which in turn would increase the levels of risks involved in investing in innovative products or processes. However, there is much that is not known about patent law as it exists today. In fact, there are certain accepted "standards" utilized in patent law that are not yet fully understood. For example, to all its 159 Member States, TRIPs mandates 20 years of exclusion rights on inventions in any field of technology. While, after much debate, the justifications for patent rights have been more or less accepted as utilitarian,⁴⁴ there seems to be no precise reason for choosing a 20 year period,⁴⁵ especially equally across all sectors of technology. Nevertheless, due to the basic substantive harmonization brought about by TRIPs as well as the general expansion of IP over the last three decades,⁴⁶ the dominant narrative for innovation theory has taken place through the conduit of patent law, and consequently, the "standards" required to be implemented by TRIPs.

Patent theory as specifically applied to the pharmaceutical field has unique positive and negative aspects, especially when compared to other sectors of technology. The positive is that it has largely been accepted that the pharmaceutical sector fits best into the patent-based innovation model, due to factors such as high innovation costs and low reverse engineering costs.⁴⁷ Pharmaceutical innovation is

⁴³ Keith E. Maskus, *Intellectual Property Rights and Economic Development*, 32 CASE W. RES. J. INT'L L. 471 (2000) [hereinafter Maskus].

⁴⁴ The other justifications for patent rights include the Lockean or desert theory, and the Kantian or personality theory. See Terry Fisher, *Theories of Intellectual Property*, in NEW ESSAYS IN THE LEGAL AND POLITICAL THEORY OF PROPERTY (Stephen Munzer ed., 2001); WILLIAM M. LANDES & RICHARD A. POSNER, *THE POLITICAL ECONOMY OF INTELLECTUAL PROPERTY LAW* 1,4 (2004).

⁴⁵ As far back as 1967, economist William Nordhaus showed that optimal patent periods depend on various factors including elasticity of demand, importance of the invention, etc. See William D. Nordhaus, *The Optimal Life of a Patent* (Cowles Foundation for Research in Economics Working Paper No. 241, 1967). Naturally, in order to ensure some practicality in operation, a certain fixed duration must be arrived at. However, the complete lack of displaying any rationale for choosing this twenty years period leaves much to be desired. Even the US, the prime mover of the TRIPs Agreement, had a 17 year patent duration before the Agreement came into effect.

⁴⁶ See James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 LAW & CONTEMP. PROBS. 33, 39 (2003).

⁴⁷ Richard C. Levin *et al.*, *Appropriating the Returns from Industrial Research and Development*,

risk heavy and the cost of R&D is very high.⁴⁸ The exclusion rights granted by the patent system are well suited to enable the recovery of costs in the light of the cheaper and less risky reverse engineering process, which would otherwise allow copies of the product to be made available for much lower than the price required to make back the initial costs.

Explaining the negative requires a bit of historical background on the role of patents as optimal methods for resource allocation. Kenneth Arrow argued way back in 1962 that the use of exclusion rights over public goods lead to inefficiencies that make it an inefficient incentive mechanism for innovation policy.⁴⁹ Demsetz later pointed out that while these inefficiencies may exist, exclusion rights may still have overall efficiency advantages due to the way that they guide decisions about the allocation of inventive resources.⁵⁰ The signals generated by consumer demand are further extended to social welfare indicators. This argument has been internalized by the IP narrative today.⁵¹ With respect to pharmaceuticals, however, there is little correlation between market signals, consumer demand and social welfare.⁵² Market signals are only generated when

3 BROOKINGS PAPERS ECON. ACTIVITY 783, 817-818 (1987).

⁴⁸ Estimates on this amount vary from \$250 million to \$1.3 billion around \$1.3 billion for a new drug. While there are disagreements as to the exact number, it is non-controversial that R&D costs for the pharmaceutical industry are considerably high. DiMasi's figures of \$800 million and \$1.3 billion have seen wide acceptance. See, Joseph A. DiMasi *et al.*, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 165, 180-83 (2003) (estimating a total R&D cost per drug of \$802 million, and clinical trial costs of \$467 million per drug). For a critique of DiMasi's paper as a gross overestimation, see Donald W. Light, *Misleading Congress About Drug Development*, 32 J. HEALTH POL. POL'Y & L. 895, 896-900 (2007).

⁴⁹ Public goods such as information have the characteristics of being non-excludable and non-rivalrous. This means that consumption of the good by an individual will not reduce nor restrict the consumption of the good by another individual. This makes it socially efficient to maximize access to new technologies and products once they are developed, at marginal production costs. Kenneth Arrow thus argues that it is more efficient to rely on government procurement rather than exclusion rights. See Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Inventions*, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS* (Richard Nelson ed., 1962) [hereinafter Kenneth Arrow].

⁵⁰ The grant of exclusion rights leads to decentralized information based on market response which then forms a link between innovative effort and consumer demand. See Harold Demsetz, *Information and Efficiency: Another Viewpoint*, 12 J. L. & ECON. 1, 11-14 (1969).

⁵¹ Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. REV. 4 (2012).

⁵² The healthcare market is not an ordinary market as consumer/patient demand is based on factors that differ from typical market demand. See e.g., Joseph E. Stiglitz, *Prizes*,

patients can afford the drugs available. This in turn directs products towards markets that can bear their costs. Patients, of course, do not choose their illnesses. At the same time, due to the link between poverty and disease,⁵³ the majority of the world's diseased population lives in developing and least developed economies.⁵⁴ These countries have greater needs in terms of sheer numbers as well as public health concerns as compared to developed countries. The WHO broadly classifies infectious diseases into three categories.⁵⁵ Type I diseases, also called "global diseases", largely occur in both rich and poor countries. These include diabetes, cardiovascular diseases and tobacco-related illnesses. Type II diseases, also called "neglected diseases" are those that occur in both rich and poor countries, but are significantly more in poor countries. Examples of these include HIV/AIDS and tuberculosis. Type III diseases, also called "very neglected diseases" are those that occur almost exclusively in poor countries. Examples of these include malaria and African sleeping sickness.⁵⁶

As a result of patent-based innovation being geared towards richer markets, treatments for poor patients and treatments for diseases that occur primarily in poorer nations are ill accounted for. Further exacerbating the consequences of this distortion of the flow of innovation is the proven link between poverty and disease.⁵⁷ Thus at the first level, the link between sales and product value is minimally useful as an indicator of the value of the innovation being encouraged by patents. Further, distortions appear when medicines are selected by third parties (doctors and/or insurance agencies) rather than by the patient themselves.⁵⁸ While

Not Patents, 42 POST-AUTISTIC ECON. REV. 48-49 (2007).

⁵³ See e.g., POVERTY AND HEALTH: A SOCIOLOGICAL ANALYSIS (John Kosa ed., 1969), where the many ramifications of the poverty-health complex are examined and analyzed. See also, Adam Wagstaff, *Poverty and health sector inequalities*, 80(2) BULL. – WORLD HEALTH ORG. 97-105 (2002); DAVID A. LEON ET AL., POVERTY, INEQUALITY, AND HEALTH: AN INTERNATIONAL PERSPECTIVE (2001). Both individual perspectives as well as institutional perspectives are examined in an analysis of 81 Participatory Poverty Assessment reports with over 40,000 participants in 50 countries around the world. DEEPA NARAYAN, WORLD BANK, VOICES OF THE POOR: CAN ANYONE HEAR US? (2000).

⁵⁴ According to WHO's Global Health Observatory, at the end of 2007, low income groups had a life expectancy of 57 and a healthy life expectancy of 49. At the same time, high income populations had a life expectancy of 80 and a healthy life expectancy of 70. WHO's Data analyzer application, *available at*: <http://apps.who.int/ghodata/#>

⁵⁵ See COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH, WORLD HEALTH ORGANIZATION, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS (2006).

⁵⁶ *Id.*

⁵⁷ See e.g., Bruce G. Link & Jo Phelan, *Social conditions as fundamental causes of disease*, 35 J. HEALTH & SOC. BEHAV. 80 (1995); EILEEN STILLWAGGON, STUNTED LIVES, STAGNANT ECONOMIES: POVERTY, DISEASE, AND UNDERDEVELOPMENT (1998).

⁵⁸ See Arti Kaur Rai, *Rationing Through Choice: A New Approach to Cost- Effectiveness*

some critics have pointed out that development could be harmed by the eventual global diffusion of the US and the European Union (EU)'s IP norms (which offer significantly higher IP protection than the standards under TRIPS),⁵⁹ there has been little study⁶⁰ of how the mentioned distortions affect the optimality of patents as pharmaceutical innovation mechanisms.

Thus while it is clear that patent rights are well suited for recouping investment and gaining revenues from pharmaceutical products, the optimality of patent rights for incentivizing pharmaceutical innovations (especially for poorer countries) is unclear at best.

1. Economics of Information

In the economics of information, knowledge or information is a “public good”. As noted by Paul Samuelson⁶¹ more than half a century ago, “public goods” have the characteristics of being non-excludable and non-rivalrous. This means that consumption of a public good by an individual would neither reduce⁶² nor restrict⁶³ the consumption of that good by another individual. Thus information or knowledge is most efficiently used when everyone can use it. It is therefore socially efficient to maximize access to new technologies and products once they are developed, at marginal production costs.⁶⁴ However, the public good nature of information allows anyone to access and reproduce it, limiting the ability of the developer to recoup investments and thus reducing the incentive for risky or

Analysis in Health Care, 72 IND. L.J. 1015, 1015-19 (1997).

⁵⁹ See, e.g., Reichman *et al.*, *supra* note 32.

⁶⁰ There has been a recent wave of scholarship where this sub-optimality has been examined in detail. However, this scholarship is still limited to academics for the most part and is yet to become part of the mainstream dialogue on pharmaceutical innovation. See e.g., Tim Hubbard & James Love, *A New Trade Framework for Global Healthcare R&D*, 2(2) PLOS BIOLOGY 147 (2004) [hereinafter Hubbard & Love]; William W. Fisher & Talha Syed, *A Prize System as a Partial Solution to the Health Crisis in the Developing World*, in INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO MEDICINES (Thomas Pogge *et al.* eds., 2010) [hereinafter Thomas Pogge *et al.*]; see also, generally, Thomas Pogge *et al.*

⁶¹ Paul Samuelson, *The Pure Theory of Public Expenditure*, 36(4) THE REV. ECON. & STAT. 387-389 (1954). For its application with respect to patent law, see Kenneth Arrow, *supra* note 49; Although information or knowledge per se may be a public good, the presence of legal norms which act as barriers to its availability or excludability sometimes lead to them being called “imperfect public goods”. See Joseph Stiglitz, *Knowledge as a Global Public Good*, in GLOBAL PUBLIC GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY 306 (Inge Kaul, Isabelle Grunberg & Marc A. Stern eds., 1999).

⁶² This is the non-rivalrous nature of a public good.

⁶³ This is the non-excludable nature of a public good.

⁶⁴ Maskus, *supra* note 43.

large investments into the discovery and development of that information.⁶⁵

Intellectual property works towards overcoming this appropriation difficulty by providing exclusion rights over this information, which gives the innovator a time limited measure of control over the usage and reproduction of that information. These time-limited exclusion rights are granted in exchange for the disclosure of the working of the information, so that once these rights expire, social welfare needs can be met by allowing the diffusion of this information. This overall equation can be more clearly represented in the form of static and dynamic efficiencies.

When the usage of a public good is artificially restricted (by the price barrier that the exclusion rights make possible), the information is inefficiently used for the duration of those rights. This under-utilization of information is a "static inefficiency" and leads to a "deadweight loss". Deadweight loss can be thought of as the welfare losses that occur when people are excluded from using goods despite their willingness to pay being higher than the marginal cost of the good.⁶⁶ In the health context, this deadweight loss is represented by deaths and other health losses due to the presence of exclusion rights, that is, the deadweight loss is represented by the loss caused when consumers who would have been able to purchase a drug at production cost aren't able to purchase the drug at the current sale price. Theoretically, a patent holder can remove this deadweight loss through perfect price discrimination.⁶⁷ Perfect price discrimination would allow the seller to charge each user based on his ability and willingness to pay. The seller would be able to sell the good to everyone at their ability (i.e., willingness) to pay above production cost without incurring any losses as they would not be getting sales from the 'deadweight' portion outlined in the earlier scenario as well. However, for this to work, methods of preventing arbitrage would be required.⁶⁸

As these exclusion rights allow for a method of countering the risks of investing in innovative public good activity, they incentivize the continuation of that innovative activity. When this innovation occurs quicker than it would have without the presence of these exclusion rights, there is "dynamic efficiency".

⁶⁵ William Landes & Richard Posner, *An Economic Analysis of Copyright Law*, 18 J. LEGAL STUD. 325 (1989).

⁶⁶ See SUZANNE SCOTCHMER, INNOVATION AND INCENTIVES 36 (2004).

⁶⁷ See, for example, Michael Kremer, *Patent Buy-outs: A Mechanism for Encouraging Innovation*, 113 Q. J. ECON. 1137 (1998).

⁶⁸ Arbitrage refers to the resale of goods, bought at a lower price, at a higher price, usually in another jurisdiction. See, for example, Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y, L. & ETHICS (2005), available at: <http://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=1101&context=yjhple> (last visited December 24, 2013).

Absent a strong incentive system such as the patent system, it is unlikely that blockbuster drugs would come into existence when they do. Similarly, it is unlikely that these incentives are required for very minor incremental changes to drugs. It is of course very difficult to accurately predict when a drug would come into existence minus a certain set of incentives, as well as how much sooner the presence of such incentives can bring the same drug into existence. However, with the decreasing rate of pharmaceutical innovation and rising levels of R&D expenditure,⁶⁹ it would not be unreasonable to say that the dynamic efficiency of pharmaceutical patents, whatever the current level, is likely decreasing.

Nevertheless, the idea that patents are optimal drivers of innovation, especially in the pharmaceutical sector, is taken for granted in today's narrative. Given that scholarship in the field generally tends to take this for granted, it may or may not be clear *why* the pharmaceutical patent regime is seeing costs that are difficult to justify.⁷⁰ The fact that such costs exist, however, cannot be missed. Flexibilities and exceptions to "...exclusion rights are capable of offsetting the static and dynamic inefficiencies generated by the patent system, only to a certain extent". However, the narrative, espoused as it is by developed countries (countries that are better though perhaps not optimally served by it) does not pay much attention to the requirement for pharma-specific inefficiency offsets. Given the nature of the dominant discourse and its dominant influents (such as the US, EU and Japan), atypical positions (such as the use of TRIPS flexibilities or other non-standard positions) start requiring further justification when it comes to the reality of

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Not only are many blockbuster drugs for the world's largest pharmaceutical companies scheduled to go off-patent in the next few years, but the pipeline that would allow these firms to replace those lost earnings is distressingly empty. The small-molecule 'blockbuster' model for developing drugs – used by many Big Pharma companies over the last decade - is showing signs of weakness as companies find they have become increasingly dependant on blockbuster drugs to maintain the industry's historically-high growth rates.

Jeff Cohen et al, *Strategic Alternatives in the Pharmaceutical Industry*, KELLOGG SCH. MGMT., available at: http://www.kellogg.northwestern.edu/biotech/faculty/articles/strategic_alternatives.pdf (last visited December 28, 2013); DEAN BAKER, STAGNATION IN THE DRUG DEVELOPMENT PROCESS: ARE PATENTS THE PROBLEM? (Center for Economic & Policy Research 2007); "By many accounts, the pharmaceutical industry is experiencing a severe decline in research productivity More and more money is being invested in R&D, but the rate at which new drugs are introduced is failing to keep pace." Iain M Cockburn, *Is the pharmaceutical industry in a productivity crisis?*, 7 INNOVATION POL'Y & ECON. 1-32 (2007).

⁷⁰ To sum up, in the case of pharmaceutical innovations, decentralized signals generated by the market do not provide any advantage with which the static and dynamic inefficiencies can be offset.

international relations⁷¹ – unless these new positions too are espoused by an influential Member or group of smaller but consolidated Members (such as India, Brazil and Thailand). This holds as true in international relations today as it did when the TRIPS Agreement was signed. However, this resistance to atypical positions refers only to the atypical-position internal to the IPR regime. A position external to the IPR regime⁷² would require much more than a simple espousal by a few Members, regardless of their influence. The atypical position of advocating the TRIPS flexibilities therefore gathers a certain amount of legitimacy from technically ascribing to the law. However, even while ascribing to the law, it questions what it means to be adhering to these supposed “norms” by looking at how the letter of the law is to be interpreted. It is this context that is important to remember when considering India's pharmaceutical innovation policies and their contribution to the global pharmaceutical innovation regime.

From the negotiation of the TRIPS Agreement onwards, India has taken a strong stance on flexibilities in the patent regime. It did so by not only accepting the TRIPS Agreement, but by embracing it in its entirety. Amy Kapczynski has demonstrated how India has used the architectural framing effects of the law to slow down and even rewrite the global diffusion of the norms espoused by the dominant narrative of patent law.⁷³ Given the potential significance of India's position, this article takes that discussion forward to discuss the legitimacy of India's position as it moves forward in response to the various push-backs against the use of flexibilities.

III. RECENT DEVELOPMENTS IN INDIA

This chapter will look to provide the factual background for the recent events in India that have led to this new wave of pressure. These include the *Novartis* and *Sunitib* judgments as well as the issuance of compulsory licenses (both *Natco* as well as Section 92 compulsory licenses). Once the facts of these situations are laid out, the essence of the criticisms leveled at these decisions as well as an analysis of the legitimacy of those criticisms will be provided. It is to be kept in mind that despite the enormous amounts of pressure, substantively not much has been argued. As these developments have certain compliancy questions and policy concerns in common, these general issues will be examined separately in Part IV.

⁷¹ To examine the policy diffusion taking place here, a frame-type analysis is being used to disentangle the complex relationships between actors, goals and behaviour in the globalization of international norms. *See, for example*, AUDIE KLOTZ & CECILIA LYNCH, STRATEGIES FOR RESEARCH IN CONSTRUCTIVIST INTERNATIONAL RELATIONS 52 (2007).

⁷² For example, alternative innovation mechanisms such as prize systems or government procurement systems.

⁷³ Kapczynski–*Knowledge Mobilization*, *supra* note 25; *see also*, Kapczynski–*Harmonization*, *supra* note 17.

A. Novartis

The *Novartis* case took on giant proportions in the already polarized debate around pharmaceutical patents, innovation and public health as the first challenge to the controversial Section 3(d) of the Indian Patents Act, 2005. The controversy around Section 3(d) stems from it being the first legislative check on the practice of “evergreening” of pharmaceutical products;⁷⁴ it prohibits the patenting of new forms of known substances unless they demonstrate enhanced efficacy over the known substance.⁷⁵ Evergreening is the policy of stacking successive patent durations for a drug by making minor changes to earlier known forms or by making changes which do not result in any significant enhancement of therapeutic efficacy. Due to the protracted nature of the legal proceedings and the significance of the Indian generics industry, the case gathered more attention as the public health versus patents debate gained traction globally. When the Supreme Court of India finally rejected Novartis’ patent application over a leading leukemia drug, Glivec, the global audience immediately reacted – with some denouncing it and others praising it as a victory for public health. This decision, along with the *Natco* decision discussed below, has been cited in nearly all of the unilateral pressure mechanisms mentioned earlier. For the purposes of this article, only the details relevant to the final Supreme Court decision will be discussed.⁷⁶

Novartis applied to the Indian Patent Office for a patent on the “beta crystalline” form of imatinib mesylate in 1998. A few years prior to this, in 1993, Novartis had patented the imatinib free base in the USA. India only started allowing product patents from 1995 onwards and thus a patent application was not filed in India. In its decision, the Supreme Court first finds that a salt of the imatinib free base, namely “imatinib mesylate” is anticipated by this 1993 imatinib free base patent in USA as well as a subsequent publication in 1996 which referenced imatinib mesylate. This was taken as the “known substance” referred to in the language of the provision. The “new form”, the beta crystalline form of imatinib mesylate, was compared to the “known substance” imatinib mesylate to

⁷⁴ Shamnad Basheer, *The “Glivec” Patent Saga: A 3-d perspective on Indian patent policy and TRIPS Compliance*, available at: <http://www.atrip.org/Content/Essays/Shamnad%20Basheer%20Glivec%20Patent%20Saga.doc> (last visited December 23, 2013) [hereinafter Basheer].

⁷⁵ Patents Act, 1970, § 3(d), amended by Patents (Amendment) Act, 2005; LOK SABHA DEBATES, 4TH SESS., VOL. VII, NO. 18, 14TH LOK SABHA (March 22, 2005), at 684 [hereinafter LOK SABHA DEBATES].

⁷⁶ For more details on the history of the case as well as detailed analysis on the provision that pre-dates the Supreme Court decision, see Shamnad Basheer & T. Prashant Reddy, *The “Efficacy” of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5(2) SCRIPTed 232 (2008), available at: <http://www.law.ed.ac.uk/ahrc/script-ed/vol5-2/basheer.asp> (last visited December 23, 2013) [hereinafter Basheer & Reddy].

see if there was any enhanced efficacy. Before this comparison was made, the Court defined “efficacy” to mean “therapeutic efficacy”. In the Court’s words, “not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy.”⁷⁷

On comparing the “known substance” imatinib mesylate with the “new form”, the beta crystalline form of imatinib mesylate, the Court found that the new form had (i) better flow properties, (ii) better thermodynamic stability and (iii) lower hygroscopicity. However, it also held that while these qualities would give the subject product improved processibility and improved storability, they do not make the new form any enhanced efficacy over the known substance. It is important to note that when looking into what constituted therapeutic efficacy, the Court held that an increase in bioavailability can be linked to enhanced therapeutic efficacy and thus could garner the protection of Section 3(d).

Thus, though Novartis presented some evidence of increased bioavailability and better storage ability, they did not present any evidence linking this to enhanced therapeutic efficacy. Instead, Novartis presented some data comparing the beta crystalline version with the free base, and the data it provided was on the alleged superiority of the physical properties of the beta crystalline version rather than increased bioavailability. As it did not have to carry out any comparison due to the lack of evidence, the Court was not required to discuss questions such as the threshold required for increased bioavailability to meet the “enhanced therapeutic efficacy” standard required by Section 3(d). Despite the global attention the decision has garnered, it is actually quite fact-specific and aside from clarifying the legislative intent of the provision and defining “efficacy” to mean “therapeutic efficacy”, the decision does not hold much in the way of precedence due to the weak case brought forward by Novartis.⁷⁸

The criticism:

While the *Novartis* judgment is being touted as evidence of India’s weak patent regime, the aspects on which the case was actually decided have not found much mention. Instead, two other facts are being mentioned in the same context as India’s denial of the Glivec patent: (1) The grant of this patent in 40 other nations; and (2) the value that Glivec has to patients. Presumably, the explicitly heightened standard which disallows evergreening of patents is the problem.

⁷⁷ *Novartis*, *supra* note 7, at 180.

⁷⁸ See also, Shamnad Basheer, *Much Ado about Nothing?*, LIVELAW.IN (June 3, 2013), available at: www.livelaw.in/much-ado-about-nothing (last visited December 23, 2013).

The analysis:

As has just been discussed, Novartis did not provide crucial evidence or data to display the enhanced therapeutic efficacy of the substance in question over the previous known form of that substance, thus rendering it un-patentable as per Section 3(d). Further, Novartis' case also suffered from bad timing. Novartis filed patents for both the base molecule (imatinib) as well as the first salt form (imatinib mesylate) in many countries just a few years prior to 1995. Had these substances been invented a couple of years later, they could have been patented in India as well. However, India enacted its TRIPS-compliant Patents Act within the required time frame and thus there was no question of TRIPS obligations arising prior to its WTO ascension and thus did not grant retrospective patents pre-1995.⁷⁹⁸⁰

However, the bigger picture requires a look at the specific provision that was at the heart of the Novartis controversy – Section 3(d) – and not just the specific facts of this case. The section was the result of a concerted effort by Indian legislators to prevent the evergreening of patents.⁸¹ While they did not define the term, the Lok Sabha (lower house of Parliament) debates indicate that the term was understood to mean: *a process of extending the term of patent protection on a drug while making minor changes which do not increase the efficacy of the drug.* Section 3(d) reads as follows:

The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least employs one new reactant.

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

⁷⁹ See Ken Shadlen, *Learning from India? A new approach to secondary pharmaceutical patents*, INDIA AT LSE (May 3, 2013), available at: <http://blogs.lse.ac.uk/indiaatlse/2013/05/03/a-new-approach-to-pharmaceutical-patents/> (last visited December 23, 2013).

⁸⁰ Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 514 (2007).

⁸¹ See LOK SABHA DEBATES, *supra* note 75, at 684-685. See also, Chan Park & Arjun Jayadev, *Access to Medicines in India: A Review of Recent Concerns*, (Soc. Sci. Res.Network, 2009), available at: <http://ssrn.com/abstract=1436732> (last visited December 22, 2013).

The following three claims are considered to be exceptions to patentability:

- (1) New form of a known substance that does not result in known efficacy of that substance;
- (2) New property / new use for a known substance; and
- (3) New use of a known process, machine or apparatus.

Of these three claims, the first one is the source of controversy. In the past, numerous authors⁸² have speculated that efficacy refers to therapeutic efficacy, which was subsequently confirmed by the Supreme Court in the *Novartis* decision. The Court did not define the threshold for this enhancement but held that it is to be examined on a case-by-case basis. Several drugs have been denied patents under this provision and their removal seems to be at the forefront of the debate on India's pharmaceutical patent regime.

B. *Compulsory Licenses*

There are primarily two types of compulsory licenses allowed under the Indian Patent regime and both types have found mention in the various denouncements of India's patent policy. The pushbacks will be given together after a description of the claimed problems of both types.

1. Natco

On March 14, 2013 India's specialized IP tribunal, the Intellectual Property Appellate Board (IPAB), upheld India's first compulsory license. The Indian generics manufacturer Natco Pharma Ltd. was granted the right to produce and sell Bayer's Sorafenib (Nexavar), a patented medicine used for treating advanced kidney and liver cancer, at a rate of 7% quarterly royalty of net sales.

The compulsory license was first granted by the Controller of Patents on March 9, 2012, based on three justifications: (1) The reasonable requirements of patients who needed the drug were not being met, (2) the drug was not affordable, and (3) the patent was not being worked in India.

On appeal, the matter went to the IPAB in Chennai, which upheld the Controller's decision and effectively allowed Natco to sell a generic version of the drug. It increased the percentage of royalty that Natco was to pay Bayer from 6%

⁸² Basheer, *supra* note 74; Basheer & Reddy, *supra* note 76; see also Rajarshi Sen & Adarsh Ramanujan, *Pruning the Evergreen Tree or Tripping Up Over TRIPS? – Section 3(d) of the Indian Patents Act, 1970*, 41 INT'L REV. INTELL. PROP. & COMPETITION L. 170 (2010); Swaraj Barooah, *A Purposive Patent Policy: Reigniting the Section 3(d) debate in the light of India's international obligations*, 6 NALSAR STUDENT L. REV. 142 (2011).

to 7%. In deciding the dispute, the IPAB referred to various international conventions such as TRIPS which allowed for compulsory licences and stated that patents were granted in the public interest and not solely for monopoly rights. The IPAB held that Bayer “had not ‘worked’ the invention on a commercial scale even if ‘import’ alone would satisfy the working condition”. Further, it was held that the price of Rs 2.8 lakhs per patient per month for Nexavar when compared with evidence of the purchasing ability of the public was sufficient to conclude that the invention was not reasonably affordable to the public. As for the question of whether Bayer satisfied the working requirement, the IPAB held that in the absence of a definition in TRIPS or the Paris Convention, this should be decided on a case-by-case basis and the definition could exclude import from the working requirement, or could be synonymous to it, or anywhere in between these two extremes, depending on the specific case circumstances. They also held that “the patentee must show why it could not be locally manufactured. A mere statement to that effect is not sufficient there must be evidence.”

The criticism:

As per Ron Waldron’s statement to the US House of Representatives, this judgment was severely problematic because the “local working” requirement left open the possibility that local working could mean only local manufacture of goods, excluding the possibility of importing the patented product. Furthermore, compulsory licenses have also been termed as problematic for innovation unless their use is justified by a public health emergency.

2. Section 92 Compulsory Licenses

In January 2013, following the recommendations of the Union Health Ministry, the Government of India, through its Department of Industrial Policy and Promotion, started the process through which compulsory licenses on three drugs could be granted.⁸³ The three were all commonly used anti-cancer drugs –

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The prices of drugs for many diseases, including cancer, have become extremely unaffordable for the common man in this country, which have also increased the pressures on the public health programmes. Compulsory licenses under the Indian Patents Act, 1970 can be issued to generic producers. Generic version of the drugs leads to significant price reductions in developing countries. ... [T]he Ministry of Health & Family Welfare, constituted an inter-ministerial committee to recommend to put such drugs, which are extremely costly and not affordable, under Compulsory Licensing... On the basis of the recommendations ... the Ministry of Health & Family Welfare recommended three cancer drugs, namely, Trastuzumab, Ixabepilone

Herceptin⁸⁴ (used for treatment of breast cancer), Ixabepilone (used for treatment of breast cancer) and Dasatinib (used for treatment of leukemia). The Union Health Minister stated:

The prices of drugs for many diseases, including cancer, have become extremely unaffordable for the common man in this country, which have also increased the pressures on the public health programmes. Compulsory licenses under the Indian Patents Act, 1970 can be issued to generic producers. Generic version of the drugs leads to significant price reductions in developing countries.⁸⁵

According to those experts, the compulsory licenses would have to be granted under Section 92(1) of the Indian Patents Act. This provision allows compulsory licenses to be granted upon notification by the Central Government in case of a national emergency (including a public health crisis), extreme urgency or in the event of public non-commercial use. These licenses are published in the official gazette, after which the Controller of Patents can grant the compulsory license to any interested party who applies for it. The Controller is required to notify the patentee of the granting of the compulsory license. However, the proceedings after this are left open to interpretation.

Section 92(3) states the procedure to be followed when compulsory licenses are granted under Section 92(1). It states that opposition proceedings are not required, so as to avoid any delay whenever a compulsory license is issued under Section 92(1) in circumstances of national emergency or extreme urgency or public non-commercial use including public health crises, relating to acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), tuberculosis, malaria or other epidemics. Two of the drugs mentioned in the notification relate to breast cancer, and one to leukemia. The open question here is whether these two types of cancer fall under this section and whether the phrase

and Dasatinib to the Department of Industrial Policy & Promotion to put them under Compulsory Licensing under the provisions of the Indian Patents Act, 1970.

See Press Release, Gov't of India, Ministry of Health & Fam. Welfare, *License for Manufacturing Generic Anti-Cancer Drugs* (April 30, 2013).

⁸⁴ Owned by Genetech, a subsidiary of Roche. Herceptin was subject to massive civil society campaigns in 2012 for the reduction in price of the drug. Treatment price was initially Rs 2.5 million. After a price reduction, it came to Rs 1.5 million. See Prashant Reddy, *Civil Society sounds the war cry for affordable Herceptin – Roche's worst nightmare comes true*, SPICY IP (28 November, 2012), available at: <http://spicyipindia.blogspot.in/2012/11/civil-society-sounds-war-cry-for.html> (last visited December 26, 2013).

⁸⁵ *Health Ministry recommends compulsory licensing of three anti-cancer drugs*, available at: <http://www.pharmabiz.com/NewsDetails.aspx?aid=75138&sid=1> (last visited December 23, 2013).

“or other epidemics” includes these two types of cancer. If they do not fall under this section, then a lengthy procedure⁸⁶ including opposition proceedings is required before the grant of the compulsory license. If they do fall under this provision, an essentially unilateral imposition of the compulsory license is allowed.

The criticism:

Compulsory licenses have generally been viewed as negative and undesirable, even as their *de jure* legitimacy has been recognized, with the claim being that they cut into the incentives to invest in innovation. There is also fear that this is the beginning of a slippery slope and many more compulsory licenses will follow. In particular, this rhetoric aims to delegitimize any ground for grant of compulsory licenses other than public health emergencies.

The analysis:

Compulsory licenses have traditionally been problematic in the TRIPS regime, with very few being granted in developing countries despite there being clear provisions in TRIPS allowing for compulsory licensing. Traditionally, developing countries have been reluctant to issue compulsory licenses for a variety of reasons, with political pressure playing no small role. The singling out of India is very strange given that the Natco decision led to India’s first compulsory license while Canada has allowed four compulsory licenses, Malaysia has allowed three, Indonesia has allowed six and even the US has allowed one.⁸⁷ Additionally, this compulsory license in India has undergone judicial review for all three grounds upon which it was granted and the 7% royalty rate is, in fact, high by industry standards.⁸⁸ However, a review of the Natco decision together with the compulsory licenses currently being processed under Section 92, reveals that the

⁸⁶ See Section 87 read with Section 84, Indian Patent Act, 1970.

⁸⁷

[T]here had been only one case of compulsory drug licensing in India (Bayer's cancer drug Nexavar licensed to India's NatcoPharma in 2012); Canada had given four compulsory licenses (including one against Bayer), Italy had four, Malaysia had three, Indonesia had six. The US itself had done so in the case of ciproflaxin (after the anthrax scare). So why was the Indian case being singled out, especially when licensing was upheld during judicial review on each of the three possible grounds.

See Chidanand Rajghatta, *Don't let rhetoric trump reason, Chidambaram tells US*, TIMES OF INDIA, (July 12, 2013).

⁸⁸ James Love, World Health Organization & United Nations Development Program, *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*, available at: http://keionline.org/sites/default/files/who_undp_2005_royalty_guidelines.pdf (last visited December 23, 2013).

controversy appears to revolve around the legitimacy of the interpretation of local working requirement.⁸⁹

C. *Sunitib Patent revocation*

After nearly 8 years of back and forth litigation, patent litigation over Sunitinib appeared to have been finally put to rest on 11 February 2013, when the Controller of Patents revoked the pertinent patent on the grounds of obviousness.⁹⁰ However, the case currently once again finds itself awaiting a decision.

On 23 August 2007, the Indian Patent Office granted Sugem (a subsidiary of Pfizer)⁹¹ a patent on "Pyrrole Substituted 2-Indolinone Protein Kinase Inhibitors" for the drug Sunitinib, which is used in the treatment of both renal cell carcinoma as well as imatinib-resistant gastrointestinal stromal tumours.⁹² A post-grant opposition was filed by Cipla, an Indian generic, on 29 August 2008. Cipla challenged the patent application on four grounds: (1) That the invention was publicly known or publicly used before the priority date claimed, (2) the invention is obvious and does not have an inventive step, (3) it is not an "invention" as per the Patents Act, and (4) information was not disclosed as required under Section 8 of the Patents Act. The Controller revoked the patent on 24 September 2012 primarily on the grounds that it did not have an inventive step. While the Controller relied on the Opposition Board's recommendations, which were based on the three prior art documents, she did not supply the parties with the relevant Opposition Board report. The non-supply of the report formed the basis for the writ action that Sugem filed before the Delhi High Court. When the High Court restrained Cipla from marketing a generic version of Sunitinib, they appealed to the Supreme Court, which then reinstated the revoked patent due to violations of the principles of natural justice. The Court directed the Controller to re-examine the opposition after giving both parties the chance to argue for or against the recommendations of the Opposition Board.

When the matter came back to the Controller, Sugem attacked the revocation order on merits. Among the contentions was that Cipla's evidence was improperly admitted and considered while Sugem's expert witness' testimony was not examined. The Controller rejected these objections and ruled that the patent was

⁸⁹ This is dealt with in chapter IV.C.1 of this paper.

⁹⁰ For an in-depth discussion of the case history, see Archana Shanker & Gitika Suri, *Indian pharmaceutical patent law: the revocation of two pathbreaking patents*, PRACTICAL LAW (May 1, 2013), available at: http://uk.practicallaw.com/3-526-7865?q=*&qp=&qo=&qe=# (last visited December 23, 2013) [hereinafter Shanker & Suri].

⁹¹ Sugem is a wholly owned subsidiary of Pfizer. See Sunitinib case.

⁹² Shanker & Suri, *supra* note 90.

obvious and lacked an inventive step, thereby once again accepting the recommendations of the Board. Sugen then appealed to the IPAB against this second revocation on the grounds that there were procedural and technical defects in the decision and that the issue of patentability, in particular the issues relating to inventive step and obviousness, were wrongly decided. The IPAB rejected all these issues except one, relating to non-forwarding of an affidavit by one of Sugen's expert witnesses to the Opposition Board. This, the IPAB opined, rendered the decision of the Opposition Board defective. Further, it expressed disapproval of the Controller's handling of the opposition proceedings.⁹³ After setting aside the order of revocation, the matter was sent back to a different Controller, and it was directed that an Opposition Board be constituted with different members. Lastly, it directed that all grounds would be open to be heard and decided afresh. In their words, "We make it clear that we have not even examined the findings in the impugned order regarding obviousness and the relevance of the prior arts, so the Controller is free to decide the issues in accordance with law uninfluenced by the earlier decisions."⁹⁴

The criticism:

The claims related to this case have been spread out and not particularly specific. A combined reading of Ron Waldron's testimony, the GIPC Report, as well as the letters from the members of US Congress indicates that the problems relate to procedural difficulty and uncertainty, as well as to the delay in the Delhi High Court's grant of an injunction against Cipla after overturning the original revocation.

The analysis:

This is clearly a mismanaged case and is the exception rather than the norm. It is clear that the case has been handled shoddily, with many procedural defects and irregularities. There is, however, no question of a lack of TRIPS compliance here. The fact that Sunitinib's patent has been granted in 90 other countries is not only irrelevant but cannot be considered useful information when India's courts are yet to determine whether the patent is to be granted in India. Thus the problematic aspect of this case is simply the lackluster work done by the Controller and Opposition Board. Given that the IPAB has taken note of this, it is a matter of

⁹³ For a discussion looking at further questions and irregularities regarding this case, see the following along with links contained therein: Prashant Reddy, *More puzzling questions about Sugen's Sunitinib patent*, SPICYIP (November 13, 2012), available at: <http://spicyipindia.blogspot.in/2012/11/more-puzzling-questions-about-sugens.html> (last visited December 23, 2013).

⁹⁴ See ¶ 23, Sunitinib case.

administrative reform rather than any change in patent policy. This is not to mean that the lack of administrative efficiency cannot affect patent policy – it can, since uncertainties may dissuade investment in the country – but this still does not raise any questions of violations of TRIPS obligations. There is also no question of a bias against foreign manufacturers, as alleged; the case being mishandled and the extreme delay in a decision is detrimental to both foreign manufacturers as well as domestic generics companies.

IV. COMPLIANTLY FLEXIBLE

As mentioned earlier, intellectual property as it exists today is faced with an increased question of whether it is the right approach towards augmenting innovation and development. While the IP regime includes all sectors of technology, the global pharmaceutical industry takes on special significance due to the direct impact on health and lives, as well as the large R&D costs that the IP system works well in recovering.⁹⁵ The degree of backlash that these recent Indian developments have attracted seems to indicate that India is falling afoul of its international IP obligations. As this section will demonstrate, that is a weak premise. This perception is significant, however, since regardless of whether the policy is good for India, falling afoul of one's international obligations not only weakens one's position on the international stage but also decreases any influence that such policies may have on other countries with similar needs.

The differences in requirements for different countries have been hardwired into the fabric of TRIPS.⁹⁶ The first problem that poor countries face with regards to (strong) patent laws is that they are catered primarily to the richer segments of society, with the poorer segments not able to pay the required amounts. In India, this poorer segment happens to be a significantly large portion of the population. Therefore, it is vitally important to ensure a threshold of patentability that provides exclusion rights only to drugs that add significant value (while still maintaining compliance with international norms).

The relevant questions⁹⁷ that need to be answered are:

⁹⁵ See generally, Paul Grootendorst, *Patents, Public - Private Partnerships or Prizes - How should we support pharmaceutical innovation?*, Social and Economic Dimensions of an Aging Population, Research Papers 250 (McMaster University 2009); Amy Kapczynski, *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH L.J. 1031 (2003).

⁹⁶ Basheer, *supra* note 74.

⁹⁷ The question of whether India's patent law is TRIPS compliant has generated much debate, but has not actually been challenged yet. For the purposes of this paper, only the questions related to the earlier mentioned developments will be examined. For general

- (1) Whether TRIPS allows sufficient flexibility so as to allow certain incremental innovations to be unpatentable;
- (2) Whether there is discrimination in terms of fields of technology;
- (3) What are the grounds on which compulsory licenses can be granted; and
- (4) Whether the “working requirement” for patents is valid under TRIPS.

A. Interpretive framework

While Member States are mandated to give effect to provisions of the TRIPS Agreement, Article 1.1 gives Member States the freedom to determine the appropriate method of implementation of the provisions within their own legal system and practice. The Panel in *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*⁹⁸ similarly held that Members were free to determine the appropriate method of implementing the provisions of TRIPS in the context of their own domestic legal system. Therefore, since Article 27.1 of TRIPS, which provides for the three standards of patentability,⁹⁹ does not provide the definition of these standards, or even the definition of an “invention”, Member States are clearly given a broad discretion to determine the level of stringency they wish to implement regarding these standards.¹⁰⁰

As per Article 64.1 of TRIPS, the relevant procedure for the settlement of any disputes is contained in the Dispute Settlement Understanding (DSU) in Annex 2 of the WTO Agreement. This Dispute Settlement mechanism is a unique one in that it establishes a set of procedures intended to make the resolution of disputes a matter of law rather than politics.¹⁰¹ This is relevant as the DSU has been explicitly

questions of compliancy and harmonization, *see generally*, Kapczynski–*Harmonization*, *supra* note 17; Shamnad Basheer, *India’s tryst with TRIPS: The Patents (Amendment) Act, 2005*, 1 INDIAN J. L. & TECH. 15 (2005).

⁹⁸ WT/DS50/AB/R S.VI (December 19, 1997).

⁹⁹ Novelty, Non-obviousness and industrial application.

¹⁰⁰

Illustratively, in 2001, the United States Patent and Trademark Office (USPTO) revised its utility guidelines to cater specifically to biotechnology inventions. It is also pertinent to note a German provision brought in to ensure that the patent monopoly on a gene sequence is limited to the specific function disclosed and not to all functions.

See Basheer, *supra* note 74.

¹⁰¹ After 10 years of its existence, in 2005 Andrew Guzman and Beth Simmons have found no evidence showing that power and politics have dissuaded developing countries from bringing claims against more powerful countries. *See* Andrew Guzman & Beth Simmons, *Power Plays & Capacity Constraints: The Selection of Defendants in WTO Disputes*, 34 J. LEGAL STUD. 557 (2005), *available at*: <http://scholarship.law.berkeley.edu/facpubs/827/> (last visited December 23, 2013).

excluded¹⁰² as an avenue for any of the pressure for reforms to Indian patent policy. With respect to the WTO DSU, Article 3.2 mandates that Member States recognize that the dispute settlement system serves to clarify the existing provisions of the relevant Agreement in accordance with the “customary rules of interpretation of public international law”. The Vienna Convention on the Law of Treaties (VCLT),¹⁰³ which governs the general framework for treaty interpretation, has been recognized as constituting customary international law.¹⁰⁴ In interpreting WTO obligations, prior Panel and Appellate Body decisions have also recognized that the principles enshrined in the VCLT are part of customary international law.¹⁰⁵ Article 31 of the VCLT, which provides the general rule of interpretation, states that “a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty *in their context and in the light of its object and purpose*”. (emphasis added)

Article 7 and Article 8 of the TRIPS Agreement are the “Objectives” and “Principles”, respectively.

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.* (Emphasis added)

Article 8: Principles

1. Members may, in formulating or amending their laws and regulations, *adopt measures necessary to protect public health and nutrition*, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to *prevent the abuse of intellectual property rights* by right holders or the resort to practices which *unreasonably restrain trade or adversely affect the international transfer of technology.* (emphasis added)

It is clear from these two articles that a necessary balance between exclusion rights

¹⁰² *Supra* note 1.

¹⁰³ Vienna Convention on Law of Treaties (May 23, 1969), 1155 U.N.T.S. 331.

¹⁰⁴ Maritime Delimitation and Territorial Questions (Qatar v. Bahr.), ICJ Reports 1995, at 6.

¹⁰⁵ *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R; *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, ¶ 114.

and ability to disseminate the fruits of innovative effort is recognized by the TRIPS Agreement, especially in the case of health. It is interesting to note, however, that neither the WTO panels nor the Appellate Body has ever made any definitive interpretation of these two articles despite the matter specifically being brought up in certain disputes.¹⁰⁶ As pointed out in the *Resource Book on TRIPS*,¹⁰⁷ Article 7 “makes it clear that IPRs are not an end in themselves”. They are part of a larger innovation mechanism that exists not only to incentivize private bodies but also to ensure the benefit of society as a whole.¹⁰⁸

At first glance Article 8.1 seems to allow for greater flexibility for countries by allowing for laws or regulations to protect public health and nutrition, as well as sectors of socio-economic or technological development that states deem to be of vital importance for themselves. However, it also imposes two restraints by way of requiring only “necessary” measures, and that these measures are consistent with the provisions of TRIPS.¹⁰⁹ This reinforces the concept of TRIPS as a minimum requirement for patent rights. Nonetheless, to ensure consistency, Article 8 needs to be read with the rest of the Agreement, including Article 7 and the Preamble. This reading allows for flexibilities so long as they comply with the basic minimum standards laid out by the Agreement. As Carlos Correa has noted,¹¹⁰

Article 8.1 is likely to be important in limiting the potential range of non-violation nullification or impairment causes, if allowed in the context of the TRIPS Agreement, as it makes clear that a wide range of public policy measure eventually changing the balance of concessions should be reasonably expected. Given the broad powers recognized to Members under Article 8.1, a Member challenging a measure adopted by another Member in pursuance of public policy objectives should have the initial burden of proof of inconsistency with the provisions of the TRIPS Agreement.

However, Member States from the developing world were concerned that these flexibilities were not sufficiently emphasized within the TRIPS Agreement. This led to the adoption of two documents during the fourth WTO Ministerial Conference at Doha – the Doha Ministerial Declaration, and the Doha Declaration on the TRIPS Agreement and Public Health.¹¹¹ The Ministerial Declaration

¹⁰⁶ See CARLOS CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 102 (2007) [hereinafter CORREA].

¹⁰⁷ UNITED NATIONS CONF. TRADE & DEV. – INT’L CENTRE TRADE & SUSTAINABLE DEV., RESOURCE BOOK ON TRIPS AND DEVELOPMENT 131(2004).

¹⁰⁸ Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 HOUSTON L. REV. 979 (2009).

¹⁰⁹ *Id.* at 16.

¹¹⁰ CORREA, *supra* note 106.

¹¹¹ Hereinafter Doha declaration.

emphasized that the development dimension must be taken into account while interpreting Articles 7 and 8. The Doha Declaration on TRIPS and Public Health specifically recognized the gravity of the public health problems faced by many non-developed countries. Paragraph 4 of the Doha Declaration states:

We agree that the TRIPS Agreement *does not and should not prevent members from taking measures to protect public health*. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be *interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all*.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the *TRIPS Agreement, which provide flexibility for this purpose*. (emphasis added)

It is thus clear that as long as the three Article 27.1 requirements for patentability are met, countries are free to adapt their patent regimes to suit their needs.

B. Evergreening Pharmaceuticals

TRIPs Article 27 mandates that “...patents shall be available for any inventions, whether products or processes, in all fields of technology...” and “...without discrimination as to ... the field of technology...”. Therefore the question that arises with respect to Section 3(d) is whether it is discriminatory with respect to field of technology. Does a specific and differential approach, which appears to impose special prohibitions on patentability of certain chemical processes and pharmaceuticals, violate TRIPS?

This question was dealt with in the *Canada – Patent Protection of Pharmaceutical Products*¹¹² case, where the Panel discussed the meaning of the term “discrimination”. It held that discrimination extends beyond the concept of differential treatment, and refers to results of the “*unjustified imposition*” of “*differentially disadvantageous*” treatment.¹¹³ The Panel also stated that Article 27 does *not* prohibit bona fide exceptions to deal with problems that exist only in certain areas. As mentioned previously, the legislative intent behind Section 3(d) was to prevent evergreening or the consequent grant of exclusion rights to drugs that do not provide any enhancement of efficacy over earlier forms.¹¹⁴ Evergreening is a problem specific to pharmaceutical products and the purpose of the provision is to prevent significant welfare losses in the form of public health

¹¹² *Canada – Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS/114/R [hereinafter *Canada – Patents*].

¹¹³ *Canada – Patents*, *id.* ¶ 7.94.

¹¹⁴ LOK SABHA DEBATES, *supra* note 81 and accompanying text.

costs, which would arise due to the higher prices that exclusion rights allow. These higher prices would lead to some people being priced out of medicines that competition would've otherwise allowed them to purchase and treat themselves with. Even for those who are not priced out, the lack of competition allowed by exclusion rights means that a segment of the population will be paying excess costs while there is no new incentive for therapeutically beneficial innovation being created.

It can thus be strongly argued that this provision is simply a justified imposition of differential treatment. Further, the intent to prevent evergreening is also a *bona fide* intention of a particular policy measure aimed at achieving a particular goal, which is in line with the objects and purposes of the TRIPS Agreement. Section 3(d) thus passes both tests of *Canada – Patents* and is not a discriminatory provision.

C. *Compulsory Licenses*

A compulsory license is an authorization given by a national authority to a person, without or against the consent of the title-holder, for the exploitation of a subject matter protected by a patent or other intellectual property rights.¹¹⁵ The two relevant provisions in India's patent regime are Sections 84 and 92 of the Indian Patent Act. Under Section 84, any interested party can make an application to the Controller three years after the grant of the patent on any of the following grounds:

- (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'

As can be seen from the rest of the section, "reasonable requirement of the public" and "reasonably affordable price" have been given liberal scopes. In the Natco case, the compulsory license was granted on all three grounds. Bayer had only satisfied 2% of the requirement and hence did not satisfy the reasonable requirements of the public. Bayer's Nexavar cost Rs 2.8 lakhs (\$ 5,160) per month compared to Natco's which cost Rs 8,800 (\$162) per month. To put that in perspective, India's per capita income is Rs. 5,729 per month,¹¹⁶ or nearly 50 times

¹¹⁵ See Art. 31 of TRIPS Agreement. *See also*, ABBOTT ET AL., *supra* note 30.

¹¹⁶ The per capita income at current prices during 2012-13 is estimated to be Rs. 68,747. *See* Press Release, Central Statistics Office, Ministry of Statistics and Programme Implementation, *Advance Estimates of National Income 2012-2013* (Feb. 7, 2013), available at: <http://pib.nic.in/newsite/erelease.aspx?relid=92062> (last visited December 23, 2013).

less the cost of Nexavar. The working requirement aspect will be dealt with in Part IV.C.1 of this article.

Compulsory licenses can also be granted under Section 92 of the Indian Patent Act. Under this provision, the Controller can grant a compulsory license upon application, only after the Central Government issues a special notification. This notification can be issued (1) in case of a national emergency, (including a public health crisis), extreme urgency, or in the event of public non-commercial use, or (2) for export. Notably, the granting of compulsory licenses under Section 92(1) cannot be challenged by the patent holder. The Controller is simply required to notify the patentee of the granting of the patent under this section. As mentioned earlier, compulsory licenses for three drugs are being processed under Section 92 currently.

TRIPS handles compulsory licenses as an exception to the Agreement's minimum requirement that all Member States afford a patentee the right of exclusivity during the complete patent term.¹¹⁷ Article 31 prescribes that a proposed user must have attempted negotiations with the patentee for a "reasonable" period of time to obtain authorization to use the patented invention on "reasonable commercial terms and conditions". An exception to the negotiation requirement can be made when there is a national emergency, or in cases of extreme urgency for non-commercial public use. Any usage under this provision must be "predominantly for the supply of the domestic market" of the authorizing nation, and the user must pay "adequate remuneration" to the patent holder, taking into account the "value of the authorization". Thus, Article 31 describes two situations where compulsory licenses can be used. One where the license is required to address an overriding public interest, and the second when patent rights are being used in an anticompetitive manner.¹¹⁸ However, it is to be noted that while Article 31 prescribes both procedural and substantive conditions for the grant of a compulsory license, it is silent on how these substantive conditions are defined. The earlier discussion on Articles 7 and 8, along with the Doha declaration are relevant at this juncture as they emphasize the flexibility Member States have when incorporating the TRIPS Agreement within their domestic legislation.

Further, Article 2.1 of the TRIPS Agreement is relevant as it directs Member

¹¹⁷ ABBOTT ET AL., *supra* note 30, at 196.

¹¹⁸ See generally, Christopher Cotropia, *Compulsory licencing under TRIPS and the Supreme Court of the United States's Decision in eBay v. MercExchange*, in PATENT LAW: A HANDBOOK OF CONTEMPORARY RESEARCH (Toshiko Takenaka & Rainer Moufang eds., 2008); Graeme B. Dinwoodie & Rochelle Cooper Dreyfuss, *International Intellectual Property Law and the Public Domain of Science*, 7 J. INT'L ECON. L. 431, 437 (2004).

States to comply with Articles 1-12 and 19 of the Paris Convention.¹¹⁹ Article 5(A)(2) of the Paris Convention states that Member States have the right to take legislative measures for the grant of compulsory licenses to prevent the abuse that might result from the exercise of patent rights. This is similar to the language used in Article 8 of the TRIPS Agreement, suggesting that Article 8's "appropriate measures" are consistent with Article 31.¹²⁰ Reading these provisions together makes it clear that that Member States have a wide discretion on choosing grounds on which to impose compulsory licenses.

Initially, countries without pharmaceutical manufacturing capacity could not make use of compulsory licensing provisions. This led to the 30 August 2003 decision¹²¹ which allowed countries with local manufacturing capacity to make and export pharmaceutical products to countries with public health needs, thereby waiving previous requirements of "predominant supply to the domestic market" and "adequate remuneration" for the exporting country. An analysis of practices around the world¹²² reveals that grounds for the granting of compulsory licenses have included the patent holder refusing to license,¹²³ public interest,¹²⁴ public health and nutrition,¹²⁵ national emergency or situation of extreme urgency, anti-

¹¹⁹ Paris Convention for the Protection of Industrial Property, arts. 1-12, 19 (July 14, 1967), 21 U.S.T. 1583, 828 U.N.T.S. 305.

¹²⁰ Ritushka Negi & Vineet Rohilla, *Compulsory Licensing: Is the Working Requirement Legitimate?*, MANAGING INTEL. PROP. – THE GLOBAL IP RESOURCE (August 15, 2012), available at: <http://www.managingip.com/Article/3084083/Compulsory-licensing-Is-the-working-requirement-legitimate.html> (last visited December 23, 2013).

¹²¹ Decision of the General Council – *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*, WT/L/540 and Corr.1 (September 1, 2003).

¹²² SISULE MUSUNGU, SOUTH CENTRE & CECELIA OH, WORLD HEALTH ORGANIZATION, THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES? 28-29 (2006) [hereinafter South Centre / WHO Report]; see also James P. Love, *Recent examples of the use of compulsory licenses on patents*, Knowledge Econ. Int'l, Research Note 2 (March 31, 2007), available at: http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf. (last visited December 24, 2013); see also Carlos Correa, *Can the TRIPS Agreement foster technology transfer to developing countries*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 227 (Keith Maskus & Jerome Reichman eds., 2005) [hereinafter Correa – Maskus & Reichman].

¹²³ For e.g. German Patent Law and China's Patent law hold that refusal by a patent holder over reasonable time and reasonable commercial terms may be a ground for a compulsory license. There is however, no definition of what "reasonable" consists of. See Correa – Maskus & Reichman, *id.* at 244.

¹²⁴ This is a standard provision in almost all patent laws.

¹²⁵ For example, French law provides for compulsory licenses to be granted "in the event of medicines being made available in insufficient quantity or quality or at abnormally high prices"; see Art L.613, Law No. 92-597 of 1 July 1992 on the Intellectual Property Code.

competitive practices, dependent patents¹²⁶ and failure to exploit or insufficient working of the patent.

The Brazilian Government has been a great example for developing countries in this regard. It aggressively pursues compulsory licensing strategies including “threatening” big pharmaceutical producers with compulsory licensing when they refused to bring down prices.¹²⁷ Other countries however, have not had it as easy. For instance, when South Africa was undergoing an AIDS crisis, the government declined to define the crisis as a national emergency (and thus invoke compulsory licenses) due to a fear of driving away foreign investment. In the example of Thailand, both the EU and the US, as well as drug companies, started pressurizing and threatening Thailand when it wanted to issue compulsory licenses for certain anti-cancer drugs, even while admitting that it was a legitimate move under the WTO system. This intense pressure can be attributed to the fact that Thailand was the first developing country to issue compulsory licenses for not only AIDS, but also other diseases.¹²⁸

1. Working Requirement

“Working requirement” has not been defined anywhere in the Indian Patents Act. The *Natco* judgment did not offer an actual definition. Instead, the Court observed that neither the TRIPS Agreement nor the Paris Convention had defined the term and held that it must be decided on a case-by-case basis. It held that the definition could range from excluding imports from the working requirement on one hand, to the requirement being completely fulfilled by imports on the other.

For the *Natco* judgment specifically, the Court held that Bayer was required to show evidence as to why Nexavar could not be locally manufactured, failing which, it would be held that they did not fulfill the working requirement. The question of whether Section 84's “worked in India” requirement could be fulfilled solely by imports comes up due to Article 27.1 of TRIPS, which states:

[...] patents shall be available and patent rights enjoyable without

¹²⁶ Where a new invention requires the use of a pre-existing patented invention for working, a compulsory license may be granted for such invention. This is provided for in Art 31(1) TRIPS; *see also* South Centre / WHO Report, *supra* note 122, at 30.

¹²⁷ A.S. Nunn *et al.*, *Evolution of Antiretroviral Drug Costs in Brazil in the Context of Free and Universal Access to AIDS Treatment*, 4(11) PLOS MED. 305 (2007).

¹²⁸ Compulsory licenses have been granted on drugs for cardiovascular diseases as well as for cancer drugs. *See* Sangeeta Shashikant, *Health: Recent Thai compulsory licenses and the aftermath*, THIRD WORLD NETWORK (March 27, 2008), *available at*: <http://www.twinside.org.sg/title2/health.info/2008/twnhealthinfo20080402.htm> (last visited December 24, 2013).

discrimination as to the place of invention, the field of technology and whether products *are imported or locally produced*. (emphasis added)

Thus it appears that if discrimination is made based on whether a drug is locally produced or imported in deciding whether the drug was worked in India, it would be violative of Article 27.1. However, Article 5(A)(1) and 5(A)(2) of the Paris Convention clearly state that failure to work a patent can lead to a compulsory license 3 years after the grant of the patent, unless the patentee justifies his inactions through legitimate reasons. This has been seen by commentators as providing developing countries the right to require local production.¹²⁹ The question of whether “working requirement” can mean local working was brought before the WTO DSU in *Brazil – Measures affecting Patent Protection*.¹³⁰ However, pressure from health groups led the US to drop the case, thus leaving the question unanswered.

Article 5(A)(2) uses words such as “abuses” and “failure to work”. According to Article 31 of the VCLT, the ordinary meaning of these terms should first be taken. However, this does not provide a clear understanding. Looking further into the context, object, and purpose of the provision, it becomes clear that Member States were granted the ability to use compulsory licenses to remedy abuses such as non-working, inadequate supply and exorbitant pricing, as well as to foster technology transfer.¹³¹ Similarly, as is clear from Article 7¹³² and the Preamble of TRIPS, the context, object, and purpose of the TRIPS Agreement also include technology transfer goals.

Further, as argued by Champ and Attaran,¹³³ the principle of *lex specialis derogate legi generali* (a specific legal provision prevails over a conflicting general provision)

¹²⁹ See e.g., Michael Halewood, *Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law*, 35(2) OSGOODE HALL L.J. 243, 245 (1998).

¹³⁰ *Brazil – Measures Affecting Patent Protection*, Request for Consultations by the United States, WT/DS199/1, G/L/385, IP/D/23 (June 8, 2000).

¹³¹ ERNEST LUNGE, *COMPULSORY WORKING AND REVOCATION OF PATENTS* (Stevens & Sons 1910); See also Thomas Cottier *et al.*, *Use it or Lose it? Assessing the compatibility of the Paris Convention & TRIPS with respect to Local Working Requirement* (Swiss Nat'l Centre Competence Res., Working Paper No. 2012/11, 2013).

¹³² Art. 7 of the TRIPS Agreement:

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.

¹³³ Amir Attaran & Paul Champ, *Patent Rights and Local Working under the WTO TRIPS Agreement: An Analysis of the U.S.–Brazil Patent Dispute*, 27 YALE J. INT'L L. 365 (2002).

may apply. In this instance, the general provision of non-discrimination is laid out in Article 27.1 of the TRIPS Agreement, and Article 5(A)(2), together with Articles 30 and 31 of the TRIPS Agreement provide the specific legal provisions allowing compulsory licenses to be issued for a failure to work the patent in question.¹³⁴

Reading all this together, the following can be concluded: Article 31 of the TRIPS Agreement allows compulsory licenses when a patent does not fulfill the working requirement of the Member State's domestic legislation. If the technology transfer goals can be achieved by means other than local manufacture, then "working" the patent does not require local manufacture. Similarly, if technology transfer goals can only be achieved through local manufacture, then importing the patented product will not fulfill the working requirement.

India's legislation has not defined the working requirement to only be local manufacture; case law has also taken a cautious approach by stating that it should be determined on a case-by-case basis. There are, however, two more provisions in India's domestic legislation worth noting in this context. Section 85(7)(d) of the Patents Act states that the reasonable requirements of the public are deemed to have not been met when the patented product is not worked in India on a commercial scale to as adequate an extent as reasonably possible. Section 85(7)(e) goes on to state that if the importation of the patented product hinders the working of the product within India, it will be deemed that the reasonable requirement of the public is not being met. Thus, it is clear that while importation *can* constitute the working of a patent, it may be problematic to assert that the product is being worked if local manufacture has not been considered at all.

It is thus likely that should a dispute be brought under the WTO DSU, India has a very strong case with respect to all possible 4 questions mentioned at the start of this section.¹³⁵

V. POLICY AND POLITICS

The legality of these developments is thus not nearly as controversial as the recent wave of pressure makes it out to be. In fact, the aversion to settling it through the WTO's dispute settlement mechanism could even be interpreted as acknowledging the potential legality of these developments. What is clear, though, is that India is pushing hard on the flexibilities agenda – more than nearly any

¹³⁴ ABBOTT *ET AL.*, *supra* note 30, at 9.

¹³⁵ To restate: (1) Whether TRIPS flexibilities can be interpreted so as to render certain types of incremental innovation as unpatentable; (2) Whether Section 3(d) discriminates in terms of field of technology; (3) What grounds compulsory licenses can be granted on; and (4) Whether the working requirement for pharmaceutical patents is valid under TRIPS.

other country. Regardless of TRIPS compliancy, however, there is pressure from several fronts for India to change their policies. It is also important to note that, regardless of whether a decision has gone against a foreign pharmaceutical company or not, India has shown a clear regard for due process with each decision being reviewed carefully. Looking at the decisions themselves, the spirit behind the widely discussed *Novartis* and *Natco* judgments has been clear – considering legitimate innovator concerns while placing them in context of the great social need in India. In fact, as mentioned previously, the 7% royalty rate granted to Bayer in the *Natco* case is amongst the highest rates granted for compulsory license royalties.¹³⁶ Furthermore, according to an empirical study on the Indian Patent Office outcomes of Section 3(d) cases, it may be true that the IPO is granting *more* patents than are technically eligible, due to resource constraints and pressures to clear applications.¹³⁷ These loosely granted patents hold extra significance in an economy where more than half the population lives on less than \$2 a day and 86% of healthcare expenses are paid out of pocket by individuals.¹³⁸

It is vitally important that India continues to withstand that pressure, not only due to the effects that upward harmonization would have in India and countries that rely on Indian pharmaceuticals,¹³⁹ but also because India's example is being closely watched by several other developing countries for purposes of their own domestic legislation. In fact, the recent past has seen several of the stronger developing economies consider incorporating a provision similar to Section 3(d) in their own legislation. Philippines has already implemented an almost verbatim evergreening provision, while Thailand, Argentina, Brazil and South Africa,

¹³⁶ Based on four different measures for calculating royalty rates in compulsory license decisions, 7% is on the high side, with an "expected" median rate being around 4%. See James Love, *Statement in Nexavar India compulsory licensing case*, KNOWLEDGE ECOLOGY INT'L (February 17, 2013), available at: <http://keionline.org/node/1657> (last visited December 24, 2013); see also, Arvind Subramaniam, *5 Take home points from India's Historic Novartis Patent Case*, ASIAN SCIENTIST (April 29, 2013), available at: <http://www.asianscientist.com/features/5-take-home-points-historic-novartis-patent-case-india-2013/> (last visited December 24, 2013).

¹³⁷ Bhaven N. Sampat *et al.*, *Challenges to India's Pharmaceutical Patent Laws*, 337 (6093) SCIENCE 414-415 (2012).

¹³⁸ THE WORLD BANK, OUT-OF-POCKET HEALTH EXPENDITURE (% OF PRIVATE EXPENDITURE ON HEALTH) (2012), available at: <http://data.worldbank.org/indicator/SH.XPD.OOPC.ZS> (last visited December 24, 2013).

¹³⁹ See e.g., Pooja Van Dyck, *Importing Western Style, Exporting Tragedy: Changes in Indian Patent Law and Their Impact on AIDS Treatment in Africa*, 6 NW. J. TECH. & INTELL. PROP. 138 (2007), available at: <http://scholarlycommons.law.northwestern.edu/njtip/vol6/iss1/8> (last visited December 24, 2013).

emboldened by India's example,¹⁴⁰ have been examining the possibility of expanding their own use of flexibilities. In the current post-TRIPS era, however, opposition has been coming in the form of some of the newer multilateral/bilateral trade agreements that are being negotiated. Legality alone however does not equate to good policy. Thus while such provisions is shown to be legitimate as per the law, the policy reasoning behind the exercising of the flexibilities in a broader context should also be looked at.

The pharmaceutical industry is far from what one could call stagnant; however the productivity of the pharmaceutical's "research and development" sector has seen a decreasing number of therapeutically important new molecules brought to market per dollar spent on R&D.¹⁴¹ There is a decreasing correlation between the amount of money being put into the developmental and production phase of the pharmaceutical industry and the amount of new, therapeutically-important medicines being innovated. The liberal granting of patents, and evergreening of existing patents, has led to pharmaceuticals becoming lax with research towards innovation. With the knowledge that they can get easy patents and hence monopoly periods, there is reduced incentive to spend more research on further innovation, especially in the case of blockbuster drugs and follow on patents.¹⁴² Prevention of evergreening would lead generics to enter the market at end of the duration of the patent. Further, it is likely that market forces would push competing generics to introduce some amounts of incremental innovation. Assuming that pharmaceutical companies will no longer be focusing on this market, there are ample opportunities for generics to provide cheaper access for the same products. Preventing evergreened products from the market would then incentivize the same pharmaceutical companies to invest in research for more therapeutically beneficial innovation, instead of taking baby steps with previously patented work.

Non-nuanced patent rights, however, can create more issues than evergreening. Given that pharmaceutical companies receive most of their revenues from developed economies, their pricing and market delivery strategies are not required to be sensitive to consumers in developing regions where purchasing power is much lower and there is little reason for a pharmaceutical company to ensure maximum availability. At the same time, in order to ensure that generic firms don't copy the drug, the firms seek out patent protection over these drugs. In

¹⁴⁰ UNAIDS, DOHA+10: TRIPS FLEXIBILITIES AND ACCESS TO ANTIRETROVIRAL THERAPY: LESSONS FROM THE PAST, OPPORTUNITIES FOR THE FUTURE (2011).

¹⁴¹ *Supra* notes 69 & 95.

¹⁴² See David Opderbeck, *Patents, Essential Medicines, and the Innovation Game*, 58 VAND. L. REV. 501 (2005).

other words, there is very little incentive to minimize deadweight loss.¹⁴³ This is an externality that a compulsory license could help negate.

As demonstrated earlier, the TRIPs Agreement does provide methods of allowing policy space for tailoring intellectual property regimes to local conditions and public health needs. The Doha Declaration played a large part by re-emphasizing 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.¹⁴⁴ However, it should be noted that despite these flexibilities, and their proven legality, countries have hesitated to use them for a variety of reasons, from political pressure to ignorance to lack of capability.¹⁴⁵ A few of the countries in the higher end of the low-income bracket, such as India and Brazil, have used the time period from the signing of the Agreement to study the effects and consequences that different provisions of the Agreement have, and have been able to reflect this in their current patent legislation and practice. India's creative adoption of the flexibilities has proven to be especially significant, given that it provides generic pharmaceuticals for a majority of the developing world.¹⁴⁶ As Kapczynski suggests,¹⁴⁷ access to medicine proponents have mobilized together to challenge the contours of patent rights by framing their discourse and strategies around traditional intellectual property and

¹⁴³ Perfect price discrimination would be required to minimize deadweight loss however this requires costly information and thus is not expected to occur in practice. *See generally*, F.M. Scherer, *A Note on Global Welfare in Pharmaceutical Patenting*, 27 *WORLD ECON.* 1127, 1128 (2004).

¹⁴⁴ Paragraph 4, Doha declaration.

¹⁴⁵ The use of compulsory licenses has dropped markedly since 2006. Due to the pressures against the usage of compulsory licenses even in upper middle income countries, it can be concluded there is low probability of continued use of compulsory licenses unless there is a change in global health governance actions. *See* Reed Baell & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals since the Doha Declaration: A Database Analysis*, 9(1) *PLOS MED.*, available at: <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001154> (last visited October 11, 2013).

¹⁴⁶ "From 2003 to 2008, in programmes supported by donor organisations like the Global Fund, Indian generic drugs accounted for more than 80% of the drugs used to treat AIDS, including 91% of paediatric antiretroviral products, and 89% of the adult nucleoside and non-nucleoside reverse transcriptase inhibitor markets." *See* Brenda Waning, Ellen Diedrichsen & Suerie Moon, *A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries*, 13(35) *J. INT'L AIDS SOC'Y* 2010, cited in James Love, *The Production of generic drugs in India*, *BMJ* (March 22, 2011), available at: <http://www.bmj.com/content/342/bmj.d1694?> (last visited December 24, 2013); India has consistently been the largest supplier of essential medicines, vaccines and medical supplies to UNICEF since 2007, with about \$558 million of services and supplies in 2012. *See* UNICEF, 2012 Supply Annual Report, available at: http://www.unicef.org/supply/files/UNICEF_Supply_Annual_Report_2012_web.pdf (last visited December 24, 2013).

¹⁴⁷ *See* Kapczynski—*Knowledge Mobilization*, *supra* note 25.

innovation policy norms, the rhetoric of which had until then been limited to big pharmaceutical companies and their supporting governments. To use a crude analogy, pro-access groups¹⁴⁸ have turned TRIPS from a stick into a fulcrum, using it to achieve more balance in access to medicine and international politics than they were able to prior to it.

However, noting the changes in positions, richer countries have accordingly adapted as well. After failed attempts at further strengthening IP regimes post-TRIPS,¹⁴⁹ several developed countries are now using methods outside of TRIPS to induce developing countries to implement TRIPS-plus provisions (standards higher than those required by TRIPS). These countries are attempting to “harmonize” their strong, TRIPS-plus IP standards with those of other countries by entering into bilateral agreements and multilateral free trade agreements (FTAs). With the WTO arena no longer easily maneuverable, these bilateral and multilateral agreements make it easier for them to pressurize poorer countries into compliance – essentially following a divide-and-conquer rule. The provisions that have been sought to be implemented include TRIPS plus provisions, or the restriction or elimination of flexibility options under TRIPS. Along with the clear direct effects, these measures can also reduce a country's bargaining power within the WTO.¹⁵⁰ The US even has a fast-tracking process that recognizes promotion of a US-styled IP regime as a negotiating objective for FTAs. The conclusion of these deals faces trouble, however, where civil society is active. The EU-India FTA, which failed in its attempt to include strong data-exclusivity provisions, is a case in point.¹⁵¹ The potential FTA is facing severe criticism from health activists¹⁵² around the world due to its potential as a barrier to access to essential medicines to all the countries

¹⁴⁸ I am using this term broadly to include developing countries, activists, academics, etc.

¹⁴⁹ For example, the Seattle Ministerial Round, 1999, which was the 3rd World Trade Organization Ministerial meeting, ended in a big failure with a number of low income countries refusing to give in to the pressure by US to reform and give in to their policy decisions. Further, the collapsed negotiations and were reconvened at the Doha round, which laid the pathway for development based agenda.

¹⁵⁰ Peter Yu, *Intellectual Property at a Crossroad: The Use of the Past in Intellectual Property Jurisprudence: Currents and Crosscurrents in the International Intellectual Property Regime*, 38 LOY. L.A. L. REV. 395 (2004).

¹⁵¹ “European commissioner for health and consumer policy Antonio Borg on Friday said the proposed trade agreement with India won't impose data exclusivity, patent extensions or linkages, in a bid to deflect criticism over the purported stance of the European Union.” Vidya Krishnan, *No patent extension clause in free trade deal: EU*, LIVEMINT (April 12, 2013), available at: <http://www.livemint.com/Companies/1HPI3KkupVmmmdHEtK7P1UN/No-patent-extension-clause-in-FTA-EU.html> (last visited December 24, 2013).

¹⁵² See Swaraj Barooah, *EU-India closer to an FTA hampered public health regime?*, SPICYIP (Jan 18, 2011), available at: <http://spicyipindia.blogspot.com/2011/01/eu-india-closer-to-fta-hampered-public.html> (last visited December 24, 2013).

that India supplies. Another prime example is the Trans-Pacific Partnership Agreement (TPP), also currently being negotiated. The TPP is remarkable in that it doesn't seem to care about appearing biased. On one hand, the negotiations are steeped in secrecy such that even Members of the US Congress do not have access to the treaty text while on the other hand, more than 600 corporate advisors involved in writing the TPP have direct access to the it. The only information publicly available on the IP chapter of this agreement has come from leaks of the treaty text.¹⁵³In fact, former USTR Representative Ron Kirk has stated that if people knew what was in the text, there was no way it would get signed into law.¹⁵⁴ This kind of underhanded treaty dealing seems to be an attempt at strong-arming an international treaty into existence. In the case of developing countries, this is problematic even for a non-signatory, since the mere existence of a bilateral or multilateral treaty that recognizes higher levels of patent protection (as compared to the TRIPS requirements) weakens the already delicate negotiation position that such a non-signatory may have in both trade as well as IP matters. However, developing country governments, academics and activists have started concerted efforts at garnering balance and transparency in these treaty negotiations. A notable example in this regard is the Max Planck Institute for Intellectual Property, which after years of careful study has recommended a set of rules and regulations¹⁵⁵ in the process of negotiations that can help achieve a mutually advantageous and balanced regulation of international IP.

It is in this context of forum hopping, strong-arming and other maximizing tactics that India's stance gathers increased significance. Several factors, including its strong generics industry and its burgeoning markets, make it a country that cannot be ignored. At the same time, its high levels of poverty make it a State that necessarily must focus on public interest. This pushes India into a position of significance as an influential figure for much of the developing world.

VI. CONCLUSION: KEY CHOICES IN THE PATH AHEAD

¹⁵³ Several leaked versions of the text have been made available by InfoJustice. See, *Trans Pacific Partnership Document Library*, INFOJUSTICE.ORG, available at: <http://infojustice.org/resource-library/tpp> (last visited December 24, 2013).

¹⁵⁴ Mike Masnick, *Senator Warren: If TPP Transparency Would Lead To Public Opposition, Then TPP Is Wrong*, TECHDIRT.COM (June 13, 2013), available at: <http://www.techdirt.com/articles/20130613/12035523456/senator-warren-if-tpp-transparency-would-lead-to-public-opposition-then-policy-is-wrong.shtml> (last visited December 24, 2013).

¹⁵⁵ Max Planck Institute for Intellectual Property, Competition and Tax Law, *Principles for Intellectual Property Provisions in Bilateral and Regional Agreements*, available at: http://www.ip.mpg.de/files/pdf2/Principles_for_IP_provisions_in_Bilateral_and_Regional_Agreements_final1.pdf (last visited December 24, 2013).

This article has demonstrated that pharmaceutical patents generate certain negative externalities, the exact cost of which is unknown. When exclusion rights are made stronger, they generate higher costs. Further, there are distortions effects that occur due to the patent system being a market-based incentive mechanism. These distortions arise from the use of market signals as resource allocators for pharmaceutical innovation, because market signals in the health sector direct resources and prices towards patients who can afford to pay the monopoly costs. Nonetheless, there are definite benefits that the pharmaceutical patent system brings to pharmaceutical innovation in the form of a strong incentive mechanism. It is very difficult to determine whether these benefits outweigh the costs, but the lowering rate of innovative activity is making strong pharmaceutical patent policy harder to justify.

In its efforts to counter these costs, India has made strong, unprecedented use of its available options without bypassing its international obligations. While these flexibilities were merely on paper before, the actual use of them in the recent past has led to renewed waves of pressure against India's pharmaceutical patent regime. In particular, its anti-evergreening provision and the broadening of its compulsory license regime have generated severe criticism. As described in earlier sections, India's pharmaceutical policies are both legally and normatively sound. As India continues taking a stance against such rights so as to minimize the negative externalities and distortions that come with the patent system, other Member States are watching closely and being influenced to do the same.

As it moves forward, India's decisions are likely to have some powerful impacts on pharmaceutical innovation. As of March 2009, the Indian market currently ranks fourteenth globally in terms of sales with about US \$19 billion and it is expected that these sales will more than double by 2020.¹⁵⁶ This is relevant as it means that India, along with other developing economies, will become significant for recouping investments made in pharmaceutical innovation. Growth potential in emerging markets combined with slowing growth in the developed economies may soon make pharmaceutical investments more reliant on developing economies. This means that if "weak" patent laws are used to reduce death and health losses now (the negative externalities), there may be less investment in innovating new drugs in the future. On the other hand, strong patent laws will allow for more negative externalities right now, and given the current lowering rate of

¹⁵⁶ PwC estimates that sales will rise by 163% to \$50 billion by 2020 making India one of the industry's top 10 markets. This growth will be due to the expanding economy and the increasing per capita GDP. See PriceWaterhouseCoopers, *Global Pharma looks to India: Prospects for Growth*, available at: http://www.pwc.com/en_GX/gx/pharma-lifesciences/pdf/global-pharma-looks-to-india-final.pdf (last visited December 28, 2013).

pharmaceutical innovation, may or may not be sufficient to incentivize innovation of new drugs in the future.

While this is certainly subject to several variations, these are the two general (divergent) directions in which pharmaceutical innovation may proceed in the future, based on reliance upon pharmaceutical patents for innovation. In either case, it seems clear that it will be incumbent upon India and similar economies to move beyond generics and get into drug innovation as well. Despite what was claimed during TRIPS negotiations, the product-patent regime has not pushed Indian companies into devoting any significant resources towards R&D for local needs.¹⁵⁷ Yet this is what will become necessary, and due to the needs of its population, India will have the herculean task of finding ways of minimizing social loss through negative externalities while ensuring sufficient incentives for investment.¹⁵⁸

There is, however, a third path that India happens to already be exploring, and this third path looks beyond the traditional view of patents as innovative mechanisms. This body of innovation mechanisms also aims to bypass the aspects of the patent system that generate negative externalities and distortions while continuing to provide incentives to innovate by venturing outside the patent system. While using flexibilities allows a country to negate some static inefficiencies and deadweight loss, venturing outside the patent system provides the possibility of addressing some problems that are inherent to the patent system.¹⁵⁹ These problems include the distortion of pharmaceutical research towards products which will generate the most revenue, rather than those which will cause the most health impact,¹⁶⁰ and the lack of incentives for the creation of vaccines and treatments for rare diseases.

¹⁵⁷ Sudip Chaudhuri, *Is Product Patent Protection Necessary in Developing Countries for Innovation?* 5 (Indian Inst. Mgmt. Calcutta, Working Paper No. 614, 2007).

¹⁵⁸ There are some methods that US has been experimenting with such as priority review vouchers and advance market commitments. These would require a much more sophisticated pharmaceutical regime than India is likely to have in the near future though. See Jeffrey Sachs, *Helping the World's Poorest*, 17 *ECONOMIST* 352 (1999); Donald Light, *Advanced Market Commitments Current Realities and Alternate Approaches*, (Health Action International, Paper Series Reference 03-2009/01, 2009); see Waseem Noor, *Placing Value on FDA's Priority Review Vouchers*, 27(8) *IN VIVO* (September 2009); Micheal McCoughan, *Treat and Trade: The New Priority Review Voucher Market*, *THE RPM REP.* (July 1, 2008), available at: <http://www.elsevierbi.com/publications/rpm-report/4/7/treat-and-trade-the-new-priority-review-voucher-market> (last visited December 24, 2013).

¹⁵⁹ See generally, text accompanying notes 39-51.

¹⁶⁰ In a study assessing the degree of therapeutic innovation of drugs approved in a decade by the European centralized procedure, the authors found that only a minority could be considered as important therapeutic innovation. Motola D *et al.*, *An update on the*

An example of this type of innovation mechanism is the Indian government's Open Source Drug Discovery¹⁶¹ (OSDD) project. The OSDD project aims to work for the development of medical technologies and drug discovery for neglected diseases and has started off with some success.¹⁶² The project is part of a larger, global open-source drug discovery movement, which aims to use various mechanisms such as private-public partnerships, decentralizing, data sharing and providing access without patents to address the abovementioned problems. The OSDD movement is still evolving and several different models are currently being examined internationally.¹⁶³ Aside from the open source model, there is a growing body of literature on other mechanisms that would fit this patent-averse pharmaceutical innovation paradigm, such as health impact funds¹⁶⁴ and other prize systems.¹⁶⁵ These mechanisms all have their merits, but need to be properly examined before being put into wide practice. One common feature though is that they all require international cooperation of some sort¹⁶⁶ – and thus India, being in a current position of influential power, has the most to gain by continuing to encourage and institutionalize incentive mechanisms that fall under this third path as it moves forward. While it is beyond the scope of this paper to detail the pros and cons of those proposals, I will conclude by proposing some key factors and

first decade of the European centralized procedure: how many innovative drugs?, 62 BR. J. CLIN. PHARMACOL. 610 (2006); *see also*, Donald W. Light, *Pharmaceutical research and development: what do we get for all that money?*, BMJ (Aug. 7, 2012), *available at*: www.bmj.com/content/345/bmj.e4348 (last visited December 24, 2013).

¹⁶¹ *See* www.osdd.net (last visited August 22, 2013).

¹⁶² *See* SwarajBarooah, *OSDD successfully maps TB Genome*, SPICYIP (Apr 13, 2010), *available at*: <http://spicyipindia.blogspot.com/2010/04/osdd-successfully-maps-tb-genome.html> (last visited December 24, 2013).

¹⁶³ *See* Stephen Maurer, Arti Rai & Andrej Sali, *Finding Cures for Tropical Diseases: Is Open Source an Answer?*, 1 PUB. LIBR. SCI. MED. 183 (2004).

¹⁶⁴ *See* Thomas Pogge, *The Health Impact Fund: Better Pharmaceutical Innovations at Lower Prices*, in INCENTIVES FOR GLOBAL HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES 135 (Pogge et al. eds., 2010).

¹⁶⁵ Hubbard & Love, *supra* note 60.

¹⁶⁶ While south-south cooperation may go a long way in the OSDD model, it alone will not be able to solve all problems of neglected diseases. *See* Krishna Ravi Srinivas, *Open Source drug discovery: A revolutionary paradigm or a Utopian model*, in INCENTIVES FOR GLOBAL HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES 263 (Pogge, et al. eds., 2010). Regardless of innovation model, international cooperation is required to address developing world diseases. Towards this goal of responding to the concern of insufficient resources being devoted globally towards developing world diseases, the World Health Assembly (WHA) established the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) in 2010. *See* Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, DOCUMENT A65/24, *available at*: http://apps.who.int/gb/CEWG/pdf/A65_24-en.pdf (last visited December 26, 2013) [hereinafter CEWG Report].

policy levers to reflect upon while venturing down this path to exploring new mechanisms for creating a more suitable drug innovation system.

A. Distributive justice

As an immediate lesson from the patent system, it is important to ensure that everyone's health issues are addressed with at least equal priority, regardless of income level, government's abilities or country of residence. For example, the current patent system incentivizes baldness creams over tuberculosis (TB) as long as bald patients (in richer countries) are able to pay more for such treatment than the usual TB patient would be able to pay for their treatment. The phrase "at least" equal priority is used here because there are also some variations of this theory¹⁶⁷ which put forward the proposition that the needs of the worst off are to be prioritized before those of the comparatively better off. Regardless, ensuring that principles of distributive justice are involved in some form would ensure that neglected diseases are addressed. A system that does not promote this kind of egalitarianism is inherently unfair.

B. Decoupling Research Costs from Sale of Products

The above goal requires that inventive resources are not directed towards maximizing revenues from sale of products. Instead, methods to measure the health benefits that a drug provides should be linked to the "reward" that is given to the innovators. This prevents distortions in the direction of R&D. If the health benefits that a drug provides are compared against the currently available drugs in the market, duplication of research would be reduced while the incentives towards creating drugs for under-researched diseases would simultaneously be increased.

C. Financing

Financing should include risks associated with research work while at the same time, not be so liberal as to encourage inefficient research work. Presuming that international collaboration would play some role, deciding to what extent governments ought to contribute seems to be the biggest issue here. Contributions proportionate to benefits would not be accepted by developing countries, since they are burdened disproportionately with disease. Implementing resource-based, or corrective justice principles (stating that rich countries "owe" the poorer countries for a variety of historical reasons) might have some validity, but it would be hard to convince rich countries to implement. Perhaps the line is somewhere between, where ability to pay, benefit received, and historical inequity as well as accountability are all considered as relevant factors.¹⁶⁸

¹⁶⁷ JEREMY BENTHAM, *THE THEORY OF LEGISLATION* 102-09 (C.K. Ogden ed., 1987) (1789).

¹⁶⁸ The CEWG Report discusses in more detail the need for better coordination to optimize the exchange of information and improve the direction of allocation of inventive

D. *Juxtaposition with the Patent System*

Even in the face of resounding success of such an alternative drug innovation system, the TRIPS Agreement would not permit countries to abolish the patent system altogether. Even in the unlikely case of a treaty amendment, any alternative innovation system would require a transition phase. Therefore, players in the pharmaceutical market would need to choose between the patent system and the alternative drug innovation system. Given that the big players cannot be mandated to join, the alternative drug innovation system would require incentives that are greater than, or easier to achieve, than the incentives provided by the patent system. This may be less difficult than it appears as decentralizing, such as the OSDDD movement for example, does not necessarily rely only on bulk sum monetary incentives.

E. *Maximise Access*

Finally, in order to truly have a successful innovation system, the knowledge and technology that it creates ought to be easily distributable with as minimal barriers to access as possible. This includes addressing the “last mile” problem, where drug innovation also takes into account the real life scenarios of poor patients in poorer countries who often lack proper transportation and maintenance facilities for drugs.

It can thus be concluded that our current times represent a period of ferment in policy making over these drug innovation systems, and India is smack dab in the middle of this. It is clear that while certain States favour stronger intellectual property as the preferred mechanism for drug innovation policy, there is what seems to be the start of another side led by India and other fast growing developing economies¹⁶⁹ which would presumably be seeking a way to maximize access to medicines while also looking out for future drug innovation. This is therefore a ripe time for policy analysts to examine, experiment and advocate for more efficient and equitable drug innovation systems which allow better drug innovation without compromising on access to medicines.

resources. It examines innovative taxing structures, and donor funds, as well as methods of coordination. See CEWG Report, *supra* note 166.

¹⁶⁹ See notes 128-129 and accompanying text. Aside from the examples of Brazil and Thailand mentioned therein, South Africa has also recently shown its intention to ensure this access – innovation balance in its recently released draft intellectual property policy. See Mathews P. George, *The Draft Intellectual Property Policy of South Africa*, SPICYIP (October 12, 2013), available at: <http://spicyip.com/2013/10/the-draft-intellectual-property-policy-of-south-africa.html> (last visited December 26, 2013).