

TAKING PATENTABILITY REQUIREMENT A NOTCH HIGHER: A LAW AND ECONOMICS PERSPECTIVE OF “THERAPEUTIC EFFICACY”

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In 2013, the Supreme Court of India gave finality to the decision of Madras High Court by narrowly construing ‘efficacy’ under §3(d) of the Patent Act, 1970 as ‘therapeutic efficacy’. This paper comprehensively deliberates upon the impacts of ‘therapeutic efficacy’ in a law and economics framework. The focus lies on the patent breadth or scope and its link with such an interpretation, in light of the indigenous pharmaceutical industry’s dependence on incremental innovation. Finally, this paper highlights the crucial nature of State funding and its importance for the effectiveness and efficiency of this judgment. Such funding shall help to fill in the void created by the judgment and a successful indigenous pharmaceutical industry would be able to emerge out of the vicious circle of reverse engineering, generics and me-too drugs.

I. INTRODUCTION

In modern society, every man generally owns what he creates.¹ An invention, which is the result of human skill and labour, essentially amounts to the production of a ‘new’ instrument or manufacture. This invention becomes the subject matter of patent rights.² A patent can be defined as a title granted by the concerned public authorities, which arguably confers an artificial monopoly upon the person applying for the ‘invention’.³ In India, a patent eligibility test has been carved out in §2(j) and §2(ja) of the Patent Act, 1970 (‘Act’), which deals with ‘invention’ and ‘inventive step’ respectively; whereas, §3(d) has been argued to lay down *another* parameter of patentability for any agricultural chemical and/or pharmaceutical derivative.⁴ Insertion of the ambiguous term ‘efficacy’ in §3(d) has been a bone of contention in many debates pertaining to

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¹ SALMOND, SALMOND ON JURISPRUDENCE 113 (1999).

² *Id.*, 114.

³ WIPO, *FAQs*, available at http://www.wipo.int/patentscope/en/patents_faq.html (Last visited on September 6, 2013); Carlos M. Correa, *Guidelines for the Examination of Pharmaceutical Patents*, January, 2007, available at http://www.iprsonline.org/resources/docs/Correa_Patentability%20Guidelines.pdf (Last visited on September 6, 2013).

⁴ Shamnad Basheer & T. Prashant Reddy, *The “Efficacy” of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5(2) JOURNAL OF LAW, TECHNOLOGY AND SOCIETY 233, 251 (2008).

patentability of pharmaceutical derivatives. In 2013, the Supreme Court's landmark decision in *Novartis AG v. Union of India* ('Novartis'),⁵ parsed the term 'efficacy' under §3(d) to imply 'therapeutic efficacy', and nothing else.

In *Novartis*, the SC construed the term 'efficacy' narrowly and stated that the said provision provides for a "second tier of qualifying standards for chemical substances/pharmaceutical products".⁶ Denying the Swiss pharmaceutical giant a patent on its blockbuster drug – Glivec, the SC further commented that §3(d) was meant to curb tactics such as 'evergreening' which such pharmaceutical giants indulge in to exploit consumers, especially those in the developing countries, but not to discourage (incremental) innovation.⁷ How much of this statement holds true needs to be judged in the light of the implications of *Novartis*.

A law and economics framework has been chosen to gauge the economic ramifications of the Court's interpretation of efficacy as 'therapeutic efficacy' on the Indian pharmaceutical industry specifically. In matters relating to intellectual property, this framework is of immense assistance in determining not only the 'effectiveness' of a judgment, but also in looking into the significance of social costs, thus determining the judgment's 'efficiency'. While *Novartis* can be said to have effectively curbed the menace of evergreening, the question that arises is whether it has *efficiently* decided the matter of incremental innovations, knowing that the indigenous industry, an important stakeholder, masters in this field.⁸

To answer the aforementioned question with respect to an efficient patent regime, the optimal 'breadth' and 'length' of the patent are two important tools which may be relied upon. Breadth refers to the scope of protection, whereas length refers to the term of patent protection. It has been noted, however, that "[t]he appropriate margin on which patent policy should operate may not be patent length, but [sic] rather patent breadth".⁹ Since, efficiency of a patent regime is *directly* related to the efficiency of a patent breadth, we have solely used breadth as the analytical tool in this paper. The efficiency of the judgment in *Novartis* depends on whether it leads to an efficient patent regime, which in turn depends on efficient patent breadth. We will predominantly assess the effects of *Novartis*' interpretation of §3(d) on the indigenous

⁵ (2013) 6 SCC 1, ¶ 157.

⁶ *Id.*, ¶87.

⁷ *Id.*

⁸ Ministry of Commerce and Industry, *Report of the Technical Experts Group on Patent Law Issues*, March, 2009, available at http://www.ipindia.nic.in/RevisedReport_March2009.doc (Last visited on February 11, 2014); White & Case LLP & Dua Consulting, *The Value Of Incremental Pharmaceutical Innovation: Benefits For Indian Patients and Indian Business*, June, 2009, available at www.indiaenvironmentportal.org.in/files/USIBCIncrementalInnovationReportFinal.pdf (Last visited on 23 January, 2014).

⁹ Richard Gilbert and Carl Shapiro, *Optimal Patent Length and Breadth*, 21 THE RAND JOURNAL OF ECONOMICS 106 (1990).

pharmaceutical firms which manufacture drugs that may prove to be efficacious, but not therapeutically efficacious. Unfortunately, as one will note later, this industry largely manufactures drugs with enhanced efficacy, but not necessarily with enhanced ‘therapeutic efficacy’.

To establish the claims made, we begin by elucidating how the indigenous pharmaceutical industry has developed a strong base in the field of innovative drugs (or incremental innovation) and how this has transformed the image of Indian pharmaceutical sector from that of an ‘imitator’ to that of an ‘innovator’.¹⁰ This part explains why the ‘innovative pharmaceuticals’ form the backbone of this industry and how this industry lacks the capital to invest in basic research. Part III discusses the two categories of patent breadths, namely narrow and broad breadth. It proceeds to state the economic efficiencies or inefficiencies in each breadth. Part IV acquaints the reader with the concepts of ‘efficacy’ and ‘therapeutic efficacy’. Having examined the data available on the Indian pharmaceutical industry and the literature available on patent breadths and on the concept of efficacy, an analysis of the same is initiated in Part V. The analysis primarily focuses on relating the subjects dealt under Part II, III and IV, to conclude that by raising the patentability standard to therapeutic efficacy, India has moved towards a patent regime which allows for a broader breadth of protection. This will necessarily stunt the growth of the indigenous innovative industry in the short run (static inefficiency) because this industry has a symbiotic relationship with incremental innovation and only a lower patentability standard that establishes narrower patent breadth will help it develop further. Subsequently, by focussing on the long run, it is argued that dynamic efficiency demands such static inefficiencies and losses (short run) need to be borne, provided the gains in the longer run outweigh them. This part further demonstrates that this dynamic efficiency (long run) will be achieved only if the Indian pharmaceutical industry is encouraged and is able to invest in New Chemical Entities (‘NCEs’). To supplement such a pattern, it is mandatory that the State invests in high-risk basic research, the capital for which indigenous firms lack. Finally, Part VI concludes the paper.

II. INCREMENTAL INNOVATION AND INDIGENOUS PHARMACEUTICAL FIRMS

Though the protection awarded by a patent is *territorial*, the information that is disclosed in the patent application is *globally* accessible.¹¹ Thus, apart from defining the scope of the claimed patent and serving other legal functions, it can be used by competing firms to derive information pertaining to the product.¹² Often, competing firms utilize this ‘information’ to make

¹⁰ White & Case LLP & Dua Consulting, *supra* note 8, 2.

¹¹ WIPO, *The Role of Patent Information in Supporting Innovation*, available at www.wipo.int/edocs/mdocs/sme/en/wipo_smes_rom_09/wipo_smes_rom_09_e_workshop02_1-related1.pdf (Last visited on September 28, 2013).

¹² *Id.*

improvements over the patented drugs and secure new patents over their own versions of the now, improved drugs. On the other hand, there are firms which do not rely upon this information, but secure fresh patents over their new, often not so efficacious, version of the blockbuster drugs over which they originally owned the patent. The indigenous firms, which are spoken about in this paper, fall in the former category.¹³

Post-independence, Indian pharmaceutical industries lacked even the most basic R&D skills required to manufacture pharmaceutical drugs, compelling India to import and thereafter sell, expensive drugs in bulk throughout the country.¹⁴ As a result, indigenous industries started reverse engineering the drugs and relied heavily on the information disclosed in the patent applications to produce their own versions of the existing drugs.¹⁵ The drugs so produced were mostly generic in nature and this segment of the indigenous industry grew at a steady pace. This trend continued till the 1990s largely because of the low R&D investment in new drug developments or innovation.¹⁶ Thus, prior to the 2005 legislation, the industry was largely characterized by generic drugs.¹⁷ Later, the new Indian policy towards incremental pharmaceutical innovation coupled with the increase in R&D investment directed towards drug innovation helped in transforming India from an ‘imitator’ to an ‘innovator’.¹⁸ Indian firms today display an expertise in follow-on innovations by working upon the existing drugs.¹⁹ The investment activities undertaken by the large, medium and even small indigenous firms, such as Ranbaxy Laboratories,²⁰ Natco Pharm.,²¹

¹³ Here, it is important to note the distinction between radical (or basic or breakthrough) research and incremental innovation (or developmental application or follow-on research): Radical innovation in the field of pharmaceuticals can be defined as the technological breakthrough research which results in creation of new class of drugs whose effects are substantially different from the effects of the existing ones (one may call them NCEs). Incremental innovations, unlike radical innovations, are modifications and/or improvements upon the existing drugs, which results in a greater number of drugs with increased efficacy, but within the given class of drugs.

¹⁴ Murali Kallummal and Kavita Bugalya, *Trends in India's Trade in Pharmaceutical Sector: Some Insights*, 5 (Centre for WTO Studies Working Paper Group, Paper No. CWS/WP/200/2).

¹⁵ *Id.*

¹⁶ *Id.*, 7-8, 15-16.

¹⁷ *Id.*; Aiswariya Chidambaram, *Indian Generic Pharmaceuticals Market - A Snapshot*, July 27, 2012, available at <http://www.frost.com/sublib/display-market-insight-top.do?id=264038078> (Last visited on January 11, 2014).

¹⁸ Carlos M. Correa, *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing*, November, 2011, available at <http://www.law.fsu.edu/events/documents/Correa.docx> (Last visited on February 2, 2014); White & Case LLP & Dua Consulting, *supra* note 8, 2.

¹⁹ *Id.*

²⁰ See, e.g., WIPO, *Patent Application No. WO/2007/029096*, March 15, 2007, available at [http://patentscope.wipo.int/search/en/detail.jsf?docId=WO2007029096&recNum=190&docAn=IB2006002443&queryString=\(PA/Ranbaxy\)%2520&maxRec=677](http://patentscope.wipo.int/search/en/detail.jsf?docId=WO2007029096&recNum=190&docAn=IB2006002443&queryString=(PA/Ranbaxy)%2520&maxRec=677) (Last visited on February 11, 2014) (This application was filed for “Novel polymorphic forms of clopidogrel hydrochloride”).

²¹ See, e.g., WIPO, *Patent No. WO/2006/082598*, August 10, 2006, available at <http://patentscope.wipo.int/search/en/detail.jsf?docId=WO2006082598&recNum=1&docAn=IN200600>

Dr. Reddy's Laboratories,²² Aurobindo Pharma Limited,²³ Wockhardt Research Centre²⁴ and many others, has been directed towards innovation. This has assisted in changing the perception of India and from being labelled as a mere 'copycat'.²⁵ The success story of Indian pharmaceutical sector indeed reveals the importance of incremental innovation.²⁶

It appears, however, that the industry has stagnated in the arena of developmental applications and hasn't progressed into basic research and development of new drugs.²⁷ The peculiarities of the pharmaceutical industry – which requires a high level of 'high risk' investment – obstruct new firms aspiring to enter into this field of NCEs.²⁸ For instance, for an indigenous firm, from the stage of basic research till the attainment of regulatory approvals for the new 'invention' of a drug, an aggregate cost of \$1 billion is incurred.²⁹ Out of the various stages involved in the development of a new drug, the stage of basic research alone accounts for 27% out of the total expenses incurred.³⁰ Secondly, the high level of Science and Technological skills required hampers the entry of indigenous firms in the field of NCEs. Hence, though India has an untapped pool of innovative capabilities,³¹ it is hard to suggest that the available potential is sufficient for the industry to successfully invest in breakthrough research and

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- 0028&queryString=FP:(WO/2006/082598)&maxRec=1 (Last visited on February 12, 2013) (The application was filed for patent over "novel crystalline forms of rizatriptan benzoate").
- ²² WIPO, *Innovating India's Pharmaceutical Industry*, available at <http://www.wipo.int/ipadvantage/en/details.jsp?id=2659> (Last visited on February 12, 2013) (Discusses how the concerned firm has initiated R&D investments in incremental innovation and how important the IPR Regime in India has been for the firm to be successful in this regard).
- ²³ See, e.g., WIPO, *Patent No. WO/2006/087629*, August 24, 2006, available at <http://patent-scope.wipo.int/search/en/detail.jsf?docId=WO2006087629&recNum=132&docAn=IB200600330&queryString=olanzapine&maxRec=3057> (Last visited on February 12, 2014) (The application filed by Aurobindo Pharma Limited for patent over "controlled Release Formulations of Oxycodone").
- ²⁴ See, e.g., WIPO, *Patent Application No. WO/2009/004592*, January 8, 2009, available at <http://patent-scope.wipo.int/search/en/WO2009004592> (Last visited on February 11, 2014) (The application was filed for "vancomycin compositions").
- ²⁵ Unichem Laboratories, *From Copycats to Innovators (India Reports)*, September, 2006, available at www.pharmexec.com/pharmexec/data/articlestandard/pharmexec/372006/371669/article.pdf (Last visited on February 11, 2014), S13.
- ²⁶ Kim Field, *When Incremental Innovation Is Radical: The 'Access To Medicines' Campaign And The Case Of Indian Generic Drugs* (Technology, Innovation and Institutions Working Paper Series, Paper No. TII-12).
- ²⁷ White & Case LLP & Dua Consulting, *supra* note 8, 4.
- ²⁸ JAKKRIT KUANPOTH, *PATENT RIGHTS IN PHARMACEUTICALS IN DEVELOPING COUNTRIES: MAJOR CHALLENGES FOR THE FUTURE* 115 (2010) (Another factor which restricts them arises from the employment of stringent patents by the MNCs).
- ²⁹ Reji K Joseph, *The R&D Scenario in Indian Pharmaceutical Industry*, 10-11(RIS-DP, Paper Number 176, 2011).
- ³⁰ *Id.*
- ³¹ PTI, *Policy, Infrastructure Main Hurdles in Indian Pharma R&D: Report*, June 20, 2013, available at http://articles.economictimes.indiatimes.com/2013-06-20/news/40093970_1_healthcare-sector-clinical-trials-usa-india-chamber (Last visited on September 28, 2013).

in the development of new drugs.³² This can be demonstrated by simply quantifying and comparing the R&D investment made by the top 10 pharmaceutical companies in India and the investment made by Pfizer, the largest pharmaceutical firm in the world: since 2001-2011 (a total of ten years), the combined R&D investment of the former is ‘\$3,172 million’, while the investment made by latter in 2008 *alone* is ‘\$7,945 million’.³³ These figures speak for themselves.

Clearly, almost the entire sector of indigenous pharmaceutical industry – neither completely committed to production of generic nor new drugs – is devoted largely to the manufacture of innovative drugs. Thus, incremental innovation forms the backbone of the Indian pharmaceutical industry.

Similarly, there also exist multinational foreign firms which produce similar innovative drugs, which may not be efficacious. Though the effects of Novartis on these foreign firms is not the focal point of this paper, a cursory reference to such firms needs to be made since these firms have recently started ‘evergreening’ their blockbuster drugs under the garb of incremental innovations. This is to say that many of the foreign pharmaceuticals companies which claim to conduct pioneering research are either marketing under-license products which are products of some other company or more importantly, are manufacturing ‘me-too’ drugs which do not achieve significant therapeutic advances.³⁴ As the name suggests, such ‘me-too’ drugs are “molecularly distinct, but *therapeutically* identical to an existing medicine”.³⁵ Recently, a sharp rise has been witnessed in the patent applications for such drugs worldwide. For instance, the Canadian Patented Medicine Price Review Board discovered that out of 1,147 newly patented drugs in Canada, 1,005 did not involve any substantial increase in therapeutic value and only 142 drugs were ‘breakthrough’ drugs.³⁶ Similarly, the paradox – of countless patents being granted, despite only few firms applying for ‘novel’ drugs and NCEs – can be well explained by the increase in firms applying for patent claims over ‘trivial’ changes.³⁷

Sadly, the situation in India is not only representative of this worldwide menace, but has also intensified post 2005. Even the mailbox facility initiated by the Indian government, as a fulfilment of its commitment to

³² Meghna Banerjee & Yajnaseni Roy, *Patentability of Incremental Innovation vis-a-vis § 3(d) of The Indian Patents Act: Striking A Balance*, 2 NUJS LAW REV 607, 617 (2009).

³³ Joseph, *supra* note 29, 13.

³⁴ GUIDO WESTKAMP, EMERGING ISSUES IN INTELLECTUAL PROPERTY 119 (2007).

³⁵ KUANPOTH, *supra* note 28, 58, 120 (The author also explains how Hoffman-La Roche, a Swiss company was able to extend its patent over ‘Valium’ and ‘Librium’. The new patented drugs produced, ‘Mogadon’ and ‘Nobrium’, were charged at a higher rate, even though all of them belonged to the same benzodiazepine group of drugs. Further, these new drugs had the same therapeutic effects as the old ones, despite having been able to extract a higher price from the consumer).

³⁶ See generally Steven G Morgan, Kenneth L. Bassett, James M. Wright, Robert G. Evans, Morris L. Barer, Patricia A. Caetano, Charlyn D. Black, “Breakthrough” *Drugs and Growth in Expenditure on Prescription Drugs in Canada*, 331 BMJ 815 (2005).

³⁷ KUANPOTH, *supra* note 28, 58.

TRIPS, received almost 9,000 applications from 1995 to 2003 which mostly related to incremental innovations.³⁸ Out of the 8,926 applications received, 7,520 belonged to foreign nationals (i.e. almost 84% of the total applications) largely relating to mere improvements upon existing drugs.³⁹ Commenting on the veracity of these claims is not the purpose of this paper; the only point sought to be made is that on one hand indigenous firms' growth has a symbiotic relationship with incremental innovation and on the other hand, foreign pharmaceutical giants have started to cover up their evergreening tactics under the guise of developmental applications. Now, *prima facie*, the judgment in Novartis tackles only the issue of evergreening; but a deeper analysis, as is undertaken in this paper, demonstrates that it inadvertently affects the incremental innovation activities undertaken by indigenous pharmaceutical industry. The subsequent part deals with the tool of patent breadth that we rely on to justify the aforementioned assertion.

III. OPTIMAL BREADTH OF PATENTS AND ECONOMIC EFFICIENCY

Only that knowledge which is protected and/or protectable can potentially result in wealth creation.⁴⁰ Even if one were to accept this statement as gospel truth, *how much to protect* and *how long to protect* would be two extremely pertinent and challenging questions which need to be answered. Late 20th century saw economists increasingly recognizing optimal breadth of patent protection as an important research subject.⁴¹ The breadth (or scope) of the patent allowed in any patent regime determines the minimum improvements which are required to be made upon an existing product for the new, improved product (with follow-on improvements or developments) to be granted a patent.⁴² In other words, it is the 'measure'⁴³ or the 'degree' of patent protection covering similar potential inventions in the future.⁴⁴ For instance, the breadth of the patent protection on a drug will determine how similar (or different) the new drug needs to be in comparison to the existing drug, so that the competitor or the same firm cannot (or can) get the new drug patented.⁴⁵ In any patent regime, the breadth of the regime is usually, though inadvertently, defined ei-

³⁸ *Id.*

³⁹ Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation Of India's Patent System and The Rise of Indian Pharmaceutical Innovation*, 68 UNIVERSITY OF PITTSBURGH LAW REVIEW 491, 521 (2007).

⁴⁰ NR SUBBARAM, DEMYSTIFYING INTELLECTUAL PROPERTY RIGHTS 19 (2009).

⁴¹ Joshua Lerner, *The Importance of Patent Scope: An Empirical Analysis*, 25(2) THE RAND JOURNAL OF ECONOMICS 319 (1994).

⁴² ROBERT COOTER & THOMAS ULEN, LAW AND ECONOMICS 120 (2000).

⁴³ Reiko Aoki, Kensuke Kubo & Hiroko Yamane, *Patent Policy and Public Health in Developing Countries: Lessons From Japan*, May, 2006, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627341/pdf/16710556.pdf> (Last visited on September 6, 2013).

⁴⁴ CENTO G. VELJANOVSKI, ECONOMIC PRINCIPLES OF LAW 73 (2007).

⁴⁵ Paul Klemperer, *How Broad Should the Scope of Patent Be?*, 21 RAND JOURNAL OF ECONOMICS 113 (1990).

ther by the patent office while granting or rejecting the patent application or by the judiciary while entertaining patent infringement suits or while determining patentability criterion.⁴⁶

A. *BROAD V. NARROW RULES OF PATENT BREADTH*

King Camp Gillette was granted a patent on the first disposable razor.⁴⁷ The invention consisted of a thin flexible razor blade and a holder to provide it enough rigidity.⁴⁸ Though a patent was granted over this invention, many other competitors started allegedly imitating the invention due to its growing publicity.⁴⁹ When one of the competitors, Clark Blade & Razor Company was sued for patent infringement by Gillette, Clark defended by arguing that since the patent application by Gillette did not bar any subsequent possible embodiments of the razor and the design contemplated by Clark was outside the range of Gillette's patent, such an infringement suit wouldn't hold.⁵⁰

Relying on *Deering v. Winona*,⁵¹ the Third Circuit rejected Clark's argument and stated that the concerned patent application need not spell out all the specific contours of an invention.⁵² This is to say that the patent application need not look into *all* future possibilities of subsequent technical advances or improvements which might allegedly infringe the original invention.⁵³ Such cases, along with the infringement suits in pharmaceutical patents, can be argued to fit in a model where the "invention [is] created through the inventor's insight and hard work [...] [and] does not point the way to wide ranging subsequent technical advances"⁵⁴

We contend that the Third Circuit's decision of holding Clark liable for infringing Gillette's patented product indicates that the Court considered Gillette's patent to be wide or broad *enough* to cover almost all subsequent innovations which could be made on the patented product. The broader the scope a patent regime allows, higher are the possibilities of patent infringement

⁴⁶ Robert P. Merges and Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990).

⁴⁷ United States Patent Office, *Patent No. 775, 134*, November 15, 1904, available at http://www.invention-protection.com/pdf_patents/pat775134.pdf, <http://www.google.com/patents/US775134> (Last visited on September 23, 2013).

⁴⁸ *Id.*

⁴⁹ Merges & Nelson, *supra* note 46, 839.

⁵⁰ *Gillette Safety Razor Co. v. Clark Blade & Razor Co.*, 187 F 149 (1911); Merges & Nelson, *supra* note 46, 846 (This case also demonstrates how the courts determine the breadth in a patent regime while accepting or rejecting the claims in a patent application and while entertaining a patent infringement suit).

⁵¹ *Deering v. Winona Harvester Works*, 155 U.S. 286, 302 (1894) *as cited in* *Gillette Safety Razor Co. v. Clark Blade & Razor Co.*, 187 F 149 (1911), 423.

⁵² *Gillette Safety Razor Co. v. Clark Blade & Razor Co.*, 187 F 149 (1911), 423.

⁵³ Merges & Nelson, *supra* note 46, 880.

⁵⁴ *Id.*

by competing products and processes (perfect or imperfect substitutes).⁵⁵ For instance, if an intellectual property regime grants patent protection over the concept of cars, rather than on a specific type or design of car, it can be argued to have allowed for broader breadths. This would imply that if any other car, other than the patented car, is produced, the former will always be held to infringe the latter. However, if protection is granted only to the specific design of a car, it is said to be narrow. This will not prevent entry of competing cars in the consumer market, but will prevent the entry of only those cars which have the same specificities as the patented car.

Patent breadths can be either narrow or broad depending on the different incentive efforts that they may have.⁵⁶ This is because applying a broad rule encourages fast, but duplicative research; whereas, a narrow rule promotes slower, yet complimentary research.⁵⁷ This assertion can be explained by the following example: in case of the pharmaceutical industry, it is assumed that two competing firms are asked to produce two separate drugs, X and Y which may be similar, but not identical. In a patent regime which allows for a broad rule, only the firm which successfully files for the patent first will enjoy monopoly.⁵⁸ In this case, if product X gets the patent first, then the patent application for product Y will be rejected as the court considers the breadth of protection accorded to X wide enough to cover Y also. However, Y can be granted a patent only in a narrow breadth regime, as only this regime may permit granting of patent protection to similar claims.⁵⁹ So, relying on such arguments, it may be concluded that there exists an argument for promoting broader rules as they minimize duplicative research.⁶⁰ This means that the demand for a broader breadth regime, where the first inventor's claims are given wider protection, is not without sound basis.

Though sound, this line of argument is not foolproof. Scholars such as Kitch, who have argued for centralizing the inventive process, ignored that acceptance of broader patent claims may lead to technological retardations as the incentive to conduct further developments on the existing research is curtailed.⁶¹ They also ignore that broader regimes encourage 'patent races' which have a tendency to increase social costs as there is wastage of resources to be the first party to successfully approach the court for getting the patent.⁶² Also, at times, the pioneering or the breakthrough innovation may lack any commercial value. So, awarding a broader protection particularly in such circumstances

⁵⁵ This statement derives authority from the concept of broad rule of breadth propounded by various scholars (Klemperer, *supra* note, 45, Merges & Nelson, *supra* note, 46).

⁵⁶ COOTER & ULEN, *supra* note 42, 121.

⁵⁷ *Id.*, 120.

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ Edmund Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977).

⁶¹ WILLIAM LANDES & RICHARD A POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY* 319 (2003).

⁶² *Id.*, 320. (They state that broad breadths might "engender wasteful races to be that prospector").

entails that investment in developments and innovations upon the breakthrough research (i.e. patented product *sans* commercial value) stands discouraged.⁶³ An extension of this argument reveals that the ‘loss of substitutes’ – where substitutes are not merely different, but also significantly improved, follow-on research products – increases the social costs in the broad regime.⁶⁴ Hence, it has been argued that a narrower rule will allow the competing (or imitating) firm to produce a product that is a ‘perfect [sic] substitute’ for the innovation, whereas a very broad patent will preclude entry of any competitor (or imitator).⁶⁵ Having assessed the preliminary arguments, it is essential that the efficiencies or the inefficiencies associated with the two breadths be examined, as well.

B. *STATIC EFFICIENCY V. DYNAMIC EFFICIENCY*

Static efficiency focuses on the short term efficiency concerns through such efficient allocation of the available resources that the maximum output can be achieved. Granting patents often result in static efficiency as the producers’ secret is replaced with property rights, which leads to further “dissemination of knowledge”.⁶⁶ Hence, in the instant case of pharmaceuticals and patents, static efficiency can be said to have increased, or said to have been achieved, when such a replacement allows other competitors to work upon the existing knowledge (pharmaceutical drug) due to disclosure of the information in the patent application. This, however, may not be the result in a broad patent regime, which *actively* bars other competing firms from making substitutes (including imperfect substitutes), even by altering or by making improvements upon the existing drug. As these competitors are disallowed to work upon the ‘knowledge’ provided by the patentee, it is hard to argue a case for “dissemination of knowledge” and thus for static efficiency in a broader regime. Secondly, as the patent creates an artificial monopoly, the prices are expected to go up which leads to an under consumption of the patented product, resulting in allocative inefficiency.⁶⁷ This results in deadweight loss – a situation often known as the social cost of monopoly – which represents the loss of economic efficiency in terms of loss of welfare which was earlier being accrued to the consumers, due to certain externalities such as an increase in the price of the product (i.e.

⁶³ COOTER & ULEN, *supra* note 42, 120.

⁶⁴ Merges and Nelson, *supra* note 46, 869.

⁶⁵ Eric Bond and Ben Zissimos, *Patent Breadth in an International Setting*, July 14, 2010, available at www.stanford.edu/group/SITE/archive/SITE_2010/segment_4/segment_4_papers/zissimos.pdf (Last visited on September 3, 2013).

⁶⁶ COOTER & ULEN, *supra* note 42, 120.

⁶⁷ Geoff Riley, *Monopoly and Economic Efficiency*, September 23, 2012, available at www.tutor2u.net/economics/revision-notes/a2-micro-monopoly-economic-efficiency.html (Last visited on September 7, 2013) (This explains the various concepts associated with monopoly and the resultant deadweight losses); See Dhananjay K. Gode, *What Makes Markets Allocatively Efficient?*, 112(2) THE QUARTERLY JOURNAL OF ECONOMICS 603-630 (1997) (Allocative efficiency is about producing from a possible combination of goods, a bundle of goods which the consumers value the most. It is thus about satisfying preferences).

monopoly pricing).⁶⁸ Simply stated, broad patents pose the problem of conferring market power and monopoly on one single ‘prospector’ thereby imposing greater losses for consumers.⁶⁹ Thus, concerns relating to static efficiency *prima facie* demand a patent regime with narrower breadth protection.

On the other hand, a dynamically efficient economy may not necessarily be a productively or allocatively efficient one. Contextually, dynamic efficiency is about distribution of the existing resources of the system in such a manner that *over time* this distribution leads to an increase in the production of concerned goods.⁷⁰ This not only signifies the relationship between the physical quantities of input and output, but more importantly it reveals the relationship between the value (or utility) of the output produced using a given quantity of the input.⁷¹ Dynamic efficiency is thus attained when better goods, i.e. products with higher value, are produced using existing resources or when better ways of producing goods from existing resources are discovered.

Nevertheless, in the context of patents it is relevant to note that though granting broader patent protection presumably leads to short term productive or allocative inefficiency,⁷² for encouraging innovative and entrepreneurial activities in long run, a fundamental trade-off between long term gains and short term losses is required to be made. Schumpeter also acknowledges this trade off when he comments upon the necessity of creating short term monopolies (inefficiencies) to incentivise economic agents to innovate.⁷³ This is the usual argument which the ardent supporters of a stronger patent regime resort to, since they believe that regimes which grant protection with broader breaths actively reward the producers in the long run, thereby encouraging pioneering innovations which have higher social value.⁷⁴ Simply stated, rewarding

⁶⁸ *Id.*

⁶⁹ See generally Edmund Kitch, *How Broad Should Scope of Patent Protection Be?*, 17 THE RAND JOURNAL OF ECONOMICS 113 (1977); VELJANOVSKI, *supra* note 44, 73.

⁷⁰ Paul Heyne, *Efficiency*, available at <http://www.econlib.org/library/Enc/Efficiency.html> (Last visited on September 25, 2013).

⁷¹ *Id.*

⁷² See generally Corinne Langinier and Gian Carlo Moschini, *The Economics of Patents: An Overview* (Center for Agricultural and Rural Development Iowa State University, Working Paper No. 02-WP 293, 2002); See generally Jesús Huerta de Soto, *The Theory of Dynamic Efficiency* in THE THEORY OF DYNAMIC EFFICIENCY 11 (2009).

⁷³ See generally JOSEPH ALOIS SCHUMPETER, THE THEORY OF ECONOMIC DEVELOPMENT: AN INQUIRY INTO PROFITS, CAPITAL, CREDIT, INTEREST, AND THE BUSINESS CYCLE (2012); Jesús Huerta de Soto., *Id.*, 11 (Jesús Huerta de Soto expresses this trade-off in the following way: “From a dynamic standpoint [...] the truly important goal is not so much to prevent the waste of certain means considered known and ‘given’ (the prime objective from the viewpoint of static efficiency) as to continually discover and create new ends and means, (emphasis supplied) and thus to foster coordination while accepting that in any entrepreneurial process new maladjustments will always appear and hence a certain amount of waste is inevitable and inherent in any market economy”).

⁷⁴ *Id.*

producers further results in higher innovation and faster development which ultimately leads to dynamic efficiency.⁷⁵

While static efficiency may demand narrow breadth to prevail, dynamic efficiency calls for a broader breadth regime. Before concluding which breadth is better for the Indian patent regime, it is essential that the cardinal principle of determining a holistically efficient breadth be mentioned. Thus, apart from the benefits and defects inherent in the two rules, it is the socio-economic circumstances that ultimately determine which rule shall be applicable.

1. Efficient Breadth

Usually, the efficient breadth will be broad when the social value of investment on pioneering inventions outweighs such an investment on incremental innovations; narrow breadth will be efficient when the investment on additional developments exceeds the social investment on research.⁷⁶ Hence, when it is known that the investment in basic research for pharmaceutical drugs is substantially higher than the investments being made by companies or competitors in subsequent innovations, it is ideal to have a broader patent regime which will incentivise the producers to come up with breakthrough groundwork on which no existing research has been undertaken. However, when the social investment is largely geared in the direction of developmental application, efficiency (at least, short run or static) mandates that the protection awarded has a narrower breadth.

Having deliberated upon the economics of an efficient breadth, it is imperative that the reasoning of the Court in interpreting efficacy as therapeutic efficacy under §3(d) be briefly discussed. This exercise assists in analysing and interconnecting the patentability standard of therapeutic efficacy *vis-à-vis* the economic tool of patent breadth, the crux of this paper.

IV. ENHANCED THERAPEUTIC EFFICACY UNDER §3(D)

In *Bishwanath Prasad v. Hindustan Metal Industries*, the Supreme Court noted that the overall objective of Indian patent law is to “encourage scientific research, new technology and industrial progress”.⁷⁷ Technological changes being witnessed in the modern era, especially in the pharmaceutical industry, necessitate that a dynamic interpretation be accorded to such settled principles of law when it comes to assessing patent law. A dynamic interpreta-

⁷⁵ COOTER & ULEN, *supra* note 42, 120.

⁷⁶ COOTER & ULEN, *supra* note 42, 120 (Usually, scope is determined by *Doctrine of Equivalents*, but that is not relevant for the purposes of this paper).

⁷⁷ *Bishwanath Prasad v. Hindustan Metal Industries*, (1979) 2 SCC 511 ¶17; AIR 1982 SC 1444, ¶17.

tion to these principles should be accorded only after duly considering the increase in the prevalence of recent practices like the practice of evergreening, a by-product of technological advancement. Thus, in context of pharmaceuticals and patent law, it becomes imperative that innovations which are new but not “useful or beneficial”, be denied patent protection as it can be said that the inventor has *not* contributed to the existing stock of knowledge.⁷⁸ The parameters to adjudge usefulness vary across the globe. Enhancement of known ‘efficacy’, however, has been seen as parameter common to many jurisdictions.⁷⁹

Efficacy is *generally* defined as “the ability to produce a desired or intended result”⁸⁰ and “ability of the drug-receptor complex to produce a physiological response”.⁸¹ In the specific context of healthcare, it is used to indicate the “beneficial change or *therapeutic effect* of a given intervention”.⁸² Often measured by the parameter E_{Max} , in pharmacology, efficacy can be defined as “maximum response achievable from a drug”.⁸³ The practical utility of the patentable product usually depends on ‘direct therapeutic utility’.⁸⁴

Post Novartis, when it comes to pharmaceuticals, India has relatively similar, yet stricter patentability requirement(s) which has clubbed together the concept of ‘efficacy’ and ‘therapeutic value’,⁸⁵ under §3(d). §3(d) is now to be read as a “refinement of the patentability criteria”.⁸⁶ By recognizing §3(d) as an extension of the definition of ‘invention’ (under clauses 2(1)(j) and (ja) of the Act), it has been argued that the said provisions clearly include substantial improvements, but cannot be deemed to include trivial changes, workshop improvements, change in colour or size and alike tweaking.⁸⁷ “Superior utility, comparative excellence, efficient production and qualitative improvement”⁸⁸ are argued to be patentability determinants for incremental improvements. Thus, introduction of §3(d) as a ‘*substratum of tests*’⁸⁹ for de-

⁷⁸ MB RAO AND MANJULA GURU, PATENT LAW IN INDIA 66 (2010).

⁷⁹ For instance, even the Food and Drug Administration (FDA) in the United States of America considers this as a pertinent factor. Even in India, a similar standard has now been imposed.

⁸⁰ Oxford Dictionaries, *Efficacy*, available at <http://oxforddictionaries.com/definition/english/efficacy?q=efficacy> (Last visited on September 26, 2013).

⁸¹ Britannica, *Efficacy*, available at <http://www.britannica.com/EBchecked/topic/180014/efficacy> (Last visited on September 26, 2013).

⁸² News-Medical, *Efficacy-What Does Efficacy Mean?*, available at <http://www.news-medical.net/health/Efficacy-What-Does-Efficacy-Mean.aspx> (Last visited on September 26, 2013).

⁸³ *Id.*

⁸⁴ RAO AND GURU, *supra* note 78, 68 (The statement mentioned in the text holds true, especially, in cases of biotechnology).

⁸⁵ Aoki, Kubo & Yamane, *supra* note 43.

⁸⁶ Basheer and Reddy, *supra* note 4, 252 (Since §3(d) calls for considering “some of the very same issues used in a non-obviousness determination”, it is more appropriate to term it as a patentability standard).

⁸⁷ SUBBARAM, *supra* note 40, 51.

⁸⁸ FEROZE ALI KHADER, THE LAW OF PATENTS IN INDIA WITH SPECIAL FOCUS ON PHARMACEUTICALS IN INDIA 31 (2007).

⁸⁹ Aditya Kant, *An Attempt at Quantification of ‘Efficacy’ Factors under Section 3(d) of the Indian Patents Act*, 18 JOURNAL OF INTELLECTUAL PROPERTY RIGHTS 303 (2013).

termining patentability of additional developments on basic research, was to prevent evergreening and to reduce product-hopping,⁹⁰ not to discourage incremental innovations. However, a stricter application of this patentability requirement and a narrower definition of ‘efficacy’ may have, arguably, resulted in such discouragement.

This demands providing a brief outline of the circumstances which prompted Novartis to approach the Supreme Court, which ultimately compelled the latter to define ‘efficacy’ the way it did.

A. *GLIVEC’S CONTRIBUTION TO INTERPRETATION OF THERAPEUTIC EFFICACY.*

In 2001, not only did FDA grant approval to Gleevec,⁹¹ but TIME also hailed it as the “magic bullets”.⁹² Novartis filed a mailbox application for the drug (IM-Beta crystalline) in July 1998, obtained marketing approval in December 2001 and Exclusive Marketing Rights (EMR) in 2004.⁹³ When the Patent Act was amended in 2005, Novartis went ahead with its patent application to be processed. The application was rejected by the Chennai Patent Office (2006) which automatically resulted in the termination of its EMR. Its appeal to the Madras HC⁹⁴ got diverted to the Intellectual Property Appellate Board (IPAB) where it was again dismissed on the basis that increased ‘therapeutic efficacy’ had not been demonstrated, despite an increase in Gleevec’s bioavailability.⁹⁵ Finally, Novartis approached the Supreme Court directly through a Special Leave Petition.⁹⁶

The Supreme Court rejected Novartis’ patent application on grounds which included lack of inventiveness under §§2(1)(j) and (ja) and non-fulfilment of patentability standards under §3(d).⁹⁷ While commenting on the interrelationship between §2 and §3, it also admitted that the:

⁹⁰ *Id.*

⁹¹ Editors Choice, *Novartis’ Gleevec Cancer “Magic Bullet” Extends Life In GIST Patients*, June 6, 2011, available at <http://www.medicalnewstoday.com/articles/227624.php> (Last visited on September 26, 2013); Elisabeth Buchdunger and Juerg Zimmerman, *The Story of Gleevec*, available at http://www.innovation.org/index.cfm/StoriesofInnovation/InnovatorStories/The_Story_of_Gleevec (Last visited on September 26, 2013); See generally FDA, *Drugs*, June 18, 2009, available at <http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm110502.htm> (Last visited on September 26, 2013); National Cancer Institute, *FDA Approves Important New Leukemia Drug*, available at <http://www.cancer.gov/newscenter/newsfromnci/2001/gleevecpressrelease> (Last visited on September 26, 2013).

⁹² See Time Magazine, *Front Cover*, November, 2001, available at http://img.timeinc.net/time/magazine/archive/covers/2001/1101010528_400.jpg (Last visited on September 26, 2013).

⁹³ KUANPOTH, *supra* note 28, 59.

⁹⁴ *Novartis AG v. Union of India*, (2007) 4 MLJ 1153.

⁹⁵ *Novartis v. IPO*, IPAB Order No. 100/2009, TA/1 to 5/200/PT/CH, June 26, 2009.

⁹⁶ KUANPOTH, *supra* note 28, 60.

⁹⁷ *Novartis*, *supra* note 5, ¶¶74-77.

“[...] amended portion of section 3(d) clearly sets up a *second tier* (emphasis supplied) of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at *repetitive patenting* (emphasis supplied) or extension of the patent term on spurious grounds”.⁹⁸

In other words, ‘efficacy’ was interpreted as ‘therapeutic efficacy’ by relying on the Dorland’s Medical dictionary. The definition of efficacy (of a drug) under §3(d) was read as “the ability of the drug to produce the desired *therapeutic effect*”.⁹⁹

Having discussed the dynamics of the Indian pharmaceutical industry, the breadth of patents and the efficacy requirement under the Indian pharmaceutical patent regime, a deliberation on the interrelationship between the three and its implication on the Indian pharmaceutical industry needs to be initiated next.

V. ANALYSIS

Scholars and economists have always studied the subject of patent breadth and efficiency with respect to ‘infringement issues’ of patentees’ rights by other *rival* companies.¹⁰⁰ In this part, however, we aim to study patent breadths with respect to ‘patentability claims’ over developmental applications (incremental innovation) filed by the *same* company or firm which also owns the patent over the results of the breakthrough research (the blockbuster drug).

A. THE QUESTION OF PATENT BREADTH

Conceivably if a higher patentability requirement has been established by Novartis for the firm which seeks a second patent on its blockbuster drug by making changes, the same criterion will also have to be satisfied by all other applicants who seek patent protection for the incremental innovations made upon the drugs owned and patented by other firms. Failing to meet the enhanced therapeutic efficacy requirement, the latter applicants will not be granted such protection, based on the rationale that they haven’t contributed substantially to the existing knowledge.

Analogous reasoning is seen in cases where the courts have held subsequent inventions as an infringement of the pioneer inventor’s claims. The previously enunciated Gillette example may also illustrate this point well. In other situations where the issue is not relating to infringement, but relates to

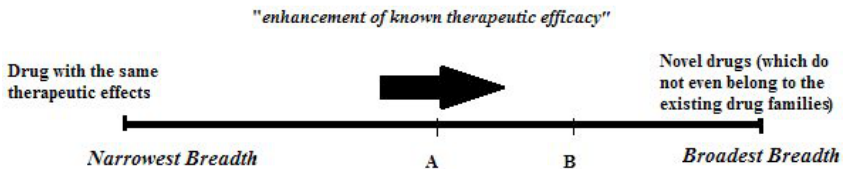
⁹⁸ *Id.*, ¶87.

⁹⁹ *Id.*, ¶¶157,158.

¹⁰⁰ Scholars such as Klemperer, *supra* note 45, Cooter & Ulen, *supra* note 42, Merges & Nelson, *supra* note 46, et al have extensively worked on this issue.

patent claims, it can be argued that similar implications arise. The following example illustrates this point well. 'A' files an application for patenting a technique to produce transgenic mice and also claims that the patent would extend not only to mice but to all non-human transgenic animals created using his technique.¹⁰¹ If 'B' wishes to create a transgenic dog, such a feat would involve considerable experimentation and investment on B's part. While A's method of producing transgenic mice would in all probability be the starting point of B's research, creating a transgenic dog would also require *significant* modifications to A's technique. Where the patentability criterion is considerably higher and A's claim has already been accepted, B will be denied a patent on the grounds that the alteration or the improvements made by him have not contributed substantially to the knowledge pool (existing work done by A). This would simply imply that the protection granted to A was extensive enough to include such modifications made by B, or vice versa. This is so because broad patent claims (claim by A), if accepted, are wide enough to include a number of improvements to the product, within their ambit. Thus, arguably, the Zimmerman Patent (the patent of Imatinib free radical)¹⁰² was wide enough to cover the Imatinib Mesylate free base and also the *beta crystalline* form of Imatinib Mesylate within its scope.¹⁰³

The argument made above has been explained with the help of the diagram below:



(Figure 1)

In the narrowest breadth regime, it is evident that the subsequent drug, which is substantially 'similar' and therapeutically 'same', but molecularly distinct as the existing patented drug(s), will be granted a patent.¹⁰⁴ The broadest patent regime is in stark contrast to this: for the subsequent drug to be patented, it has to be novel and should *not* even closely resemble, molecularly or therapeutically, the existing drug in any manner. It is assumed that point A (refer to Figure 1) is representative of the Indian patent regime before Novartis.

¹⁰¹ Merges and Nelson, *supra* note 46, 839 (They have used a similar example, as well).

¹⁰² Novartis, *supra* note 5, ¶¶96, 97.

¹⁰³ Novartis, *supra* note 5, ¶¶112, 113.

¹⁰⁴ This is because the scope of the protection that is awarded to the original inventor in the narrowest possible regime is almost negligible. This implies that even if the subsequent product has frugal or trivial changes, they will be sufficient for the subsequent product to be considered substantially different from the existing one.

It is contented that post-Novartis, the Indian Patent regime has moved towards a broader breadth paradigm in the particular context of pharmaceutical inventions, represented by point B. So, when a condition is introduced which makes patentability of a pharmaceutical invention contingent on the increased or substantially enhanced *therapeutic* benefits it offers, the character of the regime changes from one which grants patents to *any* alleged incremental innovations, even when it truly is not the case, towards a regime which favours significant innovations, the yardstick of distinction being enhanced therapeutic efficacy. Hence, it appears that the Indian patent regime is moving towards a broader breadth regime, as the circumference of the pool of existing knowledge has been expanded which makes it difficult for the new claimant to establish that his contribution is beyond the boundaries of this pool. This may have negative implications for the indigenous industry.

B. IMPLICATIONS ON THE INDIGENOUS PHARMACEUTICAL INDUSTRY

In Part II, it has been observed that incremental innovations (pharmaceuticals) are the lifeline of the indigenous pharmaceutical industry and that this industry evidently lacks the capital to invest in high-risk, radical innovations. This means that if a broader breadth regime has been inadvertently established, the indigenous industry will be adversely affected since a broader patent regime arguably discourages future innovations, in comparison to a narrower one. For pharmaceuticals, in particular, it *might* impede potential improvements to be made upon the existing drugs by the indigenous companies as those willing to invest in such improvements will be sceptical of: (a) not receiving patent protection over their product; and (b) facing infringement suits from the ‘prospector’, due to higher, perceivably unattainable patentability requirements (i.e. therapeutic efficacy) for the claimed product to be established as “novel, useful and non-obvious”.¹⁰⁵

Predictability of patent-eligibility and patentability is a matter of supreme consideration for an inventor.¹⁰⁶ Broader patent regimes may create uncertainty around the extent of patent rights available with the patent holder (foreign pharmaceutical giants) since the advent of a new, relatively broader breadth regime creates confusion for the patentee (indigenous firm). Thus, broader regimes may stifle the entry of competitors in the field of further research creating an apprehension of potential patent infringement.¹⁰⁷ Moreover, since MNCs are the institutions which usually hold the patents for breakthrough researches due to capabilities to invest in the same, they can sustain high litiga-

¹⁰⁵ See Part IV which suggests that the patent eligibility criterion under §2(1)(j) and (ja) is inter-linked with the patentability requirements under §3(d).

¹⁰⁶ *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002).

¹⁰⁷ See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

tion costs, which the allegedly infringing (indigenous and relatively smaller) firms cannot as they are financially incapable to bear such costs.

Having argued that Novartis establishes a broader breadth patent regime which might adversely impact the indigenous industry, it is also necessary to note whether such effects on the industry in the short run are viable. In other words, the economic efficiency of this decision has to be calculated considering the trade-off between long run and short run impacts it may potentially have.

C. THE QUESTION OF EFFICIENCY

As mentioned in Part III, a trade off between static losses and dynamic gains is viable or efficient only when the social value that is “added by the increased rate of innovation [in the long run] makes up enough social value”¹⁰⁸ that is lost in the short run by granting such protection.

If a patent regime was to reward the innovators of ‘me-too’ drugs, the social value addition to the society would be abysmally low.¹⁰⁹ This is true as the subsequent drug would offer the same therapeutic benefits as the existing, patented one offered. Since there is a clear lack of any substantial therapeutic advancement, the trade-off will demand that patent protection must not be awarded in such cases. Only when the subsequent innovation substantially enhances the therapeutic efficacy of the existing drug thereby generating considerable social value and surpassing the static loss endured by the society, can the grant of exclusive rights to its inventors or innovators be justified.

Taking this line of argument a step ahead, it can be contended that though short run concerns demand that incremental innovations be augmented further since the indigenous pharmaceutical industry primarily thrives on it; in the long-run, the society demands that invention of ‘novel’ drugs be promoted since social investments on existing drugs fail to yield enhanced therapeutic effects. This is to say that in the long run, by construing patentability requirements strictly, the judiciary has indeed *indirectly* encouraged basic research and pioneering inventions (new drugs/pharmaceuticals) by the indigenous industry.¹¹⁰ Though far-fetched, it is argued that this may assist the Indian pharmaceutical industry to *independently*¹¹¹ (emphasis supplied) escape the vicious

¹⁰⁸ Swaraj Barooah, *Patents and Innovation*, February 13, 2010, available at <http://www.spicyindia.blogspot.in/2010/02/patents-and-innovation.html> (Last visited on September 29, 2013).

¹⁰⁹ *Id.* (This holds true even though the private returns for the innovators are much higher).

¹¹⁰ Since it tries to limit incremental innovation by higher patentability standards, it indirectly promotes firms and individuals to undertake researches which are *comparatively* more novel (therapeutically efficacious) than the existing ones.

¹¹¹ While the indigenous pharmaceutical industry has made some contributions to the fields of NCEs, it has always been in collaboration with giant MNCs. In such R&D arrangements,

cycle of generics, reverse engineering and incremental innovations, and enter the field of NCEs in the near future.

However, this argument may appear to be a preposterous one since the indigenous industry lacks the ability to invest in the invention and/or development of new drugs, as mentioned in Part II. Then, it becomes pertinent to note that dynamic efficiency demands the government to come to the rescue of the indigenous industry by funding such basic, fundamental research.

1. Need for State investment in basic research

Due to the lack of commercial application of basic research and finances to initiate such high risk research, it is proposed that the government (in India) and its allied institutions should undertake the responsibility of investing and promoting the research and development of new drugs. Perusing the available literature on the positive externalities generated by public funding of basic research, it cannot be denied that government funding has played a major role in the development of certain sectors, primarily the pharmaceuticals sector.¹¹² Such research provides private players a foundation to build upon; a foundation which they themselves cannot afford to create.¹¹³

Moreover, basic research also has the potential of yielding commercially exploitable techniques and instruments as by-products.¹¹⁴ A prominent example of this is the Cohen-Boyer recombinant DNA technique¹¹⁵ which was a by-product of a publically funded basic research in the field of molecular biology. This technique was commercialised in the 1980s and provided “a new technology platform for a range of industries, resulting in over \$35 billion in sales for an estimated 2,442 new products”.¹¹⁶ Publically funded research

Indian firms are always at a ‘subordinate’ position with respect to the MNCs. Hence, they are not able to truly, independently contribute. See Joseph, *supra* note 29, 6.

¹¹² Ammon J. Salter and Ben R. Martin, *The Economic Benefits of Publicly Funded Basic Research: A Critical Review*, 30 RESEARCH POLICY 509, 517 (2001).

¹¹³ It has also been argued that fundamental research is only feasible in a publically funded research regime. See Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Invention* in THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 618 (1962), available at <http://www.nber.org/chapters/c2144.pdf> (Last visited on October 1, 2013).

¹¹⁴ Bhaven N. Sampat, *The Impact of Publically Funded Biomedical and Health Research: A Review* in MEASURING THE IMPACT OF FEDERAL INVESTMENT IN RESEARCH: A WORKSHOP SUMMARY 156 (2011), available at <http://www.ncbi.nlm.nih.gov/books/NBK83131/pdf/TOC.pdf> (Last visited on October 1, 2013).

¹¹⁵ Chemical Heritage Foundation, *Paul Berg, Herbert W. Boyer, and Stanley N. Cohen*, available at <http://www.chemheritage.org/discover/online-resources/chemistry-in-history/themes/pharmaceuticals/preserving-health-with-biotechnology/berg-boyer-cohen.aspx> (Last visited on October 1, 2013).

¹¹⁶ Maryann P. Feldman et al., *Lessons from the Commercialization of the Cohen-Boyer Patents: The Stanford University Licensing Program*, available at <http://www.iphandbook.org/handbook/chPDFs/ch17/ipHandbook-Ch%2017%2022%20Feldman-Colaianni0Liu%20Cohen-Boyer%20Patents%20and%20Licenses.pdf> (Last visited on October 1, 2013). See also Sally

undertakings also invest some effort in developing prototypes. Upon further private development, such prototypes often blossom into commercially marketable products and are regarded as significant outcomes of the research process by private entities.¹¹⁷ For instance, *Xalatan* which was conceived as a prototype during basic research, was lucratively developed by Pfizer later.¹¹⁸ The drug has been a huge commercial success and had worldwide sales of over \$1,200 million in 2011.¹¹⁹

An insight into the deep relationship existing between publically funded basic research and private sector innovation in the pharmaceutical industry, allows one to contend that publicly funded research can be used to generate ‘fundamental knowledge’ which can be utilized by private sector entities to yield commercially viable products and techniques. Ultimately, this has a direct impact on the dynamic efficiency of the entire system. Thus, the importance of publically funded research in pharmaceuticals cannot be underscored.

In fact, there has been worldwide acceptance of the significant role attributed to government’s initiative in this field. In the United States of America, public funding of R&D for pharmaceuticals alone is the highest and has proven to be rather successful.¹²⁰ It not only helped United States to emerge as one of the foremost developers of new drugs internationally, but such public funding also focussed on diseases which the private sector would not have invested in.¹²¹ China, too, has aimed at establishing its prowess in the international pharmaceutical market through its National Intellectual Property Strategy Compendium (NIPSC) which focuses on independent innovations by inventing NCEs.¹²² One of the primary tools being used for achieving the said purpose is a substantial increase in R&D investment by China in the

Smith Hughes, *Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology*, 92(3) ISIS 541 (2001).

¹¹⁷ Salter and Martin, *supra* note 112, 523.

¹¹⁸ Sampat, *supra* note 114, 155.

¹¹⁹ Evaluate, *Xalatan*, available at <http://www.evaluategroup.com/Universal/View.aspx?type=Entity&entityType=Product&lType=modData&id=13514&componentID=1002> (Last visited on October 1, 2013).

¹²⁰ Salter and Martin, *supra* note 112, 528.

¹²¹ Moran M., *Global Funding of New Products for Neglected Tropical Diseases* in INSTITUTE OF MEDICINE (US) FORUM ON MICROBIAL THREATS, THE CAUSES AND IMPACTS OF NEGLECTED TROPICAL AND ZOONOTIC DISEASES: OPPORTUNITIES FOR INTEGRATED INTERVENTION STRATEGIES (2011), available at <http://www.ncbi.nlm.nih.gov/books/NBK62528/> (Last visited on October 1, 2013).

¹²² Jingxi Ding, Yajiong Xue, Huigang Liang, Rong Shao and Yongfa Chen, *From Imitation to Innovation: A Study of China’s Drug R&D and Relevant National Policies*, 6(2) J. TECHNOL. MANAG INNOV. 1, 9 (2011) (The article assumes four stages that the Chinese pharmaceutical industry has gone through, namely “(1) pure imitation, (2) innovative imitation, (3) imitative innovation, and (4) independent innovation”. It is the last phase, where the industry is expected to discover and/or invent the NCEs using innovative and technological advances, which requires the government funding and support. It aims at “asserting that China would be transformed into a country with high level of creating, utilizing, protecting and administrating intellectual properties by 2020”).

development of NCEs to help the Chinese pharmaceutical industry become independent and innovative in the international market.¹²³

On the other hand, for India, historically, the overall R&D spending financed by the State has been deplorably low and for the pharmaceutical industry, it is even below the 2 percent benchmark.¹²⁴ The Pharmaceutical Research and Development Support Fund (PRDSF), launched in 2004 under Department of Science and Technology, Government of India with a corpus of Rs. 150 Crores,¹²⁵ is one of the very few schemes and policy initiatives undertaken by Indian government with respect to domestic development of NCEs. It was established with an aim of directing resources to the development and advancement of scientific and technological know-how in the pharmaceutical sector. Though this scheme has successfully collaborated with academicians, universities etc. on various fronts, the focus has still been on development and innovation of *existing drugs*.¹²⁶ The pattern of the projects undertaken as a part of the scheme also corroborates the view that government focus on basic research or pioneering inventions or NCEs has been negligible.¹²⁷

Such figures clearly demonstrate the sheer deficiency of State financed basic research in the Indian pharmaceutical sector. This requires the Indian policymakers to appreciate the nuances of effectiveness *versus* efficiency of a legal decision: effectiveness demands the objective be achieved; efficiency demands the objective be achieved at the lowest cost-minimizing option.¹²⁸ Though the judiciary has given a verdict which is effective in curbing the ill-practices of evergreening and promotes therapeutic advances, the 'efficiency' of this decision can only be achieved if the losses caused to the indigenous pharmaceutical industry thriving on incremental innovation can be mitigated in the long run by government intervention.

¹²³ *Id.*; See generally KPMG, *China's Pharmaceutical Industry- Poised for the Giant Leap*, available at <http://www.swissnexchina.org/foryou/kpmg-china-pharmaceutical-201106.pdf> (Last visited on September 30, 2013).

¹²⁴ Joseph, *supra* note 29, 7.

¹²⁵ Cabinet Committee on Economic Affairs, *Dissolving of Pharmaceutical R&D Support Fund Corpus*, January 24, 2006, available at <http://www.pib.nic.in/newsite/erelease.aspx?relid=15120> (Last visited on September 30, 2013).

¹²⁶ DST, *Annual Report 2004-2005*, available at http://www.dst.gov.in/about_us/ar04-05t-d.htm (Last visited on September 30, 2013); DST, *Annual Report 2011-2012*, available at http://www.dst.gov.in/about_us/ar11-12/default.htm (Last visited on September 30, 2013) (The mission has been able to establish programmes and projects which related to 'sustained release drug delivery system for treatment of MDR tuberculosis', 'enhancement of Benzaldehyde biotransformation', 'development of diagnostic kit for detection of Mycobacterium tuberculosis' amongst other developments. They relate only to innovation upon existing drugs).

¹²⁷ *Id.*

¹²⁸ Michael G. Faure & A.V. Raja, *Economic Analysis of Public Interest Litigation in Environmental Cases in India* in *ECONOMIC ANALYSIS OF LAW IN INDIA: THEORY AND APPLICATION* 185, 186 (2010).

VI. CONCLUSION

Patents assume a greater role in the field of pharmaceuticals which has been one of the “most innovative sectors in the world”.¹²⁹ Increase in the importance given to intellectual property rights, particularly pharmaceutical patents, behoves upgrading the quality of granted patents. This implies that in the name of promoting innovation, patents should not be granted liberally to all those who claim it. Rather, both the patent eligibility and patentability criterion should be made stringent enough to *effectively* deter the evergreening tactics. Novartis can be deemed to be a step in this direction. However, effectiveness of the legal standard that is established by Novartis is not the sole criterion to be considered. In this paper, we have tried to argue that since the patent breadth regime established by Novartis results in economic inefficiencies, the judgment itself is not efficient, but merely effective. ‘Efficiency’ of law is relatively more significant as it not only assesses whether the objective of the decision has been effectively achieved, but also quantifies the social costs and benefits resulting from the decision. This makes an interdisciplinary study of the Novartis judgment and its impact on the society imperative.

In a law and economics framework, it can be posited that *prima facie* by taking the patentability standards a notch higher, evergreening will be effectively curbed, but, the social costs of doing so will be tremendously high due to the continued dependence of indigenous industry on incremental innovations. As the social investment in incremental innovations is substantially higher than social investment made by the indigenous industry in development of relatively newer drugs (and/or NCEs), the social costs generated by Novartis judgment – which inadvertently establishes a broader breadth regime discouraging incremental innovations – may outweigh the benefits the judiciary hoped would accrue to the society at large. These costs can be, however, compensated by increased government spending aimed at basic research of newer drugs in Indian pharmaceutical sector. Historically also, public funded basic research has created a number of desirable externalities which have in turn promoted widespread innovative activity in the private sector. Along with generating “fundamental knowledge”, creating commercially constructive “by-products”, and producing prototypes, such research is also effective in dealing with the problem of lack of capital in the high-risk basic research which plagues private innovators. Thus, publically funded research can be significant in stimulating innovative activity in the private sector by giving private entities a foundation to build upon. Not only will this lead to a dynamically efficient outcome, but it will also fulfil the societal need of having therapeutically efficacious innovations.

¹²⁹ International Federation of Pharmaceutical Manufacturers & Associations, *The Pharmaceutical Industry and Global Health: Facts and Figures*, available at http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_-_Facts_And_Figures_2012_LowResSinglePage.pdf (Last visited on October 1, 2013).