ISSN 2582 - 211X

LEX RESEARCH HUB JOURNAL

On Law & Multidiciplinary Issues

Email - journal@lexresearchhub.com

VOLUME II, ISSUE III
JULY - SEPTEMBER, 2021

https://journal.lexresearchhub.com

Lex Research Hub
Publications

DISCLAIMER

EDITORIAL BOARD

Assistant Editors

ABOUT US

Lex Research Hub Journal On Law And Multidisciplinary Issues (ISSN 2582 – 211X) is an Online Journal is quarterly, Peer Review, Academic Journal, published online, that seeks to provide an interactive platform for the publication of Short Articles, Long Articles, Book Review, Case Comments, Research Papers, Essays in the field of Law and Multidisciplinary issues.

Our aim is to upgrade the level of interaction and discourse about contemporary issues of law. We are eager to become a highly cited academic publication, through quality contributions from students, academics, professionals from the industry, the bar and the bench. Lex Research Hub Journal On Law And Multidisciplinary Issues (ISSN 2582 – 211X) welcomes contributions from all legal branches, as long as the work is original, unpublished and is in consonance with the submission guidelines.

SECTION 3(D) OF PATENTS ACT, 1970 – A CASE FOR WIDER INTERPRETATION OF 'EFFICACY'

Author –

Makrand Chauhan

LLM Graduate

Jindal Global Law School, Sonepat

ABSTRACT

The Indian Patents Act, 1970 brought a patent regime that would encourage the development of the domestic pharmaceutical industry and make life-saving drugs affordable for common people. The framework initially allowed the indigenous generic drug manufacturing companies to produce cheaper versions of patented drugs by using 'reverse engineering. However, in 1995, when India joined the WTO, the immediate pressure was to make its patent law TRIPS compliant. Article 27 of TRIPS indicated that other than providing patents on the processes, the regime needed to extend protection to the corporation-produced pharmaceutical products as well. Additionally, it was required to grant Exclusive Marketing Rights for certain pharmaceutical products awaiting patent recognition in India. Finally, the Patent (Amendment) Act, 2005 introduced patent protection for these pharmaceutical products as required under TRIPS.

Section 3(d) in the Act is vital for protecting public health since it is the only provision which can stop pharmaceutical giants from extracting prohibitive prices for life-saving drugs by lengthening patent protection through ever greening.

This article highlights that by reducing the scope of patentability to only those products which pass the threshold of enhanced 'therapeutic efficacy', the legal instrument unintentionally restricts technological advances in drug development which are not directly related to such efficacy. This may appear small but have long-term positive implications anyway. The article also puts forth three main arguments which pin the case for a wider interpretation of the definition of 'efficacy' so that incremental innovations and follow-on inventions are not lacerated out of the pharmaceutical scene. Finally, the article concludes by advancing propositions by esteemed legal luminaries in this field and attempts to reach a middle ground to this contentious issue.

Keywords: *Section 3(d), Efficacy, Secondary Use, Incremental Innovation, Spill-over Effect*

1. INTRODUCTION

Laws and regulations on patents in India are intended to grant monopoly right(s) to an individual who has either invented a new and useful article or has recognized and devised an improvement of an existing article or a new process of making an article. Incidentally, patents for 'pharmaceutical substances' are also covered under the same act as defined under Section (ta). The Patents (Amendment) Act of 2005 brought India into compliance with TRIPS by giving full patent protection to pharmaceutical products.[1]

Although India has been considered as the pharmaceutical hub for nations across the world, by being the largest provider of generic drugs globally and catering to over 50% of global demand for various vaccines, the pharmaceutical innovator companies continue to thrive due to a large, technologically savvy workforce and the Indian patent regime which progressed for the better after having undergone multiple transformations during the last many years in an attempt to comply with TRIPS.

However, some pharmaceutical companies end up abusing this tool to extend their patents (patent ever-greening) and achieve more economic advantages by using different approaches, like combining, finding new medical treatments, formulations or minor changes in older medicines. Such medication cannot therefore be considered new because of the lack of complete requirements of an invention such as novelty and inventive step. This commercially inclined practice of ever-greening pharmaceutical patent contradicts the spirit of innovation, invention and marketing.

Section 3(d) is a unique provision in the Indian patent regime that is focused on preventing this by prohibiting the patenting of 'new forms' of existing pharmaceutical drugs that do not show enhanced efficacy. It was substituted by the Patent (Amendment) Act in 2005 to balance out the competing interests of many other stakeholders like domestic generic medicine producers, multi-national pharmaceutical companies & civil society groups.

Although, Section 3 of the Patents Act, 1970 is dedicated to enlisting those inventions which cannot be patented, there are no clear guidelines or substantial clarity on what constitutes the aspect

[1]Shamnad Basheer, India's Tryst with TRIPS: The Patents (Amendment) Act, 2005, 1 INDIAN J.L. & TECH. 15, 16–17 (2005) [hereinafter India's Tryst with TRIPS]

of ‘efficacy’ in the provision itself. A very strict reading of the term could result in very few patents being granted for incremental pharmaceutical innovations.

In many decisions which involved the said section, the courts observed that ‘efficacy’ meant the ability to produce a desired or intended result. In other words, the test of efficacy would depend upon the function, utility or purpose of the product under consideration. Therefore, in the case of a medicine that claims to cure some disease, the test of efficacy can only be 'therapeutic efficacy'.

Under such an explanation, the types of derivatives that qualify for patent protection are likely to be constrained. The restriction also weeds out many non-therapeutic advantages like bio-availability, heat stability, manufacturing efficiency etc. which involve a considerable amount of research and funds and may certainly be considered more ‘inventive’ than a mere showing of an increase in known efficacy.

Most of the well-known pharmaceutical companies based in India earn by supplying generic drugs to other countries across the globe. Their usual practice is to create (and invest in) non-therapeutic inventions popularly referred to as ‘inventing around inventions’. For example, Ranbaxy’s CIPRO pill has an able drug delivery system which permits a patient to take medicine just once a day in place of a regular twice a day regimen. But under Section 3(d), this drug will pass off only as a combination and will be considered ‘non-patentable unless if proves enhanced efficacy over Bayer’s CIPRO.[2]

Not every country has the resources and wealth to invest in the field of innovation at the level of molecular and/or chemical entity and India is undoubtedly not a case of exception. Thus, even the prominent scholars of intellectual property like DL Burk and M A Lemley propose that the term ‘efficacy’ may be used by the courts as a policy lever as per the convenience of countries (and industries).[3] This theoretical work makes a case for a wider definition of the term ‘efficacy’ because even small improvements at the mechanical and processing level go a long way in making any endeavour for progress in the pharmaceutical industry a success.

[2] Aditya Kant, ‘Section 3(d): 'New' Indian Perspective’ (2009) 14 JIPR. 385-396.
[3] Mark A. Lemley and Dan L. Burk, ‘Policy Levers in Patent Law’. Virginia Law Review, Vol. 89, p. 1575, 2003

2. CASE FOR WIDER INTERPRETATION OF SECTION-3(D)

As already mentioned above before, legal professionals across the spectrum argue that the term 'efficacy' in Section 3(D) should not be merely restricted to the aspect of therapeutic efficacy, but should also include all the other kinds of properties which have been designated as 'secondary' but are still advantageous in the long term, viz., heat stability, humidity resistance, enhanced bioavailability, new drug delivery mechanisms etc. Historically, Indian cultural tradition has been socialist towards the concept of medicines and health. In fact, the same had been advocated by Prime Minister Indira Gandhi when it was conveyed by her in a speech before the World Health Assembly that a better-ordered world would mean one where scientific innovations and discovery around medicinal drugs would not be accompanied by its patent protection and every citizen would have an equal right to health and well-being, irrespective of his/her financial condition.[4] Inspired by such a homily from the leader of the country, India became one of the important members of those circles of countries which instead of investing their public resources towards research in pharmaceutical drugs, adopted weak patent protection. This paved way for the practice of free-riding wherein a foreign patent is disregarded for the choice of utilizing the knowledge behind the patent for the production of generic drugs. Thus, most domestic Indian pharmaceutical industries in the country indulged in the art of reverse engineering which involved a slight alteration in the production processes of patented drugs so that they could be produced for mass consumption at a cost which most people could afford.[5] It was touted that the development of such a highly competitive generic industry thrived in India, for some reason, due to stringent Indian patent law in existence.

2.1 Argument of Pharmaceutical companies

In a press release, it was claimed by many pharmaceutical companies that although the drafting of Section 3(D) to prevent ever-greening was highly well-intentioned, it left much to be desired. The skeletal nature of the provision posed a difficulty in determining as to what level of enhancement could be understood to be remarkable enough to pass the muster of Section 3(d) and the explanation attached therewith. Moreover, it was contended that path-breaking innovations to

[4] Johanna Sheehe, *Indian Patent Law: Walking the Line?* 29 Nw. J. INT'L L. & Bus. 577, 580 (2009).
[5] ibid

'enhance' the efficacy of drugs were relatively rare compared to incremental innovations.[6] The most prominent examples of these 'incremental innovations' are:

i) Improved safety and effectiveness of the drug,

ii) Greater stability during storage and transportation,

iii) Lesser side-effects, and

iv) New formulations of the product aimed at specific patient groups such as children. [7]

2.2 Benefit to small corporate entities:

Since, the concerned provision did not provide for any guidelines as to the determination of 'enhancement of efficacy', the High Court in the *Novartis* case decided to look for the meaning of the same in Darland's Medical Dictionary, which defined it as 'the ability of a drug to produce the desired therapeutic effect' where efficacy is independent of the potency of the drug.[8] Furthermore, the dictionary meaning of the term 'therapeutic' was realized to be 'healing of disease - having a good effect on the body.[9] This argument put forward by this work is that the aspect of Section 3(D) should be widened enough to include all other kinds of advantageous properties under the term 'efficacy' as mentioned before since the grant of a patent for those drugs exhibiting such properties would have the dual benefit of helping the small corporate entities in a nation with 'transitional economy' to achieve its rightful position in the global value chain[10] as well as providing developing countries a chance to grow and improve their socio-economic conditions by incentivizing indigenous pharmaceutical majors which have been not yet excelled in more expensive 'new molecular entity (NCE) innovations but have instead been efficacious in non-therapeutic ways.

Since, availability and procurement of drugs, medicines and other pharmaceutical products are closely linked to the role of contemporary IP tools in the promotion of the right to access public

[6] Steven Globerman and Kristina M. Lybecker, The Benefits of Incremental Innovation: Focus on the Pharmaceutical Industry. Fraser Institute (2014)
[7] Press Release, PhRMA, Indian Court Decision Weakens Incentives for New Innovations that Benefit Patients (Aug. 6, 2007) available at http://www.phrma.org /news-room/press-releases/indian_court-decision weakensincentives_for-new-innovation s_thatbenefit-patients/
[8] Darland's Medical Dictionary
[9] Novartis case, (2007) 4 MLJ 1153, para 13.
[10]FOLLOW-ON INNOVATION AND INTELLECTUAL PROPERTY – WIPO <https://www.wipo.int>

health, the issue would be addressed with two examples, viz., i) Secondary uses and ii) NDDS i.e. novel drug delivery systems.

2.2.1 Secondary Use Patents

In most cases, an innovator company does not secure a patent only on the active ingredient in a novel drug. For varying disease burdens on humanity, a chemical compound in a drug may have two or more potential therapeutic applications, which can raise the insinuation of patents for 'secondary patents'.[11] Astonishingly enough, there could be many other peripheral features of the same drug for which a secondary patent has been previously argued for by the intellectual property lawyers in this field, such as (i) tablet coating, (ii) a naturally-occurring intermediate product that appears after the ingesting of the drug, (iii) an unconventional method(s) of use, & (iv) different delivery route.[12]

Again, there are two aspects to the concepts of the phenomenon of 'secondary use patents. Purists insist that the introduction of such patents in the market sphere is intentionally done by the innovators exclusively to maximize their returns on research and development and consequently, maintain their market share. Legal scholars and researchers, in favour of either the generic industry or public health issue, generally tend to attack the filing of such patents using terms with negative connotations, such as 'product hopping', 'ever greening' and even 'pejorative'.[13] Critics pan this industry practice by declaring that the patents obtained like that are petty and only meant either to extend the term of the initial patent or delay the entry of generic products in the market.[14]

However, this claim was refuted in AstraZeneca's most successful yet most heavily attacked and defamed chiral-switch drug, Nexium. This enantiomer patent meant for gastric acid-related problems, like gastroesophageal reflux diseases, was challenged in courts against the criteria of 'non-obviousness across the globe; yet it was validated due to the exhibition of 'unexpected or surprising results' on account of the application of its stereochemistry principles.[15] As of the

[11] FOLLOW-ON INNOVATION AND INTELLECTUAL PROPERTY – WIPO <https://www.wipo.int>
[12] Ho, Cynthia M., Should All Drugs Be Patentable? A Comparative Perspective, 17 Vand. J. Ent. & Tech. L. 295 (2014-2015)
[13] Israel Agranat and HiliMarom, In Defense of Secondary Pharmaceutical Patents in Drug Discovery and Development. ACS Medicinal Chemistry Letters 2020 11 (2), 91-98
[14] Saritha Kiran, SivakamiDhulap& Mohan Kulkarni, 'Secondary patents: innovator and generic strategies'
[15] Ibid at 9

allegation regarding delaying the entry of drugs, an analysis by field researchers of the patent portfolios of the prominent pharmaceutical companies revealed that the grant of such patents neither ceased the generics from getting an entry in the market nor extended the term of the 'primary' patent filed before.[16] It was also realized in their study that innovators sustain a patent portfolio like that, not keeping the generic industry in mind but mostly in their quest to curtail the entry of another innovator in the same field, which could be unpredictable.

2.2.2 Novel Drug Delivery Products (NDDP)

Acclaimed researchers like Gehl Sampath and Sudip Chaudhari have, in their respective academic works, made a strong case for the expansion of the scope of 'efficacy'. In their observation, some of the most notable inventions that the Indian pharmaceutical companies have brought up have been in the sphere of NDDS (new drug delivery systems) products which have had a metamorphic impact to both industry and customers in a non-therapeutic manner.[17] Gehl has gone so far as to refer to this patent strategy wherein such NDDS-based products are gotten hold of by the firms as 'Positive patenting'.[18]

Instead of advancement at the chemical level, the patent eligibility of these new drug delivery mechanisms is based on the progress in material science, which is also considered to be a substantial technological improvement in the field of medical science. Some of the most common types of novel drug delivery systems (NDDS) devised to mitigate side-effects and/or increase patient compliance are: (i) Extended-release formulation of existing oral therapies, (ii) Development of alternative delivery routes (oral & injectables), and (iii) Purification enhancement of the product to reduce dosing and side effects.[19]

Under NDDS, there are two oft-cited and leading examples of products that have made a mark in the pharmaceutical patent industry and will be discussed as follows:

[16] Ibid at 10
[17] Sudip Chaudhuri, 'Is Product Patent Protection Necessary in Developing Countries for Innovation: R&D by Indian Pharmaceutical Companies After TRIPS' Working Paper No. 614 (Indian Institute of Management, Kolkata), 2007, 15.
[18] Gehl Sampath, 'Economic Aspects of Access to Medicines after 2005'
[19] Sudip Chaudhuri, 'Is Product Patent Protection Necessary in Developing Countries for Innovation: R&D by Indian Pharmaceutical Companies After TRIPS' Working Paper No. 614 (Indian Institute of Management, Kolkata), 2007, 15

2.2.2.1 Ranbaxy's CIPRO pill (as new dosage formulation)

A most commercially successful example of NDDS and sold worldwide as 'Cipro-OD', Ranbaxy's ciprofloxacin allows a patient to take their medicine only once a day, instead of its earlier required dosage of twice a day. This new dosage form has been put on the market by the company through its licensing to Bayer AG, which is a sequential innovator of the original drug and provides Ranbaxy with suitable royalties on the same. It must be noted that the US FDA had approved it even though the patent on the original molecule had expired.[20] However, if tested against the criteria set by the Explanation to Section 3(d) of India's Patent Act, this drug form would only qualify as a 'combination' and therefore, fail to pass the muster of patentability.

2.2.2.2. U.S. Patent 6,623,762 (as an innovative drug delivery system)

This U.S. patent was granted in 2014 for a biochemical composition which permits the controlled release of vaccines encased in soluble glass-like microspheres made of sugars.[21] It was realized that this innovation acted as a ground-breaking delivery vehicle for existing substances as it could withstand temperatures up to 55° for months on end, which for other delivery systems could have posed a serious problem in conserving the vaccine itself. Other merits included:

(i) Direct administration of vaccines (the system eliminated the need for dissolution of the drug in its powdered form in injection water)

(ii) Elimination of the requirement of artificial preservatives

(ii) Enabling ingestion of an assortment of vaccines in a single jab (due to encasement in microsphere)

According to The Economist[22], this technology displayed the potential to save up to $300 million a year in global vaccine costs itself and as a positive consequence, around ten million more children could be protected from debilitating diseases. This U.S. Patent 6,623,762 holds importance

[20] Singh, Malvinder Mohan. "Will India Become the Global Centre for Pharmaceutical Research & Development?" Journal of Generic Medicines, 3(3) (2006).
[21] U.S. Patent Number 6,623,762 granted in 2004. See World Intellectual Property Organization Secretariat, Follow-on Innovation and Intellectual Property, 13-14 (20 May 2005) (Submission to WHO's CIPIH): http://www.who.int/entity/intellectualproperty/submissions/Innovation%20&%20Intellectual%20Property%20WIPO.pdf
[22] The Economist, Oct. 23rd 2004 at 77-78

because it forces a public welfare perspective rather than a strict IP protection one. The prime concern is that a technical improvement like this might not contribute directly to 'therapeutic efficacy', but would most probably help save government expenditure in the delivery of essential health services to remote areas and related mass immunization campaigns.

2.3 Spill-over Benefits

Innovations in the pharmaceutical industry have been essentially categorized into two forms: 'incremental' and 'breakthrough'. Even though both of these forms have their significance and private-sector organizations invest in either depending upon their company's goals and capacities, there is an increasing call for the firms to prioritize the breakthrough innovations over the incremental ones based upon the massive social benefits that can be realized from the former.[23] In economic parlance, these so-called 'benefits' are also referred to as 'spill-over benefits'.

More elaborative, this term means that the commercial (or financial) benefits of any innovation in a particular field can be captured by partakers in the same economy other than the innovating organization. Economists Steven Globerman and Kristina Lybecker in their paper are affirmative of the fact that innovation is a key step in the undertaking of gross technological change, which is nearly always responsible for the actual economic growth and society's improved standard of living.[24] Understandably then, policymakers in developed countries have been focussing upon promoting the same through the instruments of tax benefits and IP-related legislation. Be that as it may, multi-national private players, especially in the pharmaceutical industry, still face criticism over their focus on incremental innovations over the breakthrough ones despite knowing that compared to the existing products, the 'new products' exhibit only modest improvements overall and don't contribute much to social welfare. However, an assumption like this wreaks more of misapprehension than clarity in understanding.

Globerman and Lybecker believe that innovations brought forth by organisations, which tend to bear economic benefits that consequently spill over to other areas of human endeavour can be of any kind. Undoubtedly, the contributions from major innovations of the world have been widely acknowledged as having a more profound impact on society; nevertheless, in comparison to

[23]Steven Globerman and Kristina M. Lybecker, 'The Benefits of Incremental Innnovation | Focus on the pharmaceutical industry (June 2014)
[24]ibid

incremental innovations, they are relatively rare and often require a huge investment in terms of manpower and technology. Even when looking at the commercial aspect, it was realized that the cumulative value derived from the incremental innovations could surpass that from radical ones solely on the account of sheer numeric difference.

Other than this, Bela Gold, Gerhard Rosegger, and Myles Boylan in their book 'Evaluating technological innovations.'[25] Have documented that for every production process, qualitative changes due to any innovation introduced at the initial stage could trickle down to the later stages of the same value chain.[26] The 'spill over effect' here is such that even when the one originally responsible for such innovation might not get fair remuneration for his work effort, the manifestation could be such it would bring economic welfare to the consumers at the industrial as well as household level.

Last but not the least, research scholars like Paul David have highlighted those radical innovations also end up being promoted due to the interesting concept of learning-by-doing whereby early bird innovations gradually build upon and influence whatever would be needed to be learnt by producers at a later stage.

3. CONCLUSION

Field experts and judges have noted that all pharmaceutical inventions are indeed not patentable and Section 3(d), at least, endeavours to draw a bright-line rule that can assist in filtering out such unworthy pharmaceutical inventions. It is still suggested that this provision has its own set of creases that can be ironed out through further amendments.

Most research works published on the subject are theoretical and only provide a few immediately implementable solutions. However, the issue at hand also has policy implications at the domestic as well as international level and would necessarily involve a more detailed empirical investigation, which at present hasn't been embarked upon.

[25]Bela Gold et al., 'Evaluating technological innovations: methods, expectations, and findings'(Lexington Books ©1980)
[26] ibid

In the paragraphs that follow, this work shall be concluded by putting forth the viewpoints of legal researchers who threw light on the aspect of efficacy in Section 3(d) and tried to either provide the solution or at least some middle path that could be followed in future.

Sadhvi Sood and Aditya Ayachit in their paper 'Taking Patent Requirement - A Notch Higher…' have looked at the problem through law and economic framework. According to them, the corporate practice of ever greening does need to be effectively curbed by taking the standards of patentability 'a notch higher'. The social costs of doing that could, however, be uncomfortably high because of the continued practice of the indigenous industries in the field to depend upon incremental innovations. For this, they propose a proactive involvement of the government which could fund basic research of newer drugs. The contention they hold here is that this could, in turn, stimulate innovative activity in the private sector by providing a strong bedrock to build upon. They hope that this should lead not only to an efficient outcome but also to a societal fulfilment of having therapeutically better innovations in reach.

Aditya Kant in his work has also accepted that due to a looming uncertainty concerning efficacy in the provision, various legal and non-legal aspects are affected and contemplates a reform in this direction. Among many options, he makes a call for balancing imperatives in reform and proposes an integrative approach under which a simple model comprising Efficacy Matrix, Score, and, Threshold (cut-off) can be developed as a thumb rule for determination of efficacy under Section-3(d). The researcher in his paper "An attempt at quantification of 'Efficacy" is positive that such a guideline would be able to reduce much inconsistency, arbitrariness, and corruption etc. to a good extent even if other reforms at the institutional level are not carried out.

According to Susan Fyan, some assurance of return on investment is required in the world of generic medicine development as well so that adequate incentive could fuel the process of bringing drugs to the market. However, in the light of the climate for patent protection in the countries like India and US becoming increasingly hostile, she suggests that the innovator companies reconsider their strategies for portfolio management. With the current model valuing return on investment (ROI) for new developmental projects pivoted on the idea of 'speed-to-market, it becomes clear as to why ever greening is a necessary evil for innovator companies. Thus, she further proposes that in cases where ever greening cannot be done without, the innovator company rethink the

development of the new drug in the first place itself. And, in cases where a lower long-term ROI can be settled with, these companies would have to deal with the fact that patent protection might not be available in case of products with incremental improvements while their precise value to the portfolio is being considered.[27]

[27] Susan Fyan, 'Pharmaceutical Patent Protection and Section 3(D): A Comparative Look at India and the U.S.' (2010) 15 Va JL & Tech 198