THE AFFAIR OF PHARMACEUTICALS AND THE SECONDARY PATENT SYSTEM IN INDIA

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ABSTRACT

The expansion of the pharmaceutical industry has been accompanied by the development and application of secondary patents. The use of secondary patents to extend periods of exclusivity has become a common practice among pharmaceutical firms. The Indian regime of pharmaceutical patents in India has been particularly controversial with its unique provisions related to the secondary patent system contained in Section 3(d) of the Indian Patent Act 1970, which restricts the ever-greening of patents. That means to qualify for the patent test of a known substance, it has to additionally pass the enhanced efficacy round. This led to the growth of the generic market in India. But it caught attention when Novartis was denied a patent for its product Glivec. This paper will highlight the evergreen debate and controversy concerning section 3(d) of the Patent Act concerning its use for rejection trends in pharmaceutical patents, the judicial interpretation as well as highlighting the EU Directive 2001/83/EC, which contains the definition of "generic substances" which in line with an explanation attached to section 3(d) to provide better legal protection to legitimate Indian Innovations and to remove the controversy and uncertainty surrounding the scope and effect of section 3(d) of the Patents Act, 1970.

Keywords: Pharmaceuticals, ever-greening, patents, innovation, generic

Introduction

The introduction of pharmaceutical patents in India has been particularly controversial. Despite the constitutional protections under Article 21 that covers the right to health[1]and also under Article 47, which places a duty on the state to improve public health, it is alleged that India has one of the world's most stringent patent laws. The objective of the Indian Patent Act is to promote invention and discovery by granting patents for new and useful processes, manufacturing and compositions of matter. However, in practice, the Indian Patent Act is often used to stifle innovation and block the development of affordable generic alternatives to expensive brand-name drugs. One of the most noted examples of this was the case of Gleevec, a cancer drug developed by Novartis.

Consequently, the Indian government operates on the premise that medicines critical to the important health care needs of the Indian population must be available and affordable. Indeed, this model is the fundamental foundation of India's vision of the right to health under article 21 of the Indian Constitution. Consequently, Indian policymakers strive to fulfil India's constitutional obligations regarding the right to health while strengthening the environmental innovation system and protecting the legitimate business interests of multinationals. The result is a series of policies and programs that have sought to strike a balance between the need for affordable access to medicines and the desire to protect the interests of innovators and manufacturers. One such program is the Patents Policy, which was introduced in India under Section 3(d) of the Indian Patent Act 1970 under which the scope of patents is limited to new and useful processes, machines, manufacturers and compositions of matter. This has been interpreted to mean that the introduction of pharmaceutical patents in India would be prohibited except in limited circumstances. The Indian patent regime has taken advantage of the flexibility provided by the TRIPS Agreement to avoid ever-greening.

Section 3(d): Finding The Patent Balance

The industry is well aware of the need to improve and enhance the quality of medicines, as well as wealth creation, competitive advantage and sustainable growth. This innovation entails high investment, high risk and high return. This is because it is a long, arduous and expensive

[1] Bandhua Mukti Morcha v Union of India 1984 AIR 802.

process to bring a new drug to market. It has the power to improve the lives of millions, while also creating a competitive advantage for firms and increasing wealth creation.

On the other hand, policymakers in the Indian government rely on the patent regime to ensure that pharmaceutical innovations deliver affordable medicines and accessible health care to all citizens. The Indian government on the other hand has been working to expand access to affordable pharmaceuticals by invoking the provisions of the patent regime to improve access to healthcare and enhance health outcomes for all citizens. This means that pharmaceutical companies are incentivized to continue investing in research and development of new medicines, which have the potential to offer affordable healthcare to the people of India. This has resulted in a cascading effect on the availability of medicines in the Indian market, as well as the investment climate for companies in the sector.

To protect the public interest and maintain a balance of access to life-saving drugs for patients, i.e. for public goods, the Indian Patent Act 1970 was amended to include Section 3 (d) in 2005 to prevent the evergreening of pharmaceutical patents by denying the patentability of a known chemical molecule unless it was shown to be more effective. The rationale for amending the law was to incentivize the pharmaceutical industry to innovate new molecules by protecting the public interest by ensuring that the patented drugs remain in the public domain for the benefit of the people. Section 3 (d) was redesigned to prohibit patents on existing compound variables without significantly improving efficiencies.

Patent Protection Under Section 3(d)

To apply for a patent, it must be competent to qualify for a patent grant. This means that it should not fall under the category of patent-exempt inventions, i.e., section 3 of the Indian Patent Act. The patented invention must be new and includes an innovative step and commercial benefit. Section 3 (d) of the invention must be subject to the patentability test in the form of efficacy along with another patentability testing.

"Section 3(d) what are not inventions. - The following are not inventions within the meaning of this Act-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."[2]

The Efficacy Requirement

The term "efficacy" is of primary importance under Section 3 (d) of the Indian Patent Law. The term is also not defined in the law. The same holds for the term 'generic' as well. The definition of generic substances is also not very detailed in the law. It is also not mentioned quantitatively about the amount of efficacy that can be considered significant.

The Supreme Court has noted in the context of the effectiveness of the pharmaceutical product as being the capacity and quality of producing the intended result or effects. Also the determination of "efficacy" is a very subjective process. It also states that the process of determining the efficacy of a molecule is not an exact science. Hence, the interpretation of the term is to be made keeping in mind various factors such as the use of the drug, its mode of administration, the disease for which the drug is intended and the standard of living of the people in different parts of the world. To understand what is significant efficacy one can refer to the case of Novartis wherein the efficacy of the drug Glivec was considered significant even though it was only 10% of the efficacy of the drug Irinotecan. This shows that the percentage of the efficacy of the drug is not the only thing that is significant.

The applicant must submit a patent application for a new drug to highlight the difference between the patent application and the patent granted based on the therapeutic effect. Establishing the "therapeutic efficacy" to the patent examiner is a difficult task for the patent applicant as most applications are filed by the pharmaceutical companies in the initial stage of drug discovery. The applicant has to provide clinical evidence for the efficacy of the molecule. This can be done by carrying out clinical trials on the drug or by providing the results of the trials carried out by the pharmaceutical companies. The applicant can also provide the results of the trials carried out by the competitors of the pharmaceutical companies. The applicant

[2] Section 3 of Indian Patent Act.

should make sure that the data is not just about showing the difference between the molecule and the reference molecule but also about showing the therapeutic efficacy of the molecule.

So the important requirement is to have a clear definition of effectiveness that can solve issues surrounding section 3(d) such as misapplication, arbitrariness, and legal suspicions. Such a step forward could lead to an amicable solution to the Indian patent system and the TRIPS Agreement.[3] The patent for a newly developed drug can only be obtained if it provides better performance and must be proven empirically. Section 3 (d) promotes the subsequent expansion of existing chemicals, compounds, technologies, processes, and existing products that help meet the public's health requirements and balance public goods with the exclusivity of patent rights.

Impact Of Section 3(d) On Patenting Trends

(A) ***Application of Section 3(d) for Rejection of Patents*** The moot question here is under what circumstances a claim for a composition can fall under the purview of Section 3(d) of the act as being a discovery of a new form of a known substance requiring enhanced efficacy to overcome the same.[4]

The statutory exceptions to patenting were also prominent in the grounds for refusal, with about 65% of refusals referring to Section 3 as the basis for refusal. Various subsections within section 3 are often cited together, with exceptions to patenting new forms of known substances (section 3 (d)), just combinations of known drugs (section 3 (e)), and methods of treatment (section 3 (i))), being the most common reasons cited in this category.[5]

Table : Comparison of Number of rejections based on Section 3.

Year	3(b)	3(c)	3(d)	3(e)	3(f)	3(i)	3(j)	3(k)	3(m)	3(n)	3(p)	Number of applications

[3] Challenges to India's Pharmaceutical Patent Laws; Available at: https://science.sciencemag.org/content/337/6093/414.

[4] India: Indian Patent Office rejects application under Section 3(d) of the Indian Patent Act ; https://www.managingip.com/article/b1kbpq7kffps0s/india-indian-patent-office-rejects-application-under-section-3d-of-the-indian-patent-act.

[5] Rejected In India: What the Indian Patent office got Right on Pharmaceutical patent application(2009-2016); available at: https://accessibsa.org/media/2017/12/Rejected-in-India.pdf.

												refused on Section 3
Up-to March 2009	0	0	21	6	0	2	0	0	0	0	0	23
2009-10	0	0	24	7	0	3	1	0	0	0	0	32
2010-11	0	0	14	17	0	6	0	0	0	0	0	30
2011-12	0	0	7	5	0	1	0	0	0	0	0	10
2012-13	0	0	2	48	35	0	31	0	0	0	4	76
2013-14	1	2	100	65	2	44	7	2	0	0	20	151
2014-15	1	1	202	128	2	93	8	0	0	6	5	266
2015-16	2	2	201	131	2	78	8	3	2	1	13	281
2016-17	2	5	154	136	3	55	7	0	0	0	9	244
	6	12	771	532	9	313	31	5	2	7	51	1113

Source: accessiba.org

Table: Landmark cases of Section 3(d) rejections[6]

[6] Controller's Decision- Indian Patent Office; Available at: https:// ipindiaservices.gov.in/ patentdecisionsearch/patentsearch.aspx.

Applicant	Application No.	Name of the drug/ tradename/ Date of rejection	Opponents	Utility	Grounds of Rejections under section 3(d)
Novartis AG	1602/MAS/ 1998 (Pre- Grant Opposition)	Imatinibmesylate (Glivec) Revoked April 2013	Cancer Patients- aid Association Natco Pharma Ltd. Cipla Ltd. Ranbaxy Laboratories Ltd.	Anti-leukemia	No significant difference with regard to therapeutic efficacy in spite of increased bioavaibility of the salt over Imatinib.
Hoffman La Roche	IN' 507	Rejected	-	Lung cancer drug	The application IN'774 was rejected as there was no significant enhancement in therapeutic efficacy.
Abraxis Bioscience	4572/CHENP/2006 (Pre-grant opposition)	Abraxane (Revoked June 20150	Natco Pharmo Ltd.	Anti-cancer drug	Combination of known substances, namely paclitaxel and anti- SPARC antibody, no demonstration of enhanced efficacy.
Boehringer Ingeleim	558/DELNP/2003/IN254813	Crystalinetiotropiumbromide monohydrate salt (Spirivia)	Cipla Ltd.	Asthma Drug	No considerable enhancement related to therapeutic efficacy over existing tiotropium bromide.

	(Post- grant opposition)	Revoked march 2015			
Hoffman- La Roche	959/MAS/1995/IN207232(Post-grant Opposition)	Valganciclovir (Revoked Jan 2014)	Ranbaxy Laboratories Ltd. Cipla Ltd.	HIV drug	Mere use of a known process and known compound with no improvement in efficacy.
Novartis AG	1440/MAS/1998 (Pre-grant Opposition)	Crystalline Ascomycin derivatives (Revoked July 2007)	Ranbaxy Laboratories Ltd.	Anti-inflammatory	The Therapeutic efficacy of the Crystalline form was not disclosed by the applicant.
Novartis AG	237/MAS/1998 (Pre-grant Opposition)	Oxcarbazepine (Revoked January 2007)	Ranbaxy Laboratories Ltd., Torrent Pharma Ltd.	For Psychomatic disturbances, Epilepsy and trigeminal neuralgia	Applicant failed to prove efficacy
Gilead Pharmasset LLC	6087/DELNP/2005(pre grant Opposition)	Sofosbuvir (Sovaldi) Revoked January 2015	Delhi network of positive people(DNP+),	Hepatitis C	Cyctotoxicity data produce by the applicant to prove the difference in properties over known compounds which is not sufficient to provr

					significant increase in the therapeutic efficacy.
Glaxo Smith Kline (GSK)	WO2000018383 (pre-grant opposition)	Combivir	The Indian Network for People Living with HIV/AIDS & the Manipur Network of Positive people	Anti-retroviral drug	Combination of two known essential AIDS drugs, Zidovudine and Lamivudine
Glaxo Smith Kline (GSK)	IN221171 (Post- grant Opposition)	Tykerb (Revoked July 2013)	Fresenius kabi Oncology Ltd.	Breast Cancer drug	Physicochemical improvement data was shown which has no connection with therapeutic efficacy

Source: ipindiaservices.gov.in

It is clear from the understanding of section 3(d) by the patent office, IPAB, and Indian courts have primarily focused on direct evidence for the enhancement of known efficacy of the drugs, and indirect evidence in terms of improved bioavailability has not been taken into consideration. The patent office has only examined the efficacy test of patentability, and the courts have not engaged in a proper assessment of the patentability of the invention. It is evident from the above discussion that there is a general lack of understanding of the secondary patent regime in India and the fact that it is not a statutory regime. The secondary patent regime has its roots in the Indian Patent Act.

Section 3(d) which deals with the patentability of known substances was raised 771 times in 69% of the cases either alone or in combination with other sections where the exceptions to

patentability were cited indicating its use as a policy tool by the IPO in rejecting applications that fell within the exceptions.[7]

The number of applications rejected under section 3 is compared from 2009-16. The data is retrieved from IPO annual reports. The number of section 3(d) citations in the controller's decision has relatively increased between 2013 and 2016 in comparison to two other subsections that is section 3(e) and section 3(i).

The increase in the frequency of citation 3 (d) is not very surprising after the Supreme Court's decision in Novartis AG vs the Union of India where it supported the rejection of the Novartis patent application by the Indian patent Office using Section 3(d).[8] After this landmark decision, patent applications dealing with new forms of known materials will also need to provide data regarding the improved "therapeutic efficacy" of the compound for which they sought a patent. This increase in rejection by using section 3(d) could be due to judicial interpretation.[9]

It was reported in a study regarding the rise in rejections based on the precedent set by the Supreme Court in dealing with Section 3(d) of the Indian Patent Act[10] in the Novartis case. "Section 3(d) was raised in 69% of the cases where the exceptions to patentability were cited indicating its use as a policy tool by the IPO in rejecting applications that fell within the exceptions," noted the report released in December 2017[11].

Judicial Interpretation Of Section 3(d)

(A) *The Landmark: Novartis AG vs Union Of India[12] (2013 (5)SCALE 12)*

This Novartis-Gleevec affair attracted great attention, not only in India but all over the world because the Gleevec patent was approved in 40 countries and Indian pharmaceutical companies

[7] Rejected In India: What the Indian Patent office got Right on Pharmaceutical patent application(2009-2016); available at:https://accessibsa.org/media/2017/12/Rejected-in-India.pdf.
[8] India: Types Of Patents Granted And Basis For Rejection,03 March 2020, By:Tushar Kohli ; Available at: https://www.mondaq.com/india/patent/898672/types-of-patents-granted-and-basis-for-rejection?signup=true.
[9] Rejected In India: What the Indian Patent Office got right on Pharmaceutical Patent Applications (2009-2016); By: Dr. Feroz Ali, Dr. Sudarsan Rajagopal, Mohamed Mustafa, Chinnasamy Prabhu, December 2017; Available at: https://accessiba.org/media/2017/12/ Rejected-In-India.pdf.
[10] Available at: https://www.ip-watch.org/2018/05/20/five-years-indian-supreme-courtsnovartis-verdict.
[11] Annual reports of the previous years, the Indian Patent Office Available at : www.ipindia.gov.in.
[12] Novartis AG vs Union of India AIR 2013 SC 1311

were manufacturing several generic versions of patented drugs and selling them not only in India but also to Third World countries.

In January 2006, the Chennai Patent Office examined and rejected a patent application for Gleevec on two grounds:- Firstly, lack of novelty and inventive steps because the 1993 patents had already claimed all pharmaceutical salt forms of imatinib and secondly, on the basis of Section 3 (d) because the new product did not demonstrate enhanced efficacy. The patent system in India also prevents the marketing of low-quality drugs, since the secondary patent regime under Section 3(d) ensures that only high-quality drugs are patented, thereby innovation is not stifled rather promoted.

The Madras High Court took up matters related to compliance with the constitution and the TRIPS Agreement, and ultimately granted a decision against Novartis. First, the court held that it lacked jurisdiction to review whether section 3 (d) was compatible with TRIPS. Second, the court held that Section 3 (d) does not violate Article 14 of the Constitution of India. Further in the appeal the Supreme Court upheld the constitutional jurisdiction of Section 3d. [13]

And the efficacy debate started[14] which the IPAB addressed the issue of the patent office's rejection of Gleevec patent application. On June 26, 2009, the IPAB issued a decision to cancel the controller's rejection of the request based on the lack of novelty and inventive steps but supporting his findings in relation to Section 3 (d).[15] Novartis appealed to the Apex Court, but the bench upheld the rejection of the patent application (1602/MAS/1998) filed with the Indian Patent Office by Novartis for Gleevec in 1998.[16] The impact of the Gleevec patent on the Indian public health system has been enormous, with the government reporting that it saved billions in the first year of the patent, and the medication was provided to millions of people at a low cost.

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[13] Section 3 (d) for precluding patent evergreening: India's attempts to improve access to medicines MHBele,2019; Available at: https://www.vital.lib.tsu.ru/vital/access/services/Download/vtls:000669793/SOURCE1.

[14] Dorothy Du, "Novartis Ag v. Union of India: Evergreening,' Trips, and 'Enhanced Efficacy' under Section 3 (d)," JIPL21, no. 2 (2014); Available at: https://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1028&context=jipl.

[15] Misc. Petition Nos. 1-5 of/2007 in TA/1-5/2007/PT/CH & Misc. Petition No. 33 of 2008 in TA/1/2007/PT/CH & TA/1-5/2007/PT/CH (IPAB, Intellectual Property Appellate Board, June 26, 2009); Available at: http://www.lawyerscollective.org/files/novartis/IIIIPAB/Novartis%20AG%20v.%20UoI%20and%20others%20[IPAB%20order].pdf.

[16] Civil Appeal Nos. 2706-2716 of 2013 (decision of the Supreme Court of India, Civil Appellate Jurisdiction, arising out of SLP(C) Nos. 20539-20549 of 2009); Available at: http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212.

(B) Roche vs. Cipla

Roche applied for a patent of Tarceva (erlotinib) in March 1996. The patent office in Chennai granted a patent for the anti-cancer drug in July 2007. However, in December 2007 Cipla started manufacturing and marketing a generic version of Tarceva (erlotinib) , claiming that the brand name product patent was invalid. In January 2008, Roche began infringement proceedings against Cipla, seeking a temporary injunction to suspend the marketing of the generic copy of Tarceva. However, in March 2008 the Single Bench of the Delhi High Court rejected the application of the temporary restraining order filed by Roche

In his judgment, S. R. Bhat, Single Bench Justice, noted:

"The Court cannot be unmindful of the right of the general public to access lifesaving drugs which are available and for which such access would be denied if the injunction were granted. The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy, even chances of recovery in some cases, would be snuffed out altogether if the injunction were granted. Such injuries to third parties are non-compensable. Another way of viewing it is that, if the injunction in the case of a lifesaving drug were to be granted, the Court would in effect be stifling Article 21 so far as those who would have or could have access to Erlocip are concerned."

The Delhi High Court stated: "The access of the general public in India to life-saving drugs is of great importance, and the public interest in increasing public access to a life-saving drug must exceed the public interest in granting an injunction to Roche." However, in 2012 the Delhi High Court held that Roche's patent was not violated by Cipla, although the court recognized Erlotinep's patent. It was contested that both Tarceva, the Roche brand-name erlotinib drug, and Erlocip, the Erlotinib drug from Cipla, were the stable form of polymorphB, consequently, the patent was rejected by the Indian patent office on the basis of Section 3 (d) among other reasons.

New Approach To Section 3(d) : Directive 2001/83/EC The 'explanation' given under section 3(d) was essentially taken from the definition of 'generic substances' given in the Directive 2001/83/EC[17] of the European Parliament; therefore, it requires an understanding of the

[17] "Part II, Annex 1 to Directive 2001/83/EC states that generic substances must also contain the same therapeutic moiety as the innovative substance. If that is not the case, the substance shall be considered a new active substance."

underlying rationale and legal effect of the Directive and to highlight the interpretation of section 3(d) of the Indian Patent Act 1970. The lack of understanding around the scope and intent of the Directive is responsible for the existing debate and controversy concerning section 3(d).

"Part II, Annex 1 to Directive 2001/83/EC states that generic substances must also contain the same therapeutic moiety as the innovative substance. If that is not the case, the substance shall be considered a new active substance."

The scope and relevance of the Directive in order to determine the suitability of a particular substance for substitution of a generic substance is to regard derivatives as generic substances. Thus, a substance which is structurally similar to a generic substance but possesses no known efficacy and has significantly increased known efficacy with respect to the generic substance would be considered as a generic substance for the purposes of substitution.[18] However, in such a situation, it may be considering the substance as a substituted generic substance if the substance is marketed and used in a way that may mislead or harm the health of users, or if the substitution of the generic substance is dangerous to human health.

Over the current position where the definition of a generic substance is not mentioned anywhere in the Act and where the definition is left open to the discretion of the IPAB. The scope of the Directive should also be considered when interpreting the 'explanation' to section 3(d) and the definition of 'known substances'. The Directive and its associated guidance documents only clarify the definition of a generic substance and do not expand the definition. Any attempt to interpret the explanation of section 3(d) beyond what is explained in the Directive would be inappropriate.

The Directive and its Annex provide a consistent framework for the interpretation of 'known' and 'known substances'. If a substance is already known, the definition of known substances under section 3(d) is limited to those substances that are the same as in the generic substance or substances that do not significantly differ with respect to properties of the same therapeutic moiety. This is clearly explained in the 'explanation' to section 3(d) and the broader scope is

[18] Proper Interpretation of Section 3(d) of the Indian Patent Act Could Save Incremental Innovations of Existing Pharmaceutical Substances; By: Naresh suri; Available at: https://www.ipwatchdog.com/2019/06/22/properinterpretation-section-3d-indian-patent-act-save-incremental-innovations-existing-pharmaceuticalsubstances/id=110581/.

also apparent from the title of section 3(d) which is 'known substances' and not 'known generic substances' or 'generic substances'.[19]

Conclusion

The increase in the frequency of citation Section 3(d) for rejection was not shocking after the Supreme Court's decision in Novaritis AG vs the Union of India rejecting its patent application which led to global debate about the stringent legislation as IPAB, and judiciary has mainly focused on direct evidence for the patent which can demonstrate the enhancement of known therapeutic efficacy of the drugs. The impact of the Glivac patent on the Indian public health system has been enormous, with the government reporting that it saved billions in the first year of the patent, and the medication was provided to millions of people at a low cost. The patent system in India also prevents the marketing of low-quality drugs, since the secondary patent regime under Section 3(d) ensures that only high-quality drugs are patented. The perplexity around the understanding of the Section3(d) requires an understanding of the scope and intent of the European Directive 2001/83/EC as the explanation attached to section 3(d) is heavily influenced from the definition of 'generic substances' as given in the aforesaid directive. The Directive and its associated guidance documents only clarify the definition of a generic substance and do not expand the definition. The Directive is a compromise between the desire to encourage innovation versus the desire to protect the public. The public's right to access to medicines is fundamental. However, it should not be abused as a barrier to innovation. If a substance is known, the definition of known substance in Section 3(d) is limited to substances that are identical to a generic substance or that do not differ significantly in the properties of the same therapeutic component. The provisions of Section 3(d) are designed to protect public health by ensuring that the patent system is used only by pharmaceutical companies producing reliable and trustworthy medicines. To clarify further, the provisions of Section 3(d) are not intended to deprive innovators of their innovation benefits. Therefore, India is trying to reconcile the two goals, the first being the economic goal of providing accessible healthcare for all citizens with the economic goal of being in line with the interests of pharmaceutical companies guaranteed by India's constitution.

[19]Proper Interpretation of Section 3(d) of the Indian Patent Act Could Save Incremental Innovations of Existing Pharmaceutical Substances; By: Naresh suri; Available at: https://www.ipwatchdog.com/2019/06/22/proper-interpretation-section-3d-indian-patent-act-save-incremental-innovations-existing-pharmaceutical-substances/id=110581/.

Acknowledgement

This article was edited by the author during the LLM dissertation work at Rajiv Gandhi School Of Intellectual Property Law, IIT Kharagpur. She extends gratitude to Dr. Niharika Sahoo Bhattacharya, Assistant Professor (Grade I), at Rajiv Gandhi School Of Intellectual Property Law, IIT Kharagpur for the guidance.