

PATENTABILITY OF INCREMENTAL INNOVATION VIS-À-VIS § 3(D) OF THE INDIAN PATENTS ACT: STRIKING A BALANCE

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*The strict standards of patentability envisaged by TRIPS posed a challenge to India's pharmaceutical industries, whose success depended on the ability to produce generic drugs at much cheaper prices than their patented counterparts. A robust patent system would severely curtail access to expensive life saving drugs. Therefore, although India amended the Indian Patent Act, 1970 to protect genuine innovations, it did not extend protection to "incremental innovation" on existing medicines unless such innovation significantly increased the efficacy of the original drug. This article explores the prevailing tension between § 3(d) of the Indian Patent Act, 1970 which excludes "incremental innovation" from patent protection, and pharmaceutical companies pressing for the recognition of the same. Firstly, the article examines the specific reasons behind excluding "incremental innovation" from § 3(d). Secondly, it distinguishes between "ever-greening" and "incremental innovation" and argue that the latter is vital for development of new medicine and thus deserves patent protection. Thirdly, it highlights the ambiguity in the language of § 3(d) and enumerates the changes which are necessary to make the provision workable. In this respect, two recent judgments, namely **Novartis AG v. Union of India** and **F. Hoffman-La Roche v. Cipla** are analyzed, in light of the impact of this provision on the pharmaceutical sector. It concludes by emphasizing on the need to strike a balance between two seemingly conflicting interests: general public interest sought to be protected*

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by § 3(d) and the incentive for research and innovation which necessitates protection of “incremental innovation”.

I. INTRODUCTION

The Indian Patents Act, 1970 was enacted to replace the Indian Designs and Patents Act, 1911, which had governed the patent system in India during the British era. The Act was based on the recommendations of the Ayyangar Committee. The recommendations highlighted the need for a patent regime that would encourage development of the domestic pharmaceutical industry and make life-saving drugs affordable for common people.¹ The Act marked a paradigm shift from the British-imposed patent laws that favoured foreign inventors at the cost of the indigenous drug manufacturers. Under the colonial rule, multinational corporations (MNCs) exploited the patent system to gain monopolistic control over the Indian drug market and blocked indigenous manufacturers from producing cheaper drugs. In spite of being one of the poorest countries in the world, India had to import life-saving drugs like penicillin from abroad and then sell them at prices which were often much higher than those in developed countries.² Therefore, the need of the hour was to reduce the dependence on MNCs and protect public health by making drugs accessible to people.

India was able to achieve both these objectives through the Indian Patents Act, 1970. It abolished patents in pharmaceutical products and provided patents on processes for a short period of time. This gave a rapid boost to the domestic generic drug manufacturing companies which produced cheaper versions of the patented drugs by using “reverse engineering”³ and sold them at lower prices to the Indian population. Thus, the Indian companies were able to effectively compete with MNCs. By 1990s, they controlled seventy percent of the domestic formulations and eighty-five percent of the bulk drug market.⁴

¹ N.R. Ayyangar Committee Report on the Revision of Patents Law (1959) as cited in Shannad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act 2005*, 1 INDIAN J.L. & TECH. 15 (2005) available at http://www.nls.ac.in/students/IJLT/resources/1_Indian_JL&Tech_15.pdf (Last visited on August 1, 2009).

² Linda Lee, *Trials and TRIPS-ulations: India Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. L.J. 281 (2008).

³ Reverse Engineering refers to the process by which an existing system is analysed for identifying its components and their interrelationships so as to create representations of that system in another form or at a higher level of abstraction. Reverse engineering usually redesigns the system to make it more maintainable or to produce a copy of a system without access to the design from which it was originally produced.

⁴ Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 9 VAND J. TRANSNAT'L L. 507 (1996).

In 1995, when India decided to join the WTO, it was brought to pressure by the western countries to bring its patent law in conformity with the standards enumerated in the TRIPS. However, India being a developing country, was given additional time to bring about the necessary changes in its domestic law. Moreover, since it did not have patent protection on pharmaceutical products, TRIPS gave it a 10 year time frame to extend protection to pharmaceuticals.⁵ However, during the transitional period India was expected to set up a system for filing patent applications in pharmaceuticals by way of “mailbox”⁶ provision. The “mailbox” would be opened and examined only on or after January 1, 2005, by which time the Indian Patents Act, 1970 was expected to become TRIPS-compliant. In addition, it had to grant Exclusive Marketing Rights (EMRs)⁷ for pharmaceutical products possessing marketing approval in India and abroad, which were patented in other countries and in respect of which patent application was pending in the Indian Patent Office.⁸ Accordingly, India amended its laws to incorporate these interim measures in 1999. Finally, the Patent (Amendment) Act, 2005 introduced patent protection for pharmaceutical products and thus a TRIPS compliant patent regime came into existence.

Even though the scope of patent protection was expanded, India was unwilling to threaten its highly developed generic industry by making the Indian Patents Act, 1970 too patent- friendly. § 3 restricts the scope of subject matter eligible for patentability by listing out what are not “inventions” within the ambit of Indian Patents Act. § 3(d) specifically disallows patents for the mere discovery of a new form of a known substance unless such form demonstrates significant efficacy over the original substance. In effect, this provision excludes from its

⁵ Vijay Yalamanchili, *State of India's Trips compliant Patent Regime*, 26 BIOTECHNOLOGY L. REP. 211 (2007).

⁶ TRIPS Agreement, Article 70.9 required India “to provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed...” Thus, India had to come up with ‘mailbox’ facility where all the patent applications for pharmaceutical products filed during the transition period had to accepted and put away to be examined in 2005. Each application had to be provided with a filing date. This system is known as ‘pipeline protection’.

⁷ EMR is a quasi-patent right granted in anticipation of a patent. Article 70.9 of TRIPS provides that certain mailbox applications which met the criteria specified therein would have to grant EMR during the transition period. Accordingly, § 24B(1) of the Indian Patents Act was amended in 1999 to provide for EMR. It states that the duration of the EMR shall be 5 years from the date of EMR grant or till the date of grant of a patent or the date of rejection of the patent, whichever is earlier. The chapter on EMRs and consequently § 24(B) was repealed by the Patent (Amendment) Act, 2005.

⁸ Janice, M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491 (2007).

⁹ Incremental innovation occurs when technical modifications are made to an existing product, process, or system, which results in improvement or enhancement of that product, process, or system.

purview most kinds of “incremental innovation”.⁹ The exclusion is based on the rationale that providing protection to such innovations promotes evergreening¹⁰ and harms long term public interest. In this article, we will explore the prevailing tension between § 3(d) and the pharmaceutical companies pressing for recognition of incremental innovation. Part A will examine the reasons why the Indian Government chose to have a unique provision like § 3(d) in the Indian Patents Act. This part will also attempt to determine the importance of this provision in the protection of public health. Part B will distinguish between evergreening and incremental innovation and demonstrate that “incremental innovations” can be vital for development of new pharmaceutical drugs and excluding them from patentability would be detrimental to the greater public interest. Part C will attempt to analyse the inherent ambiguities in this provision which makes it problematic. It will critically examine *Novartis AG v. Union of India*¹¹ and *F. Hoffman-La Roche v. Cipla*¹² in context of interpretation of § 3(d). This part would also discuss the various changes that need to be introduced in order to make this provision more objective and eliminate the uncertainties created by its ambiguous language. Part D would argue that in spite of the problems surrounding § 3(d), doing away with it wholly is not a favourable option for India, given the fact that the ultimate aim of the provision is to weed out frivolous patents and recognize genuine innovations. Although other WTO countries like USA do not have a specific provision like § 3(d) of Indian Patents Act, 1970, they have a number of indirect ways to limit the grant of patent for insubstantial modifications of known drugs. If the provision is properly amended to provide concrete guidelines for determining the patentability, (so that valuable incremental innovations are not neglected) it would be possible to strike a balance between the interests of the inventors and the general public. Finally the article will conclude by reiterating that a clearer and more specific wording of § 3(d) would ensure that India remains true to its commitment of filtering out undeserving pharmaceutical inventions while giving due recognition to meritorious innovations in the field of medical science.

A. THE NEED FOR § 3(D) IN THE INDIAN PATENT SYSTEM

Although the Patents (Amendment) Act, 2005 significantly expanded the scope of patentability by allowing patents for both processes and products, it wanted to provide a mechanism to weed out undeserving patents. It was with this rationale that § 3(d) was amended to its present form. This section discusses subject matter not eligible for patent protection, in context of new forms or new use of known substances. § 3(d) as amended by the Patents (Amendment) Act, 2005 reads as follows:

¹⁰ Evergreening occurs when a manufacturer ‘stockpiles’ patent protection by obtaining separate 20-year patents on multiple attributes to a single product. See Shamnad Basheer & T. Prashant Reddy, *The “Efficacy” of Indian Patent Law: Ironing out the Creases in § 3(d)*, SCRIPTED, Volume 5, Issue 2, August 2008, available at <http://www.law.ed.ac.uk/ahrc/script-ed/vol5-2/basheer.asp>. (Last visited on September 7, 2009).

¹¹ (2007) 4 MLJ 115.

¹² 2008 (37) PTC 71 (Del).

“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 of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least 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.”

In essence, § 3(d) does not allow patent protection for the discovery of any new form of known substance unless it enhances the efficacy of the original substance. It also acts as a bar on new-use patents by stipulating that mere discovery of any new property or new use of a known substance would not be patentable. Further, the explanation to this section expressly states that salts, esters, ethers and other derivatives of a known substance would be considered to be the same as the original substance (and thereby non-patentable) unless these derivatives are significantly different in terms of efficacy. Thus, the provision aims to restrict the scope of patent protection in pharmaceuticals by excluding incremental innovation which does not meet the criteria of enhanced efficacy.

More specifically, § 3(d) aims to prevent evergreening, a process by which a company introduces minor modifications in the patented product by way of “incremental innovation” and then gets a new patent for its product on the strength of the alterations made. By acquiring secondary patents over related or derivative technologies, these companies can extend the life of the patent.¹³ For instance, patents can be obtained for novel uses of a known drug or new methods of administration or production, reduced dosage formulations, or new versions of the active compound or combinations that produce fewer side effects than the original drugs.¹⁴ Typically the patentees apply for protection prior to the date of expiry of the original patent and get additional twenty-year patents on different attributes of the same drug. As a result of this, the entry of the generic industry into the market is delayed. This allows the patent holders to enjoy a lengthier monopoly over the drugs and profit from their R&D investment.¹⁵

This practice of evergreening has anti-competitive effects as it enables the pharmaceutical MNCs to eliminate competition from the generic manufacturers

¹³ Adarsh Ramanujan & Rajarshi Sen, *Pruning the Evergreen Tree: § 3(d) of the Indian Patents Act, 1970*, 31 (3) E.I.P.R. 135, 135-146 (2009).

¹⁴ *Id.*

¹⁵ Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503 (2009).

and charge exorbitant prices for their patented drugs over a prolonged period of time. Generic companies have no option but to wait till the patent period expires before they start manufacturing cheaper versions of the patented drugs or negotiate with the patent holders on commercial terms for getting access to the subject matter of patent.¹⁶ In both ways, it takes a long time before they can start manufacturing the generic version. This not only hampers technological progress but is also detrimental to public interest since many essential drugs become inaccessible to the general public on account of prohibitive pricing.

It was India's concern for public health issues that compelled it to exclude pharmaceutical patents from Patents Act, 1970. The lack of patent protection had ensured that Indian companies could access all the latest drugs developed in the international market, re-engineer them through new processes and sell them in the domestic market.¹⁷ As a result, India emerged as one of the top ten producers of generic pharmaceutical products in the world.¹⁸ In fact, by early 2005, Indian drugs were providing treatment to half the HIV infected people in the developing countries.¹⁹ Furthermore, generic manufacturers like Cipla and Ranbaxy Laboratory had significantly assisted in driving down the prices of annual antiretroviral treatment from \$15,000 per patient to \$200 within less than a decade.²⁰ From the above discussion it is obvious that patent evergreening poses a serious threat to cheap medical facilities.

After India introduced product patents for pharmaceuticals in the Patents Ordinance of 2004 (*hereinafter* the Ordinance), it was feared that there would be a sharp increase in the price of life-saving drugs which would take them beyond the reach of the common man.²¹ There was also a growing feeling among the generic drug manufacturers in India that the Ordinance was unduly tilted in favour of the multinational pharmaceutical corporations which would jeopardize their position in the global pharmaceutical market.²² The political parties, too, were divided over the issue of pharmaceutical patents with the Left threatening to oppose the Bill if it did not adopt strong measures to prevent evergreening.²³

¹⁶ Radhika Bhattacharya, *Are Developing Countries going too far on TRIPS? A closer look at the Laws in India*, 34 AM. J.L. & MED. 395 (2008).

¹⁷ *Supra* note 4.

¹⁸ *Id.*

¹⁹ Randeep Ramesh, *Cheap Indian Drugs under Threat*, THE GUARDIAN, (U.K) March 23, 2005, available at <http://www.guardian.co.uk/world/2005/mar/23/india.aids1> (Last visited on September 2, 2009).

²⁰ *Id.*

²¹ *Id.*

²² *Supra* note 16.

²³ Mueller, *supra* note 8; During the Parliamentary debates, Lok Sabha member Shri Suresh Kurup had regarded amendment to § 3(d) to be vital if pharmaceutical companies were to be prevented from obtaining multiple patents on the same medicine. See Transcript of Lok Sabha Debates, March 22, 2005 available at <http://164.100.47.132/textofdebates/15/II/030809.pdf>. (Last visited on August 29, 2009).

Under these circumstances, the Indian government was reluctant to provide for unrestricted patent protection that would substantially harm its indigenous generic drug companies and create public health issues. By incorporating the enhanced efficacy requirement in § 3(d), it sought to allay the fear regarding patent evergreening through incremental innovation and at the same time implemented its obligations under TRIPS.

It is believed that out of 9,000 patent applications waiting to be reviewed by the Indian Patent Office, approximately three-fourths are for modifications of existing drugs.²⁴ In the absence of a provision like § 3(d), a majority of the newly discovered uses or altered forms of patented medicines would become patentable, thereby creating a difficult situation for developing countries that are waiting for patents on drugs to expire so that they can purchase the cheaper, generic versions.²⁵ Therefore, when the pharmaceutical giant Novartis challenged the constitutionality of § 3(d) on being refused patent for its anti-cancer drug Glivec (which allegedly did not meet the criteria of enhanced efficacy in § 3(d)), nearly half a million people all over the world voiced their concern on the impact which the decision would have on the developing world if the Court decided in favour of Novartis.²⁶ Although the decision did not lay down any standard for differentiating incremental innovation from evergreening, by upholding the constitutionality of § 3(d), the Court prevented exacerbation of evergreening which would have severely affected India and other developing countries relying on imports from Indian generic industry.²⁷

Many proponents of § 3(d) also argue that providing patent protection to incremental innovation freely would lead to the thinning of the already fine line between evergreening and valuable incremental innovations. This, in turn, would present a tempting option to pharmaceutical companies to focus only on improving or modifying existing drugs since they are low-risk and high-reward ventures.²⁸ This would discourage the development of new molecules that may lead to major technological breakthroughs, but require risky and time-consuming R&D efforts.²⁹ However, this concern is not very well founded upon as it assumes that all drug companies are similar in their objectives. It is only those manufacturers whose primary aim is to enhance short-term profits by making trivial modifications to

²⁴ Sara Beth Myers, *Healthy Solution for Patients and Patents: How India's legal victory Against Pharmaceutical giant reconciles Human Rights with Intellectual Property*, 10 VAND. J. ENT. & TECH. L. 763 (2008).

²⁵ *Id.*

²⁶ Medicines Sans Frontiers, Press release, *Indian Court Ruling in Novartis Case Protects India as the "Pharmacy of the Developing World"* (August, 6, 2007) available at <http://www.accessmed-msf.org/media-room/press-releases/> (Last visited on August 29, 2009).

²⁷ *Id.*

²⁸ Amit Bhaskar, *Rethinking § 3(d) in light of Novartis judgment*, available at <http://www.indlawnews.com/display.aspx?3793> (Last visited on August 29, 2009).

²⁹ *Id.*

existing drugs which might move away from new drug development. Companies coming up with truly inventive incremental innovations would actually use them as stepping stones for developing novel drugs.

B. IMPORTANCE OF PROTECTING INCREMENTAL INNOVATION

1. Radical Innovation v. Incremental Innovation

The term innovation which broadly refers to the development of new ideas, methods or products, is divided into two categories, namely radical and incremental innovation. While the former refers to a whole new class of medicines, with a new mechanism of action,³⁰ the latter includes new drugs in an already existing class which have a similar mechanism of action as the first-in-class, but differ in features such as, therapeutic profile, metabolism, adverse effects, dosing schedules, delivery systems, etc.³¹ While radical innovation is uniformly protected in all patent regimes, incremental innovation is generally regarded not worthy of protection because of the prevailing notion that they represent nothing more than copies of existing molecules.³² Critics of incremental innovation, who refer to the class of drugs developed through incremental innovation as “me-too”³³ drugs, argue that the manufacturers of such drugs only aim to maximize profits and do not undertake any substantial research for their creation.³⁴

The rationale behind the differential treatment of radical and incremental innovations is fundamentally flawed. More often than not, they are interrelated and depend on one another. Radical innovations in the form of “blockbuster drugs”³⁵ often result from hundreds and thousands of smaller improvements carried out on an existing class of molecules over a long span of time. Moreover, incremental innovation increases the number of drugs within a specific class and makes them safer, more efficacious and better suited to individual patient profiles than the original drug.³⁶ The National Research Council had pointed out that “the

³⁰ GlaxoSmithKline, *Incremental Innovation*, January 2008, available at <http://www.gsk.com/policies/GSK-public-policy-on-incremental-innovation.pdf> (Last visited on August 29, 2009).

³¹ *Id.*

³² Albert I. Wertheimer & Thomas M. Santella, *Pharmcoevolution: The Benefits of Incremental Innovation*, (IPN Working Papers on Intellectual Property, Innovation and Health, 2005), available at <http://www.policynetwork.net/uploaded/pdf/Pharmcoevolution.pdf> (Last visited on September 6, 2009).

³³ “Me-too” drugs refer to drugs which belong to the same chemical class and target the same medical conditions as other drugs already on the market. Critics claim that they add little or no therapeutic value and pharmaceutical companies only manufacture them to enhance their profits at the cost of the customers. *See Id.*

³⁴ *Supra* note 32.

³⁵ Blockbuster drugs refer to drugs which are the product of radical innovation and are the first in a new class of drugs having a particular mechanism of action.

³⁶ *Supra* note 32.

cumulative effect of numerous minor incremental innovations can sometimes be more transforming and have more economic impact than a few radical innovations or ‘technological breakthroughs’.³⁷

Contrary to the popular perception, “me-too” drugs are not copies of existing molecules. Even though their molecular structure is similar to already known drugs and they target the same type of medical conditions,³⁸ they typically represent medical advancement over the known drugs. Therefore, one cannot assume that their development does not require any R&D efforts or creativity. Any manufacturer trying to improve upon an existing drug is likely to expend considerable time and money in order to ensure that he/she can emerge as the market leader in that specific class of drugs.³⁹ Further, incremental innovation assists in the development of “blockbuster drugs”. Developing an entirely new class of drugs is a long and arduous process involving huge investment with no certainty of success. Incremental innovation enables companies to generate revenue by improving existing drugs and this in turn, help support massive R&D investment required for new drugs.⁴⁰ Thus, excluding incremental innovation from patent protection would kill the incentive to improve existing drugs and thus reduce the financial resources for new drug discovery.

2. Evergreening v. Incremental Innovation

Although it is important to protect newly discovered uses and improved versions of existing drugs which benefit patients, it is important to differentiate between evergreening and incremental innovation. While the latter has huge potential for the development of drugs with superior health benefits, the former is a strategy adopted by pharmaceutical companies to prevent their patents from expiring. Pharmaceuticals indulge in evergreening with the sole aim to prevent losing out market shares to the generic versions of its patented drug.⁴¹ The changes made may add little therapeutic or clinical value to the original patented product, but the company is able to enjoy continued patent protection. On the other hand, patents on incremental innovation seek to protect discoveries relating to the new uses, active principles, molecules or compounds that have been previously patented.⁴²

³⁷ National Research Council, *Prospectus for National Knowledge Assessment* (1996) as cited in *supra* note 32.

³⁸ *Supra* note 32.

³⁹ *Id.*

⁴⁰ Commission on Intellectual Property, *The Importance of Incremental Innovation for Development* (International Chamber of Commerce Issues Paper, 2005) available at http://www.theworldbusinessorganisation.org/uploadedFiles/ICC/policy/intellectual_property/pages/Incremental_Innovation_submission_to_WHO_CIPIH_27May05.pdf (Last visited on September 2, 2009).

⁴¹ *Supra* note 32.

⁴² *Supra* note 24.

It is undisputed that in some cases, evergreening and incremental innovation might overlap. Nonetheless, the differences are very real and any attempt to categorise the constructive process of incremental innovation with evergreening may be unfair to those who are striving to develop more effective treatment options through incremental advances.

3. Benefits of Incremental Innovation and feasibility of the Indian Approach.

As discussed earlier, modifications to existing drugs are often looked upon as innovations of little value. This view overlooks the fact that these changes may greatly improve the quality of life of patients. “Blockbuster drugs” often exhibit side effects and other limitations which need to be improved upon to make the drugs safer and more effective. Incremental innovations commonly appear in the form of new dosage formulations (once-daily formulations), or delivery systems (e.g. time release delivery for existing drug) which can reduce side effects and prevent toxicity as well as add to the efficacy and convenience of the older drug.⁴³ For instance, efforts are being made to develop oral and inhalable forms of insulin drug because of the difficulties in administering insulin injections to small children and old and frail people.⁴⁴ This is an incremental advance over injection based treatment which would prove to be highly beneficial for diabetics. Incremental innovation also encourages patient specific treatment .By increasing the number of drugs available in a given class, it causes greater drug selectivity.⁴⁵ Since different patients would show different responses to various forms of the drug within a specific therapeutic class, this allows physicians to calibrate their prescriptions to address the specific needs of the patients.⁴⁶

In India, patent protection is accorded primarily to “New Chemical Entities”.⁴⁷ In order to get a patent in India, the patentee would have to show that his/her invention is in respect of patentable subject matter and satisfies the criteria of patentability set out in the Act. The claimed invention must be novel, involve an inventive step and should be capable of industrial application.⁴⁸ An incremental

⁴³ US India Business Council, *The Value of Incremental Pharmaceutical Innovation: Benefits for Indian Patients and Indian Business* June, 2009, available at <http://www.ahealthyindia.org/NR/rdonlyres/edq7axj5zukil311137sy7ulswpiz4r7xt6ktixqqjanixt3xummbg6xcq4ffgye25jirgu53segs7y4fbistcxyob/USIBCIncrementalInnovationReportFinal.pdf>. (Last visited on September 2, 2009).

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Supra* note 32.

⁴⁷ According to the United States (US) Food and Drug Administration (FDA), new chemical entity (NCE) means a drug that contains no active moiety that has been approved by FDA in any other application submitted under § 505(b) of the Federal Food, Drug, and Cosmetic Act. In essence, new chemical entity means a drug which is first of its class.

⁴⁸ The Indian Patents Act, 1970, § 2(1)(j) defines invention as “a new product or a process involving an inventive step and capable of industrial application.”

innovation may satisfy all the three criteria of patentability, i.e., it could be truly inventive but would still be unable to cross the threshold set out by § 3(d) which lays down a category of non-patentable subject matter. By reducing the scope of patentability to only new forms of known substances which enhance the efficacy of that substance and derivatives of known substances that significantly differ in properties with respect to efficacy, § 3(d) excludes majority of useful pharmaceutical innovations. As discussed later in the article, the terms “efficacy” and “significantly” are neither defined in the Act, nor are any guidelines provided to that effect. Thus, drug manufacturers have no way of knowing what is the standard required for an incremental innovation to be patentable. In *Novartis AG v. Union of India*,⁴⁹ the term “efficacy” was narrowly interpreted to mean “therapeutic” efficacy which implies that any other innovation like reduced dosage patterns or new formulations would not be patentable.⁵⁰ Furthermore, in the initial stages of drug development, pharmaceutical companies find it difficult to exhibit data to demonstrate the therapeutic efficacy of the new form or new use as stipulated by the provision.⁵¹ Thus, it is clear that § 3(d), in its present form, is not conducive to pharmaceutical innovation.

While curbing evergreening is important, care needs to be taken that this does not compromise the development of Indian pharmaceutical sector. As pointed out by the Mashelkar Committee, discouraging incremental innovation could dissuade both Indian and foreign investors from investing in India.⁵² The impact is worse on Indian drug companies that invest substantially on the improvement of existing drugs. Majority of them lack adequate resources to develop research intensive “blockbuster drugs”. Thus, if bereft of ample incentive to undertake R&D efforts for incremental innovation in India, they would have to search for alternative markets which do not have the efficacy requirement.⁵³ At present, it is only the MNCs which have the kind of resources necessary for creating new chemical entities.⁵⁴ Providing protection to only new drug classes would effectively ensure that most pharmaceutical patents are owned by MNCs.⁵⁵

4. Incremental Innovation and Public Health

Allowing patent protection for incremental innovation may also be beneficial in dealing with public health concerns.⁵⁶ Firstly, by increasing the number

⁴⁹ *Supra* note 11.

⁵⁰ *Id.*

⁵¹ *Supra* note 43.

⁵² Report of the Technical Expert Group on Patent Law Issues, March, 2009, available at <http://www.patentoffice.nic.in/> (Last visited on September 2, 2009).

⁵³ Shamnad Basheer, *Limiting the Patentability of Pharmaceutical Inventions and Micro-organisms: A TRIPS Compatibility Review*, November 2005, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1391562. (Last visited September 2, 2009).

⁵⁴ The current cost of developing a breakthrough drug from discovery to market today may be as much as US\$1 billion. (*See supra* note 43).

⁵⁵ *Supra* note 52.

⁵⁶ *Supra* note 43.

of different drugs in a specific class, it can increase the price competition among those drugs. This would result in decline of drug prices thereby making them accessible to ordinary people.⁵⁷ Secondly, it can reduce the cost of healthcare by improving the quality and selection of drugs available to the patients. Further, the presence of multiple drugs within the same class ensures that there are adequate back-ups in case a drug goes out of market.⁵⁸ Thirdly, the revenue from incremental innovation can be used to fund development of research intensive “blockbuster drugs” which make new medicines available to the public in the long run. Fourthly, new formulations and drug delivery systems can be developed which are specifically suited to Indian climate. For instance, use of microspheres for the controlled release of vaccines which make them resistant to extreme heat conditions could greatly help people living in remote areas of India where there is no refrigeration.⁵⁹ The importance of these drugs can be gauged from the fact that 60% of the essential medicines on the World Trade Organization’s Essential Drug list represent incremental innovation over existing drugs.⁶⁰ Thus, it is clear that equating all kinds of incremental innovation with evergreening, would fail to protect genuine innovations that could greatly benefit millions of people.

C. PROBLEMATIC ASPECTS OF § 3(D): FINDING WAYS TO MAKE IT WORKABLE

As discussed earlier, § 3(d) is a provision unique to India and seeks to protect the generic industry by weeding out frivolous patents. However, since the § is not drafted in clear terms, there is a lack of clarity regarding the criteria of patentability for incremental innovations. The uncertainties become apparent when one looks at the interpretation of this provision by the Courts.

1. Glivec Patent Rejection

Glivec (Imatinib) is an anti- cancer drug which is used for the treatment of a specific medical condition known as chronic myeloid leukaemia. The development of Glivec started after Novartis researchers came upon the active molecule imatinib which could target specific cancer causing enzymes without affecting other enzymes.⁶¹ In 1993, Novartis filed patents worldwide covering the free base imatinib. Later on, imatinib was improved upon by converting it into a salt form called imatinib mesylate, from which Novartis derived the more stable beta crystalline form.⁶² After India’s entry into the WTO, Novartis claimed patent

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ Secretariat, World Intellectual Property Organization, *Follow- on Innovation and Intellectual Property*, May 2005, available at http://www.wipo.int/patentscope/en/lifesciences/pdf/who_wipo.pdf (Last visited on September 6, 2009).

⁶⁰ *Id.*

⁶¹ *Supra* note 2.

⁶² *Id.*

over this beta crystalline form in India through a mailbox application.⁶³ It was also granted EMR over this drug in 2003.

The Madras Patent Office refused to grant patent to the beta crystalline form of imatinib mesylate in January 2006. The chief grounds of rejection were lack of novelty and failure to meet the criteria in § 3(d) which requires new forms of known substances to show “enhanced efficacy” over the original substances in order to qualify for patent protection.⁶⁴ Aggrieved by this rejection, Novartis AG along with its Indian subsidiary Novartis India filed two writ petitions in the Madras High Court. One of the petitions, which sought a reversal of the order of rejection by the patent office, was transferred to the Intellectual Property Appellate Board (IPAB). In the other petition, Novartis asked for a declaration that § 3(d) was unconstitutional and violative of TRIPS.⁶⁵ With respect to the first ground, Novartis argued that the use of expressions such as “enhancement of known efficacy” and “differ significantly in properties with regard to efficacy” without accompanying guidelines specifying their ambit made § 3(d) ambiguous and arbitrary and gave uncontrolled discretion to the Patent Controller to apply his own standards.⁶⁶ Such arbitrary exercise of power went against the basic principles of equality enshrined in Article 14 of the Constitution. With regard to the second issue raised by Novartis, the Madras High Court declined to examine whether § 3(d) was TRIPS-compliant. It held that that it did not have any jurisdiction in the matter as the TRIPS had expressly provided that any kind of dispute should be taken before the Dispute Settlement Body of the WTO. It decided only on the issue of constitutionality of the provision.⁶⁷ The Novartis patent rejection provides an ideal opportunity to look into the various issues surrounding § 3(d).

2. A Narrow Construction of § 3(d).

The relevant part of § 3(d) is reproduced below:

“[T]he 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...” (Emphasis supplied)

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers,

⁶³ Johanna Sheeche, *Indian Patent Law: Walking the Line*, 29 NW. J. INT'L L. & BUS. 577 (2009).

⁶⁴ Novartis AG v. Natco Pharma and Others, Indian Patent Office, Application No.1602/MAS/1998 (January 25, 2005) as cited in MANUAL OF PATENT PRACTICE AND PROCEDURE, 2008, The Patent Office, India, available at http://www.patentoffice.nic.in/ipr/patent/Patent_Manual_Feedback/WO_Ga_34_China.pdf (Last visited on September 7, 2009).

⁶⁵ *Supra* note 11.

⁶⁶ *Id.*

⁶⁷ *Id.*

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.”

The provision makes those new forms or derivatives of a known substance patentable which enhance the efficacy of the first substance. The rationale behind the Explanation to the § seems to be that various salt forms, isomers, polymorphs etc of a known substance that are structurally similar to the original substance are likely to function in a similar manner and therefore should not be granted patent protection. A combined reading of the main part of the § along with the explanation shows that “only those pharmaceutical derivatives of the original substance which show “significantly” enhanced “efficacy” are patentable.⁶⁸

By making the above distinction, the provision intends to separate evergreening from incremental innovation. However, it does not specify the level of efficacy required to cross the threshold of patentability. For example, even though studies conducted by the technical experts showed that the beta crystalline form of imatinib mesylate showed an increased bioavailability⁶⁹ of 30% over the imatinib free base, the Assistant Controller of Patents and Designs refused to accept this as “enhanced efficacy”.⁷⁰ Moreover, he failed to provide adequate reasoning to support his decision. Nothing in the § or in the Act indicates the kinds of improvements which would qualify as “efficacy”. In the absence of a clear understanding of the term efficacy, it is even more difficult to understand what constitutes “significantly” enhanced efficacy. Unless one at least has an idea as to what the type of efficacy is which the § is speaking about, the inclusion of “differ significantly in properties with regard to efficacy” in the explanation serves no meaningful purpose. In other words, if one is not sure whether increase in bioavailability itself qualifies as “efficacy”, how can one determine whether 30% increase in bioavailability should or should not be regarded as “significant” enhancement in efficacy? The patent office did not make any effort to clear any of these confusions created by § 3(d) with respect to the use of the term “efficacy”.

Another problematic aspect is with respect to “interpretation of known substance”. In the case of Novartis, the beta crystalline polymorphic form was derived from imatinib mesylate which in turn was an improved form of the imatinib free base. The question which one might ask is whether the comparison of efficacy should be with the free base or imatinib mesylate.⁷¹

⁶⁸ *Supra* note 10.

⁶⁹ Bioavailability can be defined as “the proportion of a drug which reaches the site of a pharmaceutical activity when introduced into the body, more loosely, that proportion of any substance so introduced which enters the circulation. *See supra* note 68.

⁷⁰ *Supra* note 64.

⁷¹ Shannad Basheer & Prashant Reddy, *Ducking TRIPS in India: A Saga involving Novartis and the Legality of § 3(d)*, NATIONAL LAW SCHOOL OF INDIA REVIEW, 2008, available at <http://ssrn.com/abstract=1329201>, (Last visited on September 6, 2009).

Although, the Assistant Controller of Patents, Chennai insisted that the free base should be taken as the benchmark for comparison, there were no concrete reasons given in support of the decision.⁷²

The Madras High Court, while examining the scope of § 3(d) interpreted “efficacy” to mean only “therapeutic⁷³ efficacy”. The Court relied on the Dorland’s Medical Dictionary which defines efficacy as “the ability of a drug to produce the desired therapeutic effect.” The Court further observed that efficacy of a drug is independent of the potency of the drug. Going by the meaning of the expression “therapeutic”, what the patent applicant would have to demonstrate is how effective the new discovery would be in the healing of a disease or producing a good effect on the body.⁷⁴ Having defined the expression “efficacy” in terms of therapeutic improvement, the Court goes on to state that it is a very simple exercise for the patentee to place on record the therapeutic efficacy of a known substance, and the enhancement in that known efficacy.⁷⁵ While making this assertion, the Court seems to have completely ignored the complexity of proving scientific propositions. Demonstrating therapeutic efficacy of a new form requires engaging in expensive clinical trials and other studies which are generally conducted at a much later stage in the drug development process.⁷⁶ Patent applications are filed in the initial stages of a drug discovery and thus the requirement of showing efficacy at this stage is an onerous one for majority of the inventors.⁷⁷

Much of the language of § 3(d) is based on Article 10(2)(b) of Directive 2004/27/EC, a European Union Directive relating to regulatory approval of drugs for human use. The Article defines a generic medicinal product as:

“a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant”[emphasis added]

⁷² *Supra* note 64.

⁷³ The term therapeutic means healing of a disease, having a good effect on the body. *See, supra* note 11.

⁷⁴ *Supra* note 11.

⁷⁵ *Id.*

⁷⁶ *Supra* note 1.

⁷⁷ *Id.*

The underlying notion of “bioequivalence” is common to both the provisions.⁷⁸ The EU Directive refers to “efficacy” in the context of drug regulation and since § 3(d) was imported from it, it may seem logical to interpret the term “efficacy” used in the latter in terms of healing effect of the drug. Nonetheless, in the absence of any stipulation in § 3(d) or in the accompanying rules and guidelines, mandating that only a technical meaning should be given to the term “efficacy”, it is not clear why the Court chose not to interpret “efficacy” in accordance with its ordinary English meaning.⁷⁹ This interpretation would have made it possible to patent any new useful properties of the new form (like increase in bioavailability) without having to prove that they enhanced the therapeutic efficacy of the original medicine.⁸⁰ Giving such a highly restrictive meaning to “efficacy” can have serious implications in terms of protecting incremental innovation. As discussed above, demonstrating enhanced therapeutic properties of the drug at the time of filing patent application is a requirement which most patentees would find very difficult to satisfy. Moreover, a narrow definition would exclude most of the inventions which are tremendously useful but in non-therapeutic ways. For instance, the humidity resistant salts and isomers of known antimicrobial substances developed by Wockhardt have much better solubility and greater stability in high humidity tropical climates as compared to the original anti-micro-bacterial compounds patented by Otsuka Pharmaceutical Company, to fight against bacteria that are immune to ordinary antibiotics.⁸¹ Notwithstanding the fact that they can be of immense value in tropical countries like India, they do not display enhanced therapeutic properties over the patented drugs and thus would be ineligible for patent protection.⁸² Similarly, Ranbaxy’s drug, Cipro-OD, which uses an innovative drug delivery mechanism to enable patients to take the medicine only once a day, would not satisfy the “therapeutic efficacy” requirement, although it is much more economical than the original medicine.⁸³ Clearly, the term “efficacy” needs to be interpreted in a more flexible manner in order to incentivise such useful innovations. However, in the absence of any further clarifications regarding the meaning of “efficacy”, the patent offices in India would continue to follow the Novartis ruling.

The Court further argued that the use of phrases like “enhancement of known efficacy” and “significantly different in properties with regard to efficacy” are not vague or ambiguous. It denied the scope for any confusion by saying it is scientifically possible to get comparative data to show whether a new form of a known substance has enhanced the known efficacy of the original substance and whether the derivatives so derived differ significantly in properties with regard to efficacy.⁸⁴ The Court opined that since Novartis was a pharmaceutical giant and

⁷⁸ *Supra* note 43.

⁷⁹ Efficacy refers to the power or capacity to produce effects. *See generally* Oxford English Dictionary.

⁸⁰ *Supra* note 10.

⁸¹ *Supra* note 53.

⁸² *Id.*

⁸³ *Supra* note 10.

⁸⁴ *Supra* note 11.

not a novice in the field of pharmacology, it cannot plead that it does not know what “significant enhancement in efficacy” means in relation to derivatives of known substances.⁸⁵ It is difficult to support this proposition as it defies common sense. Since at the time when Novartis had applied for the patent, Indian patent laws were still in transition, it had no way of knowing that post-2005, § 3(d) would incorporate the “enhanced efficacy” requirement. Moreover, it is a provision unique to India as no other country makes a distinction between patentable and non-patentable pharmaceutical inventions. Further, even assuming that Novartis had envisaged that there would be some threshold criteria for patentability under the amended Indian Patents Act, 1970, it would have never imagined that its invention would have to meet the stringent standard of “therapeutic” efficacy. Therefore, it is unreasonable to expect that Novartis should have been completely familiar with the precise meaning and scope of § 3(d).⁸⁶

3. § 3(d) and the Feasibility of the Constitutional Challenge

Although the language of § 3(d) is unclear, it does not necessarily follow that it is violative of Article 14 of the Indian Constitution. It was submitted that since the wording of the § and the explanation provided therein were vague, there was a likelihood of the provision being misused.⁸⁷ As rightly observed by the Court, the fact that legislation does not include clear definitions or guidelines, cannot suffice as proof of its arbitrariness.⁸⁸ It has to be shown that the provision is ex-facie violative of Article 14. Moreover, simply stating that the § 3(d) confers uncanalised power on the Patent Controller is not a ground to challenge the validity of the §. Novartis also argued that an essential legislative function has been delegated in the process of conferring power upon the Patent Controller’s office to determine as to what constituted a significant enhancement of efficacy.⁸⁹ But the Madras High Court relied on the Supreme Court ruling in the case of *Jyoti Pershad v. Union Territory of Delhi*⁹⁰ that as long as the legislature is able to convey the objects and purposes of a particular legislation, the legislation cannot be attacked on the ground that there has been an excessive delegation of legislative power amounting to an abdication of its functions, or that the discretion vested is uncanalised and unguided which may possibly lead to discrimination. The Court had opined that:

“If the power or discretion has been conferred in a manner which is legal and constitutional then the fact that Parliament could possibly have made more detailed provisions, could obviously not be a ground for invalidating the law”⁹¹

⁸⁵ *Id.*

⁸⁶ *Supra* note 10.

⁸⁷ *Supra* note 11.

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Jyoti Pershad v. Union Territory of Delhi*, MANU/SC/0079/1961.

⁹¹ *Id.*

The Court also depended on the theory of “guided power”⁹² which states that equality is not violated by mere conferment of discretionary power. It is violated only when it is exercised arbitrarily by those on whom it is conferred. Further, this doctrine assumes that in the event of such misuse, courts can step in to remedy the situation. Therefore, in case the statutory authority exercises its discretionary power in an arbitrary manner, reliefs are available through courts.⁹³ Hence, § 3(d) cannot be held to be violating Article 14 simply on the ground that it allows for a possibility of misuse of power conferred upon the statutory authority.

4. Significance of the IPAB Decision on Glivec Patent Application

On June 26, 2009, the IPAB ruled that Glivec cannot be patented. As expected, the primary ground of rejection, was the failure to satisfy the efficacy standard in § 3(d). It stated that even though the invention is both novel and inventive, Novartis could not demonstrate that the beta crystalline form was “significantly” more efficacious than imatinib mesylate.⁹⁴ This means that even if an invention is otherwise patentable as per the patentability criteria, it could still be barred by § 3(d).⁹⁵ Further, considering that the Board referred to § 3(d) as a “higher standard of inventive step” and at the same time found that the beta crystalline form to be “inventive”, how did it conclude that the latter still does not satisfy § 3(d)?

One possible reason for the above incongruity can be the narrow interpretation of “efficacy” by the Board to mean only “therapeutic efficacy”. The Board held that although the beta crystalline form had many advantages such as improved bioavailability, thermodynamic stability, enhanced flow properties and lower hygroscopicity, these did not amount to an increase in the “therapeutic” efficacy of the drug.⁹⁶ Thus, even if a new form is inventive in that it has genuine non-therapeutic advantages, it would not qualify under § 3(d) which requires only heightened “therapeutic efficacy”.⁹⁷ The Board did not try to explain the rationale behind limiting patentability to only therapeutic improvements or the factors to be taken into account while determining increased “therapeutic efficacy” of a new drug form.

The Board also did not allow Novartis to add data to substantiate the patentability of its invention. The Board held that Novartis had to rely on the material provided on the date of application of the patent.⁹⁸ This finding is also

⁹² H.M. SEERVAI, CONSTITUTIONAL LAW OF INDIA, 546 (2000).

⁹³ *Supra* note 11.

⁹⁴ Intellectual Property Appellate Board, Order No. (100/2009), June 26, 2009, available at <http://www.ipab.tn.nic.in/Orders/100-2009.htm>. (Last visited on September 2, 2009).

⁹⁵ Shammad Basheer, *Breaking News: Indian IP Tribunal Denies Patent to Novartis' Glivec*, July 3, 2009, available at <http://spicyipindia.blogspot.com/2009/07/breaking-news-novartis-loses-glivec.html> (Last visited on September 6, 2009).

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Supra* note 94.

unreasonable since Novartis could not have known on the date of applying for patent (India was still updating its patent laws) that it would have to produce material sufficient to satisfy the “enhanced efficacy” standard under § 3(d).⁹⁹

The Board’s ruling against Novartis was also influenced by the high pricing of the drug.¹⁰⁰ It observed that granting patent on Glivec, would severely affect the availability of the medicine, which in turn would be detrimental to public order. According to it, this was a valid reason for denying patent to Glivec, under § 3(b).¹⁰¹ Going by the argument of the Board, it seems that granting a patent to a drug would not only depend upon satisfaction of the patentability criteria but also on its pricing. It is true that a concern for public health is a substantial one for a country like India. However, this does not warrant using drug pricing as a factor for determining whether patent should be granted to a drug.

Not only did the Board fail to provide any clarification regarding the true meaning and scope of § 3(d), but by relying on extraneous factors like drug pricing, it also created further uncertainty regarding patentability of pharmaceutical inventions.

5. Roche v. Cipla Controversy:

Roche had developed an anti- cancer drug Erlotinib, which was being marketed as Tarceva. It had obtained patent for the drug in 2007. A year later, Cipla introduced a generic version of the drug Erlocip at one-third the price of Tarceva. Roche sued Cipla and approached the Delhi High Court for a grant of interim injunction restraining Cipla from manufacturing, selling or exporting Erlocip. Cipla retaliated by challenging the validity of the patent itself and argued that the patent should not have been granted in the first place.¹⁰² Cipla contended that as admitted by Roche itself, Erlotinib was a derivative of a known compound Quinazoline. Therefore, it lacked an inventive step as it only improved upon a prior art.¹⁰³ More specifically, it claimed that it was a derivative of a known product, Gefitinib, which was structurally similar to Erlotinib and as such the patent application fails to provide any data to show that Erlotinib is more efficacious than Gefitinib.¹⁰⁴ Therefore, it failed to meet the standard of “efficacy” set out for derivatives in § 3(d). According to Cipla, Roche was indulging in evergreening, a phenomenon which § 3(d) specifically sought to prevent.¹⁰⁵ Another argument of

⁹⁹ *Supra* note 95.

¹⁰⁰ *Id.*

¹⁰¹ The Indian Patents Act, 1970, § 3(b) states “an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment”.

¹⁰² *Supra* note 12.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

Cipla was that since the price-differential between the two drugs was so high, public interest dictated that no injunction be granted in favour of Roche.¹⁰⁶

Although the single judge of the Delhi High Court conceded that Cipla had raised a credible challenge to the validity of the patent, it declined to examine whether Erlotinib was in fact a derivative of Gefitinib, at the interlocutory stage. However, it concluded that the test of non-obviousness of an invention and discovery of existence of significantly enhanced efficacy are both equally important for determining patentability.¹⁰⁷ Thus, even if a pharmaceutical innovation involves an inventive step, if it is a new form of a known substance, then it has to prove that the invention significantly enhances the efficacy of the known substance. This seems to indicate that § 3(d) involves a standard over and above the inventive step, which must be satisfied by derivatives of known substances in order to get a patent. The Court's refusal to grant injunction in favour of Roche was, however, based on the public interest factor. In this regard, it relied on an US Supreme Court decision, *E-Bay v. MercExchange*,¹⁰⁸ where it was held that granting injunction in patent cases was a discretionary remedy rather than a right and had to be granted keeping in mind several factors, one of which is public interest.¹⁰⁹ The crucial issue before the Court was which party would suffer "irreparable injury" by granting or refusing to grant the injunction. In this regard, it opined that any damage caused to Roche, which is a pharmaceutical giant, could be compensated in monetary terms. On the other hand, granting injunction in their favour would actually deny patients access to a life-saving drug on account of Roche's monopoly pricing.¹¹⁰ Thus, irreparable hardship would be caused to thousands of cancer patients who are dependent on Cipla's generic version of Tarceva.¹¹¹ Therefore, the Court found that the balance of convenience had to be tilted in favour of providing access to a life saving drug.

While the judgment takes the view that § 3(d) is a heightened standard of non-obviousness,¹¹² a stand taken by the IPAB as well while rejecting the application for Glivec, it does not shed much light on the contours of § 3(d). In the appeal, the Division Bench of the Court adopted a strict interpretation of § 3(d). It was held that Erlotinib would be obvious to a person skilled in the art in view of the existence of the earlier known compound Gefitinib.¹¹³ § 3(d) clearly provides

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *E-Bay v. MercExchange*, 547 US 388 (2006).

¹⁰⁹ Shamnad Basheer, *Indian Express Piece: The Rhetoric of Patent Busting*, April 12, 2008, available at <http://lawandotherthings.blogspot.com/2008/04/roche-vs-cipla-rhetoric-of-patent.html> (Last visited on September 2, 2009).

¹¹⁰ *Supra* note 12.

¹¹¹ *Id.*

¹¹² *F. Hoffman-La Roche Ltd & Anr. v. Cipla Ltd*, F.A.O. (OS) 188/2008.

¹¹³ *Id.*

that derivatives of known substances, unless they demonstrate significant increase in efficacy, would not qualify for patent protection. Thus, the patent could not be granted in this case unless it is shown that Erlotinib is more efficacious than Gefitinib. The Court states that since Roche had failed to provide any evidence before the Controller of Patents in support of this, the validity of the patent was in serious doubt.¹¹⁴

The decision seems to have considered Erlotinib as a derivative of Gefitinib in which case it would be deemed to be the same substance as Gefitinib in the absence of any increased efficacy over the latter. However, the Court's decision's does not clarify whether a derivative refers only to structurally similar compounds (in this case Gefitinib had a similar chemical structure to Erlotinib) within the meaning of § 3(d). This may cause confusion regarding the scope of the term "derivative".

6. Resolving the Ambiguities of § 3(d)

a) Patentability criteria or patent eligibility.

§ 3(d) is one of the most important provisions in the Indian Patents Act, 1970 as it deals with pharmaceutical inventions. However, as it is clear from the discussion above, the structure and wording of the § suffers from many infirmities. This part will discuss certain changes that would assist in making the § more coherent.¹¹⁵

§ 3(d) covers those subject matters which are not eligible for patent protection, and in that respect it is a patent eligibility test. However, as seen in the cases discussed above, the enhanced efficacy requirement embodied in § 3(d) is often looked upon as heightened standard of non-obviousness in addition to the non-obviousness test¹¹⁶ used to measure the "inventive step" criteria. This causes confusion as to whether § 3(d) represents a patent eligibility criteria or a patentability standard. While the former determines whether an invention falls within the scope of subject matter suited for patent protection, the latter refers to requirements that must be fulfilled before a patentable invention can be granted patent protection.¹¹⁷ Moreover, eligibility test is conducted at the beginning

¹¹⁴ *Id.*

¹¹⁵ The changes suggested in this part are based on those proposed by Basheer and Reddy, *supra* note 10.

¹¹⁶ The earlier § 2(ja) defined 'inventive step' as "a feature that makes the invention not obvious to a person skilled in the art." After the 2005 Amendment, the section reads as 'inventive step' means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to the person skilled in the art". The yardstick for measuring an 'inventive step' remains the same as before, that is, "not obvious to a person skilled in the art". However, there is a stipulation that the invention should involve a 'technical advance' or have some 'economic significance'.

¹¹⁷ *Supra* note 10.

whereas a non-obviousness requirement is examined much later on. It is evident that § 3(d) involves examination of non-obviousness standards that determine patentability rather than patent eligibility. Therefore, it would be more convenient if the provision is specifically referred to as a patentability criterion rather than a patent eligibility standard.¹¹⁸

b) Inconsistency between the Main part and the Explanation

From the wording of the section, it is not clear whether the Explanation broadens the scope of the main section with respect to the requirement of efficacy. The main part of the provision refers only to “enhancement of known efficacy” while the Explanation is more expansive and speaks of “significant differences in properties with regard to efficacy”. While the former narrows down the parameters for the determination of “efficacy”, the latter seems to interpret the term “efficacy” more broadly. This creates a tricky situation when a new form of a known substance is found to have a new property or aspect hitherto unknown.¹¹⁹ For instance, if a new form of an existing substance which is as potent as the original substance in treating a disease (A), is highly effective in curing a different medical condition (B) as well, under the main part of the section it would not be patentable since it is not more efficacious than the original substance in treating disease (A). This result is anomalous since the objective of § 3(d) is to keep out only those patents that lack genuine innovation. Given the fact that an entirely novel use of the new form is more inventive than an “enhancement in known efficacy”, it is highly unlikely that the section would exclude it from patentability.¹²⁰ However, the new form having the capacity to treat disease (B) would be patentable under the Explanation since the term “efficacy” used in this part is not qualified by the word “known”. The new use of the new form (treating disease B) would clearly fall within the scope of the expression “differ significantly in properties with regard to efficacy”. Therefore, it is clear that the Explanation has to be read expansively in order to include new uses of new forms of a known substance within the scope of patentable subject matter. This inconsistency in the wording of § 3(d) has to be resolved by including new use of a new form as patentable subject matter.¹²¹ This can eliminate any confusion with regard to the true import of this provision.

c) The Definition of Known Substance needs to be clarified

Under § 3(d), it is not clearly discernible what constitutes a known substance with which comparison of the new form is to be made. For instance, in the Novartis case,¹²² how was one to determine whether it was the Imatinib free base or the Imatinib Mesylate which would be regarded as “known

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.*

substance” for the purpose of comparing the “efficacy”? The IPAB held Imatinib Mesylate as the “known substance” on the ground that the patent obtained by Novartis, for imatinib free base and all the acceptable salts, had disclosed and enabled its development. However, in situations where a new form is merely obvious from prior art but not anticipated¹²³ from it, it may not be accurate to classify it as a known substance. Thus, § 3(d) needs to be amended to clarify that a known substance is one which is not novel in order to ensure that all obvious substances are not categorised as “known”.¹²⁴

d) Efficacy Requirement and Standard of Proof

As discussed earlier in this part, attributing a narrow meaning to the term “efficacy” is not feasible since it excludes useful non-therapeutic innovations which otherwise satisfy the patentability requirements. A more liberal construction of “efficacy” would ensure that various useful properties like heat stability, humidity resistance, increased bioavailability, etc. are also protected.¹²⁵ India could also incorporate the non-obviousness principles used in the USA when dealing with similarly structured compounds. For example, in *Takeda v. Alphapharm*,¹²⁶ it was held that if a new form is structurally similar to the original substance, this does not show prima facie obviousness. There has to be evidence to prove that it would have been obvious to a skilled person to reach the new form by modifying the original substance in a particular way.¹²⁷ In India, however, a structural similarity of the new form with the “known substance” is enough to prove that the new form was obvious.¹²⁸ Moreover, in US, “unexpected results” are not restricted to therapeutic efficiency. *Takeda v. Alphapharm*,¹²⁹ considered less toxicity of the new form of the older compound to be an “unexpected property”.¹³⁰ However, given the fact that the efficacy standard of § 3(d) applies to only therapeutic improvements, it is highly unlikely that less toxicity would have qualified as “enhanced efficacy”.

¹²³ Anticipation happens when a prior art reference or event discloses all the features of a claimed invention and enables a person of ordinary skill in the art to make and use the invention. In such a case, the claim is then said to lack novelty. In *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), it was held that “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”.

¹²⁴ *Supra* note 10.

¹²⁵ *Id.*

¹²⁶ 480 F.3d 1348 (Fed. Cir. 2007).

¹²⁷ *Id.*; Shamnad Basheer, *Takeda v. Alphapharm: Implications for § 3(d)*, November 6, 2007, available at <http://spicyipindia.blogspot.com/2007/11/takeda-vs-alphapharm-implications-for.html>. (Last visited on September 6, 2009).

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ *Id.*

Presently, it is not certain what kind of information is required to prove “enhanced efficacy”. As discussed earlier, if the efficacy is construed to mean only therapeutic efficacy, then the applicant might have to conduct clinical trials in order to provide the relevant data which is very difficult to procure. Moreover, conducting clinical trials might entail disclosing the invention to the public before filing for patent.¹³¹ This can threaten the novelty of the invention. Thus, § 3(d) could provide that the standard of proof required for establishing “efficacy” “is one that is easier to fulfil requiring only that amount of data that is relatively more ethical to generate”¹³²

e) How to construe “significantly” used in § 3(d)

It is not possible to set one particular standard for determining when the increased efficacy of the new form would qualify as “significant efficacy” within the meaning of the provision. The Patent Office Manual also seems to support the above view when it observes that:

“The efficacy need not be quantified in terms of numerical value to determine whether the product is efficacious because it is not possible to have a standard numerical value for efficacy for all products including pharmaceutical products.”¹³³

Even the Madras High Court, in *Novartis AG v. Union of India*¹³⁴ had pointed out that it would be imprudent to fix a specific formula to be applied in all cases in order to find out whether a newly discovered form of a known substance shows enhanced efficacy over the original substance or whether the derivatives of a substance differ significantly in properties with regard to efficacy.¹³⁵ Scientific development leads to unforeseeable inventions and devising a static formula for determining whether the increase in efficacy is sufficiently “significant”, would severely curtail the discretionary powers of statutory authorities while determining

¹³¹ *Supra* note 10.

¹³² For fixing a standard of proof, the decision given by the US Court of Appeals for the Federal Circuit in *Nelson v. Bowler*, 626 F.2d 853 can be looked into. This case held that when a patent is claimed for a therapeutic use of an invention, the patentee need not prove that the claimed therapeutic use is correlated to a specific pharmacological or biological activity as a matter of statistical certainty. The applicant also need not demonstrate that the claimed invention is actually successful in treating human beings. Only a reasonable correlation has to exist between a particular activity and the claimed use. The patentee can establish this reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in scientific journals), or any combination thereof. [See United States Patent and Trademark Office, Special Considerations for Asserted: Therapeutic or Pharmacological Utilities, available at http://www.uspto.gov/web/offices/pac/mppep/documents/2100_2107_03.htm. (Last visited on September 2, 2009)].

¹³³ *Supra* note 64.

¹³⁴ *Supra* note 11.

¹³⁵ *Id.*

patentability of new pharmaceutical inventions.¹³⁶ Thus, instead of attempting to establish a uniform standard for construing the term “significantly”, it is much more feasible to determine “significance” on a case to case basis depending upon the comparative data and other materials provided before the decision-making forum. In this regard, the PHOSITA test can be used.¹³⁷ In other words, when a new form is derived from an existing substance, the views of a person skilled in the art should be used to assess whether the new form demonstrates “significantly enhanced efficacy”.¹³⁸

D. STRIKING A BALANCE BETWEEN INCREMENTAL INNOVATION AND PUBLIC HEALTH

Every patent system employs some mechanism or the other to ensure that the monopoly rights enjoyed by the patent holders do not compromise public health by denying access to pharmaceutical drugs. § 3(d) is one such provision in the Indian patent system which uses a refined form of “non-obviousness”¹³⁹ standard in order to protect the general public from the harmful effects of evergreening. While the provision is not clearly drafted and creates scope for confusion, it cannot be denied that it has gone a long way in promoting access to cheap generic medicine. Providing a proper definition of “efficacy” is therefore, necessary to ensure that the § is not continuously attacked on the ground of “vagueness” which would serve to undermine its significance.

1. US Position on Protection of New Forms

It is often argued that India is the only country to adopt a restrictive approach towards patentability of new forms or new uses of known substances. This notion is not wholly accurate since most countries have myriad ways to exclude minor alterations of known active ingredients from patentability. This is true for even USA whose patent regime is generally considered to be “patent-friendly”. The US courts, have used a number of principles to disallow patents on derivatives of known substances. For instance, in *Schering Corp v. Geneva Pharmaceuticals Inc.*,¹⁴⁰ the Federal Circuit Court employed the doctrine of inherent anticipation to hold that a patent on a previously unknown compound may be invalidated as inherently anticipated if the compound is later discovered to be a metabolite of another compound in prior art.¹⁴¹ It opined that inherent anticipation

¹³⁶ *Supra* note 10.

¹³⁷ Person having Ordinary Skill in the Art. (*See id.*).

¹³⁸ *Id.*

¹³⁹ “Under § 3(d) most forms of existing pharmaceutical substances are deemed obvious unless they demonstrate increases efficacy” (*See supra* note 53).

¹⁴⁰ 339 F.3d 1373, (Fed. Cir. 2003).

¹⁴¹ Michael K. O’Neill & George K. Ng, *Doctrine of Inherent Anticipation is Clarified: Patents may be invalid if compound metabolite of prior art*, NATIONAL LAW JOURNAL, December 8, 2003, available at http://www.fitzpatrickcella.com/images/pub_attachment/attachment118.pdf. (Last visited on September 2, 2009).

does not need appreciation and recognition in prior art, so long as the disclosure is a “necessary and inevitable” outcome of prior disclosures.¹⁴² Accordingly, it rejected the patent on the metabolite of an antihistamine drug because the metabolite “necessarily and inevitably” formed upon ingestion of the previously patented antihistamine under normal conditions’.¹⁴³

The US courts also use the doctrine of double patenting to prevent patenting of new forms of already known substances. This doctrine prevents an inventor from claiming more than one patent on the same invention or obvious modifications or alterations of the same.¹⁴⁴ The phenomenon of double patenting is very similar to patent evergreening as both serve to enhance the profits of the manufacturer of the patented drug by eliminating competition from other drug manufacturers. The purpose of the double patenting doctrine is to allow public to get free access to the original patented product and all the obvious modifications of the same after the expiration of the period.¹⁴⁵ This is similar to the rationale behind § 3(d) of the Indian Patents Act, 1970 which also creates a bar against insignificant modifications. Furthermore, as with § 3(d), double patenting also compares a claim for modification over an existing patent with the original invention to determine if the variation satisfies non-obviousness standards.

The patent misuse doctrine used in the US also provides another parallel to § 3(d). It prevents pharmaceutical companies from extending patent protection over their drugs by acquiring a multitude of patents covering essentially the same invention.¹⁴⁶ In such cases, the courts invoke the non-obviousness principle to invalidate patents. For instance, in a recent decision *Pfizer Inc. v. Apotex Inc.*, Pfizer’s patent on a hypertension drug was invalidated as its active ingredient was a salt form of a known substance.¹⁴⁷ The Court had opined:

“[A] rule of law equating unpredictability to patentability, applied in this case, would mean that any new salt ... would be separately patentable, simply because the formation and properties of each salt must be verified through testing. This cannot be the proper standard since the expectation of success need only be reasonable, not absolute.”¹⁴⁸

¹⁴² *Supra* note 140.

¹⁴³ *Id.*

¹⁴⁴ Paul Pitts, *Eli Lilly v Barr: Double Patenting Analysis can be anything but Obvious*, 4 TUL. J. TECH. & INTELL. PROP. 253 (2002).

¹⁴⁵ *Id.*

¹⁴⁶ Daniel J. Gifford, *Government Policy Towards Innovation in the United States, Canada, and European Union as manifested in Patent Copyright, and Competitive Laws*, 57 SMU L. REV. 1339 (2004).

¹⁴⁷ 480 F.3d 1348, 1364 (Fed. Cir. 2007).

¹⁴⁸ *Supra* note 147.

Providing limited patent protection to new forms or combinations of known substances, which is the rationale behind § 3(d), is not a radical deviation from the normal practices used in other countries to regulate patenting of derivatives. US, which has much more liberal standards of patentability with respect to incremental innovations, has also adopted methods to prevent patenting of minor follow-on inventions. However, the threshold of patentability for new forms or new uses of known substances would inevitably depend on the socio-economic factors of the country. To this extent, differences are bound to exist.

2. § 3(d): Exploiting the Flexibilities under TRIPS

As discussed earlier, Novartis had challenged § 3(d) as being incompatible with the TRIPS. Although the Madras High Court did not decide this issue stating that the proper forum in this regard would be the Dispute Settlement Body of the WTO, nonetheless it is important to examine whether § 3(d) is in consonance with TRIPS requirements of patentability.

Article 27 of the TRIPS provides that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application”. This Article enjoins a responsibility on the member states to adopt certain minimum standards to provide patent protection in all fields of technology. However, since none of the terms have been specifically defined in the Agreement, it allows the member countries to design their patent laws according to their own convenience so long as they satisfy the broad patentability requirements. TRIPS also gives due importance to protection of public health. In this regard, Article 8 provides that “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”. Article 7 of TRIPS addresses the social and economic concerns of the member nations. It specifically states that “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 balance of rights and obligations.” Additionally, TRIPS allows the member countries to depart from the ordinary patentability requirements under exceptional circumstances. Article 27 states that “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.”

A bare perusal of the relevant provisions in TRIPS clearly shows that the member nations have been given significant flexibilities to frame patent

laws which reflect their social and economic needs. As mentioned earlier, terms like “invention”, “inventive step”,¹⁴⁹ and “industrial application”¹⁵⁰ used in Article 27.1 have not been specifically defined giving the member countries freedom to decide the criteria of patentability within the broad parameters of TRIPS.¹⁵¹ In the absence of a precise definition of patentability, there is nothing to prevent § 3(d) from using an “efficacy” requirement for determining patentability of new forms of known substances. More importantly, Article 8 gives considerable leeway to the developing countries to design a patent system which is conducive to the protection of environment and public health. Article 27.2 enhances the scope of this flexibility by permitting member nations to exclude certain inventions from patentability for protecting public interest. As discussed earlier in the article, high drug pricing, which is a natural consequence of evergreening, restricts access to essential medicine, especially in developing countries like India. Since § 3(d) specifically aims to prevent evergreening, it clearly qualifies as a “measure necessary to protect public health” within the meaning of Article 8. Virtually none of the member nations have utilized the flexibilities in the TRIPS provisions for promoting public interest.¹⁵² § 3(d), if properly amended to remove the ambiguities surrounding the definition and scope of “efficacy”, represents an innovative way to utilize the flexibilities provided in TRIPS. Thus, even if § 3(d) is challenged before the WTO panel, it is unlikely that it would strike down a provision which seeks to provide low cost medicines to the general public by creating an “efficacy” barrier. However, care needs to be taken that “efficacy” is not construed in such a narrow manner that patents are restricted to only new chemical entities as this may amount to a TRIPS violation.¹⁵³

3. Balancing Patent Rights and Public Interest:

§ 3(d) is often viewed as an undesirable provision because of its restrictive approach towards incremental innovation. However, removal of this provision altogether from the Indian Patent Act, 1970 is not a feasible option for India. § 3(d) filters out the unmeritorious inventions in the initial stages thereby decreasing the workload of the understaffed patent office. It acts as an additional safeguard against frivolous patenting. In its absence, there would be no check on the patentability of new forms of known substances, which would significantly enhance the incidence of evergreening.

¹⁴⁹ Article 27 of the TRIPS which defines “patentable subject matter”, specifically explains that “the terms ‘inventive step’ and ‘capable of industrial application’ may be deemed by a Member to be synonymous with the terms ‘non-obvious’ and ‘useful’ respectively.”

¹⁵⁰ *Id.*

¹⁵¹ *Supra* note 24.

¹⁵² M. Ho Cynthia, *A New World Order for Addressing Patent Rights and Public Health*, 82 CHI. KENT. L. REV. 1469 (2007).

¹⁵³ Shamnad Basheer, *The Glivec Patent Saga: A 3-D perspective on Indian Patent Policy and TRIPS Compliance*, available at <http://www.atrip.org/upload/files/essays/Shamnad%20Basheer%20Glivec%20Patent%20Saga.doc>.

Today, India is a developing country having technological know-how comparable to many developed countries. Its patent system needs to incentivize innovations in sectors like pharmaceuticals which are developing rapidly.¹⁵⁴ At the same time, given the existing level of poverty in the country, high pricing of drugs would deny millions of people access to life-saving drugs.¹⁵⁵ While protecting innovations like new drug delivery systems developed by domestic majors like Ranbaxy is helpful in promoting new research and development, one cannot ignore the fact that liberal interpretation of patentability criteria can have serious repercussions on public health. Therefore, there is a need to strike a balance between the two conflicting priorities: interest of the inventors who undertake considerable R&D investment on incremental innovation and the general interest of the public which requires restricting the scope of patentability of pharmaceutical substances. § 3(d) can help strike this balance by protecting only those new forms of known pharmaceutical substances that represent genuine incremental innovations. However, this would hinge on the interpretation of the term “efficacy”. If it is interpreted too strictly to mean only “therapeutic efficacy”, it would harm innovation prospects in the pharmaceutical sector. Moreover, given the difficulty in proving such efficacy, it might effectively restrict patents to only new chemical entities.¹⁵⁶ On the other hand, too liberal an interpretation would dilute the efficacy standards and encourage frivolous patenting. Thus, a proper balancing of these two conflicting interests requires that standard of efficacy should be fixed at a reasonable level.¹⁵⁷ A reasonable standard of efficacy entails some level of certainty with respect to the meaning of “efficacy”. Therefore, there is an immediate need to amend § 3(d) to provide clearer standards of patentability for pharmaceutical innovations.

II. CONCLUSION

After independence, India’s patent system was geared towards establishing a patent regime conducive to the development of an indigenous generic pharmaceutical industry. For this purpose, pharmaceutical products were excluded from patentability under the Indian Patents Act, 1970. However, when India became a part of the WTO regime, it was compelled to expand patent protection to pharmaceutical products in order to align its law with the requirements set out in TRIPS. Nonetheless, the fear of frivolous patenting in the form of evergreening in pharmaceutical products gave rise to the urgent need to provide for a specific provision aimed at curbing this pernicious practice. It was with this objective in mind that § 3(d) was amended to incorporate the enhanced efficacy requirement for determining the patentability of incremental innovation. Although the object behind § 3(d) is a laudable one given the fact that it seeks to protect

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Supra* note 153.

¹⁵⁷ *Id.*

larger public interest, the broad language used in the section excludes most kinds of incremental innovation. This can be harmful in the long run since genuine incremental innovations play a vital role in the development of new medicine. Such innovations also serve to enhance the safety and efficiency of existing drugs thereby improving the quality of life of patients. However, most of them would find it difficult to satisfy the enhanced efficacy standard, especially if it is interpreted in a drug-regulatory sense to mean only “therapeutic efficacy”. A patent regime which protects only new chemical entities would fail to provide any incentive to domestic majors like Ranbaxy which undertake considerable R&D efforts for improving existing drugs. A case study on the issue shows that the ambiguous wording of § 3(d) makes the patentability requirements for incremental innovation highly uncertain. Thus, amendment of § 3(d) is very important in order to bring some clarity in the law relating to pharmaceutical innovations. A clearly worded § 3(d) would be able to peg the efficacy requirement at a more reasonable level, which in turn would enable the protection of truly inventive innovations without exacerbating the chances of evergreening.