A CRITIQUE AND ANAYLSIS OF THE NOVELTY OF PATENTS IN INDIA

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ABSTRACT

The novelty of a patent has been prioritized and provided significance to by the legislators and the judiciary from the time when laws regarding patents began to be recognized in India. Right from *the Act VI of 1856*, where 'prior public use of an invention' was first recognized, to the Patents Act of 1970, which prides itself on the strict criterion it lays regarding anticipation and novelty while taking into consideration *the TRIPS Agreement*, patent laws in India have certainly come a long way.

The Patents Act, 1970 has defined the terms "invention" and "new invention", hence indicating that significance has been particularly imposed on the novelty of an invention. There should be no 'prior art' or the invention must not have been anticipated, and the invention must be a 'state of the art' for it to qualify as eligible for a patent. The new invention should not be a mere improvement, and must actually create a benefit to the citizens in a way.

Though the improvements to the novelty-based provisions are laud-worthy, one can simply not dismiss the drawbacks that the laws entail currently. There seem to be some provisions, particularly those like Section 3(d), that states that a mere acknowledgment of a new property or use of an already existing invention cannot be deemed novel, and Section 2(1)(l), that defines the term "new invention", that seem rather incoherent and loose-ended. Apart from this, though Section 3(d), whose existence is meant to prevent the appalling issue of evergreening has served some benefits, one cannot disregard the fact that it does create issues like inaccessibility, monopoly, discouragement of research, and investment by foreign companies, especially in the case of the pharmaceutical industry, which need to be immediately tackled.

INTRODUCTION

A patent is essentially an intellectual property right that is granted to an inventor who has concocted a completely new idea or innovation. In other words, it is a monopoly that is granted to that innovator over their invention that is 'novel' or new, has an industrial step, or is non-obvious to a person who is already rather established in the industry, and finally, is valuable and has an industrial application. One of the most significant requirements for the patentability of an innovation is its novelty. If the invention is question has already been anticipated, where prior art already exists, that invention will not be deemed to be novel. The Indian Patents Act, 1970, i.e., the legislation that applies to patents, for the time being, has also clearly established that the invention must be 'new', and must not have been anticipated within the country or outside of it. This is truly crucial because an invention that is anticipated would, primarily, not contribute anything to human knowledge, as the invention and the knowledge to be disseminated already exists within the population. Secondly, in such cases, there would be no consideration shifting from the patentee to the inventor of the prior art in any way. Finally, the invention in question would not be of any use to the general public since it has already been anticipated, unless it is a significant improvement to the prior art, or makes it cheaper to use.

The laws regarding novelty have undergone several amendments and changes in consonance with the period of application and the evolution of intellectual property in India. The TRIPS agreement has particularly had a significant impact on the Patent laws in general, since 2005, i.e., when the Indian patent laws were necessitated to align with the aforementioned agreement. Though novelty and the necessity for it in India have come a long way, resulting in the protection of true and novel inventions and innovators, several factors of the Patent Act, 1970 have also persisted as a hindrance to the implementation of the novelty laws, and also to the accessibility of the inventions to the public in several circumstances.

Novelty and patentability laws do not merely require the invention to be new. The laws are not wholly objective only, where if prior art exists the invention will be automatically rejected. It requires for the invention to significantly improve a ‘prior art’, if it exists, or the lives of the population, while ensuring that the rights of all the inventors are protected, hence intending to enable divergent innovation.

RESEARCH QUESTIONS

The research questions that have been focussed upon are as follows:

1. How have the laws regarding novelty progressed through the years in India?
2. What does the Patent Act, 1970, elucidate about novelty and anticipation of inventions?
3. Though the laws regarding novelty have come a long way, what are the benefits and the drawbacks that they come with?

THE PROGRESSION OF NOVELTY IN INDIA

Novelty, especially in India, has always been a facet that has been necessitated when considering inventions that are sought to be patented. One of the most significant and salient features of the *Patent Act*[1], in fact, was the "adoption of absolute novelty in case of publication". The Bombay High Court[2], while elucidating on the significance of novelty in an invention had stated that though a patent's approval is dependent upon both novelty and utility, it is primarily essential for there to be novelty as there would be absolutely no new advantage availed by the public otherwise.

Prior to the Act[3], there were other legislations that existed, that also prioritized novelty in order to ensure that the creative outputs of an entity that conceived the invention first is respected. The *Act VI of 1856*[4], which was significantly based on the *UK Act*[5], had established that 'prior public use' or 'publication in India or the United Kingdom' would be taken into consideration while identifying the novelty of an application. This was then renamed *The Patterns and Designs Protection Act*[6] which went a step further and established that the invention, prior to the application, must be disclosed in an Exhibition of India, so that it could be conspicuous for the other innovators, who could potentially spot any similarity with an already existing invention.[7] A grace period of about six months was granted to the innovator for filing such applications after the exhibition has been conducted.

Given how the primary reason for the existence of patent law is to encourage new technology and research, it would be essential for the invention or discovery is done with the potential patentee to be of their own, as opposed to a mere verification of an invention that already exists. It should result in a completely new output, or at least, must be significantly better or cheaper

[1] The Patents Act, 1970.
[2] Lallubhai Chakubhai Jariwala vs Chimanlal Chunilal And Co. (1935) 37 BOMLR 665.
[3] Ibid.
[4] Act VI of 1856.
[5] The United Kingdom Act,1852.
[6] The Patterns and Designs Protection Act XIII of 1872.
[7] Controller General of Patents, Designs & Trademarks, India, Manual of Patent Practice and Procedure, Intellectual Property of India, 3rd Ed., 2008.

than the existent product.[8]

Currently, post all the amendments and changes that the patent laws had undergone, the Act that applies to the patents in India would be the Patents Act, 1970. This Act is essentially a result of the provisions of the TRIPS Agreement[9] and the mandate for Indian Patent Law to be in consonance with it, the evolution of the pharmaceutical industries and the rise in evergreening in India, and so on. Though several benefits arise to the inventors from the Act, there exist certain hindrances as well, unfortunately.

NOVELTY AND ANTICIPATION ACCORDING TO THE PATENTS ACT, 1970

The Act that currently applies to patents in India is the Patents Act, 1970. Under the definitions, the term "invention"[10] indicates to any 'new' product or a process that involves an inventive step and is capable of industrial application. The usage of the term 'new' indicates the significance imposed on the novelty of any product or process that is to be patented. Further, the term "new invention"[11] has also been defined to be an invention that has not been 'anticipated' in India or any other country around the world before the patent application is filed, and where the invention does not fall within the ambit of public domain or does not constitute a 'state of the art'. Though the term 'state of the art' has not necessarily been mentioned, can be comprehended through legal precedents to mean prior art, prior knowledge, and prior use that would potentially infringe the right of the patentee claim, and if the invention implemented, would be deemed to be anticipated.[12]

Anticipation, in a sense, would literally indicate a lack of novelty in the invention. *Section 13*[13] mandates the *'examiner to whom the application is made'* to investigate whether the invention in question has been anticipated or not. The anticipation of such a claim of anticipation is done in two ways[14]:

The first way is through identifying the existence of prior art. If prior art already exists, that uncannily fits into the scope of the description of the invention in question, provided that the

[8] Bishwanath Prasad Radhe Shyam v. Hindustan Metal Industries PTC suppl 1 SC 731.
[9] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) *(Hereinafter referred to as the TRIPS Agreement).*
[10] Section 2(1)(j), The Patents Act, 1970.
[11] Section 2(1)(l), The Patents Act, 1970
[12] Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd [1996] RPC 76.
[13] Section 13, The Patents Act, 1970.
[14] Novartis Ag vs Union of India & Ors. (2013) 6 SCC 1.

prior art is, in fact, enabled or whose details are sufficiently disclosed, it would be deemed anticipation. In such a case, there would not be a necessity for the invention to be put to use or examined to be able to determine whether it is anticipated, as the prior art would be properly enabled and the subject matter would be similar. In such cases, the tack through which the innovator can get their invention patented would be through proving that though there was disclosure, the art was not enabled.[15]This is essentially done by proving, with the approval and monitoring of skilled professionals, that an ordinary person is not able to implement the invention as put forth in the description.

The second way is by proving that the implementation of the invention is question would indubitably result in the very same output that was carried out in the prior art as well, regardless of how it is implemented. However, if the invention can be carried out in a way that would result in a different output than the prior art, anticipation can be avoided.

The novelty of an invention is further identified through a set of comparisons that are performed between the two inventions in question.

Firstly, it must be examined whether a prior art that has already been published in any specification that was filed for attaining a patent in India or around the world, as per *Section 29.* It is not necessary for the public to actually have read the document in which the prior publication is accessible, it merely has to be easily available for the public to consume.[16] An exception to this, however, can be taken if it can be proved that the subject matter that was published was actually claimed from the subsequent innovator.

Secondly, if the prior art in question has already been in public use before the patent application was made, it would imply anticipation. However, if the prior art has been in public use for one year[17] before the priority date by the patentee or any other third person, but such public use was merely for 'reasonable trial', such an invention would not anticipate the latter invention. The invention in question, if it has been used for the purpose of trade or sale[18], if it is not been utilized without the observation of secrecy[19] and even if it is, if the procedure of manufacture can be identified through an examination, shall constitute a public use.

[15] Paroxetine Methanesulfonate Patent (2006) RPC 10.
[16] Lallubhai Chakubhai v. Chimanlal Chunilal & Co. AIR 1936 BomHC 99.
[17] Section 32, The Patents Act, 1970.
[18] Ibid.
[19] Monsanto Co. V. Coromandel Indag Products (P) Ltd. 1986 A.I.R. 712.

Further, another important aspect that is interconnected to the novelty of a patent would be the non-obviousness of the invention, to a person skilled in the art.[20] A person skilled in the art[21] would be one who has the necessary experience in the field, and could carry out tests to comprehend whether the invention was, in fact, anticipated. This person would essentially require all the information, indubitably through the prior publication, to be able to perform the inventive step test. Though there is no objective test laid down to identify the non-obviousness, certain cases[22] had laid down that the test for novelty and that for non-obviousness are both interrelated. Therefore, if the process of formulation of the invention is already known by the public and is being used, then the invention would not be patentable. Basically, apart from the necessity for novelty and for the invention to be new, it should also significantly contribute to the intellectual effort of the prior art, and must not be a mere 'workshop improvement'.[23]

A CRITIQUE OF THE NOVELTY LAWS OF INDIA

Several amendments were made to the Patent Act of 1970, in 2005 due to the mandate of the Indian Patent Law to be in consonance with the *TRIPS Agreement*.[24] One such significant amendment that came in 2005 was the addition of the definition of the term "new invention".[25] This definition is set apart from the definition of the term "invention", primarily due to its intent to eradicate any geographical hindrances or boundaries pertaining to the origin of the prior art. Therefore, now, the prior art now has a global scope, which would indicate its consonance with standards of the *European Patent Convention*. However, some issues that arise accompanying the definition, would be a few drawbacks. It is rather incoherent as to how the Indian Patent Office or the Courts that would adjudicate upon a matter of novelty would actually have the statutory authority or the jurisdiction to adjudicate upon the prior art that belongs to another country. Further, though a definition has been incorporated, it has actually not been adopted into any of the existing provisions of the Patent Act, hence rendering the existence of the definition rather unavailing. In fact, several provisions, like *Section 13,*[26] categorically keep prior art situated in countries outside India out of the ambit of the question itself, as it pertains only to prior art, whose application or claim of any other complete specification was sought for

[20] Section 2(1)(ja), The Patents Act, 1970.
[21] Supra at 7.
[22] Bilcare Limited v. Amartara (P) Ltd. MIPR 2007 (2) 42.
[23] Gillette Industries Ltd., v. Yeshwant Bros. A.I.R., 1938. Bom. 347.
[24] Supra at 9.
[25] Supra at 10.
[26] Supra at 12.

only in India and nowhere else. Further, the pre-grant[27] and post-grant[28] opposition shall be made based on the prior knowledge or use of innovation only in India. Therefore, it is rather evident that the definition of 'new invention', which includes prior art from another country, would not actually factor into the Patents Act for the time being.

One commendable implementation, however, is how high the barometers regarding patent applications have been set by India, especially pertaining to pharmaceutical Companies or multinational corporations that attempt to opt for the process of evergreening of their patents to attain further commercial opulence. The amendments that came about in 2005 were implemented for the provisions to be in compliance with the patentability requirements as prescribed under the TRIPS, especially pertaining to pharmaceuticals. However, since the provisions could be implemented based on the requirements and preferences of the countries[29], Section 3(d)[30] was implemented, where though there was a mandate to begin granting patents on pharmaceutical inventions, the mere discovery of a new property or use of a known invention cannot be deemed to be a novel invention. This understanding of novelty regarding pharmaceutical products is rather stringent, especially in comparison to the laws that are observed in other developed countries like the USA and UK[31], which broadly permits the patenting of a product that merely has a new use or property, and would not be considered to be anticipated. This stringent[32] implementation of the law on novelty primarily prevents the aforementioned practice of evergreening, which has frequently been deemed to be a 'common abusive patent practice'[33]where the big pharmaceutical Companies tend to extend, or apply for new patents by merely making minute changes to their already existing inventions, hence garnering the monopoly over the manufacture of the drug in question even after the expiry of the said patent. In a landmark case in 2006[34], a Swiss-based pharmaceutical Company, Novartis AG, had argued that Section 3(d) was not only in violation of Article 27 that mandated the provision of patent protection by all the members of the World Trade Organization to all sectors alike without discrimination[35], but also unconstitutionally vague. In this case, since the

[27] Section 25(1)(d), The Patents Act, 1970.
[28] Section 25(2)(d), The Patents Act, 1970.
[29] Article 1, The TRIPS Agreement.
[30] Section 3(d), The Patents Act, 1970.
[31] John K. McDonald, A Patent Practitioner's Perspective: Advising Pharmaceutical Clients, 17 Emory International Law review, 2003, pp. 521.
[32] Rumman Ahmed & Amol Sharma, Novartis Fights India for Cancer Pill Patent, Wall Street Journal, 19th August 2012.
[33] Leena Menghaney, India's Patent Law on Trial, BMJ Group Blogs, September 2012.
[34] Supra at 13.
[35] Article 27, The TRIPS Agreement.

'significant enhancement of the known efficacy' was not established, it was held that the Patent could not be granted. This goes to show how high the benchmark for determining novelty, efficacy, and patent approval is set by India, which is definitely favourable. The TRIPS mandates for the parties to it, to only comply with the minimum intellectual property protection requirements that have been set forth by it. It does certainly allow the countries to frame the laws regarding patenting based on the economic and social scenarios that they are set in, which essentially allows for India to actually retain Section 3(d).

Though several benefits arise out of the stringent establishment of the Indian Patent laws, there are several drawbacks as well. Firstly, the stringency ensures that there cannot be more than one version of a similar drug with a different use or property, which in turn does create a monopoly of the drug naturally. Monopoly over a certain drug by a single entity can be quite dangerous, especially in cases of pharmaceutical inventions, as it essentially results in the drug being rather expensive and possibly even unaffordable for many. Generic pharmaceutical companies, who could potentially create alternatives that could probably be cheaper, or offer a variety of uses to the drug in question, would not be allowed to manufacture the drug, hence resulting in the inaccessibility of it to several people. Monopolies seemingly only discourage efficiency and increase the price of the innovation,[36] according to economists. This would wreak havoc in the country, especially when the drug in question is one that could be life-saving for people in dire need of it, as they would not be able to consume it at a time of need due to the unaffordability and inaccessibility of the drug. In fact, 75% of the anti-retroviral drugs have been completely controlled by monopolies.[37] Further, since the test for novelty is actually not one that is relative, but is actually absolute, there would be very few pharmaceuticals that would clear the test, which would also lead to lesser inventions and more monopoly.

Further, due to the rigidity of the patent law regarding novelty, generic pharma would actually be discouraged from indulging in drug research that could possibly be rather crucial. Though there indubitably is a need for a high benchmark for novelty in India, there should be a sound balance created between the proprietary rights and the needs of the society.

Apart from this, the stringency has, and will further result in the deterring of investment in

[36] K. D. Raju, Interpretation of Section 3 (D) in the Indian Patents Act 2005: A Case Study of Novartis, Indian Journal of Intellectual Property Law, 1 2008, pp.1.

[37] Christiane Fischer, The Indian Patent Law and Access to Antiretroviral Drugs in Sub-Saharan Africa." The Politics of the Pharmaceutical Industry and Access to Medicines, Routledge, 2017, pp.225-247.

India by big pharmaceutical Companies across the world. For example, right after the Novartis case[38] was adjudicated upon, Novartis announced that it would cease all the investments that it was making in India, and would prefer investing in countries that 'encouraged innovation and protection of innovations'. Though one can rely on Indian Companies to discover significant drugs, the stringency would also affect the availability of any new drug that could also be a dire need for the patients in India.

Another issue that arises is with respect to how the Indian Patent law regarding novelty is actually relatively incoherent about certain aspects. Section 3(d)[39] establishes that an invention cannot be patented if it is a known invention with a new use or property, merely. However, if the new invention is proved to be significantly more efficacious than the former invention, they would not be deemed anticipation, and the patent can be granted. However, the demonstration of the efficacy or supremacy of the latter invention in comparison to the former, comes with several hindrances of its own. There could be several instances where the latter drug actually proves to be potent and effectual for a few, but rather worse for others. In such situations, it is unclear how the interpretation of the provision shall be performed. Further, if the drug actually does not function as anticipated, but is being sold at a cheaper price and is affordable to all sections of the society, there has been no clarity on what would be done in such a case as well.

CONCLUSION

Patent laws in India have truly come a long way, from the mere acknowledgment of the term "Prior use", to the exhibition of the art being conducted to determine Novelty, to the Patents Act, 1970, which in itself has undergone several amendments and developments by virtue of the TRIPS Agreement. The primary goal of the patent legislation must always be to encourage innovators with pioneering inventions and to ensure the protection of the already existing inventions. Apart from the aforementioned, it is also crucial for the patent office prior to the grant of a patent to affirm that the invention in question indubitably creates significant value to the public or to the existing invention that is being bettered, or is making the invention cheaper and relatively accessible to the public at large.

The provisions that govern novelty do unequivocally serve their purpose and ensure that the invention is not anticipated, and is not obvious to a person skilled in the art. However, the

[38] Supra at 14.
[39] Supra at 30.

stringent provisions, and the rather incoherent ones too, serve as a hindrance to the fruitful growth of patents in India, especially in the pharmaceutical sector, which is the need of the hour. If the hindrances, especially the ones that cause inaccessibility of drugs to the public are not duly addressed, not only with the development of patents in India cease, it will also wreak havoc upon the health of the population which is quite appalling. Any innovation that is being patented must provide significant benefits to the public. However, if the provisions are incoherent and possibly result in inaccessibility, they do not necessarily serve a great purpose, hence trivializing the invention itself, which is not an ideal result. Therefore, the patent laws must be strengthened and bettered based on necessities post-haste, in order to avoid the subsistence of the hindrances for too long.

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