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Biotechnology and The Problem of Non-Obviousness

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*Biotechnology, the combination of biology and technology, is at the forefront of growth in industries including health, food production, and natural resource management. Nevertheless, the notion of non-obviousness in the field of biotechnology creates broad problems in the sphere of patent law. Non-obviousness entails that an invention must be distinguished from what already exists, which separates invention from improvement. This issue is especially problematic in biotechnology as often one scientific accomplishment is based on some biological processes. Patent authorities are thus in a position where they have to determine whether biotechnological inventions are capable of providing an adequate degree of novelty important for purposes of patent protection in the form of adequate inventive steps. In this paper, I address the problem of non-obviousness in the context of the biotechnology industry and a range of old and new leading and landmark cases, including *KSR Int'l Co. v Teleflex Inc.* and *In re Kubin*. It is a discursive concern that enforces a relationship between the stimulation of innovation and the minimisation of monopolies and makes sure that biotechnological inventions undergo critical assessments.*

Keywords: *genetic engineering, property rights, patentability, creativity, patent, protection, intellectual property.*

INTRODUCTION

Being the science that integrates biology with technological developments, biotechnology is one of the most important fundamentals of post-industrial societies. From farming to medicine, from biotechnology and everything in between, biotechnology is at the forefront of new technologies and making a real difference in people's lives. However, this inexorable expansion of the field of biotechnology means that the legal ground rules for dealing with biotechnological inventions have become that much less clear. Another major consideration that exists in patent law is the question of whether an invention is nonobvious or not to merit a patent. When findings are made in increments, as is frequently the case in the field of biotechnology, distinguishing between genuine inventions and changes that are logically foreseeable poses a formidable conceptual and legal problem.¹

Another argument that needs to be taken into account at the same time is legal claims on the utility of modern biotechnology patents also suffer from analysis under the guidelines put forward by more recent cases, including **KSR International Co. v Teleflex Inc.**² and in **Re Kubin.**³ These cases have even gone further in defining the criteria for non-obviousness, hence reducing the possibility of biotechnological inventions passing through the test. KSR broadened the possible results concerning the issue of obviousness while Kubin focused on the biotechnological inventions, stating that if an invention in biotechnology is a biotechnological improvement over the prior art, it need not be considered non-obvious.

ROLE AND RELEVANCE OF NON-OBVIOUSNESS STANDARD OF PATENTABLE SUBJECT MATTER IN INDIAN BIOTECHNOLOGY PATENTS:

Non-obviousness in the Indian patent system has its origin in **Section 2(1)(a)** of the **Indian Patents Act 1970**⁴. It describes the 'Inventive Step' as the feature of an invention that must embody a technical advance relating to discovery or an economic improvement over existing knowledge, which would not be apparent to a genuine person in the field of the invention. This

¹ William Cornish, *Intellectual Property: Patents, Copyright, Trademarks and Allied Rights* (7th edn, Sweet & Maxwell 2010)

² *KSR International Co v Teleflex Inc* [2007] 550 US 398

³ *In Re Kubin* [2009] 561 F.3d 1351

⁴ The Patents Act 1970, s 2(1)(ja)

subclass examines how the Indian legal system accredits inventive steps to biotechnological inventions.

The Indian law also checks the inventive step, which means that the invention is required to be new and greater than what a PHOSITA can foresee. In the case of biotechnological inventions, it may often become difficult to define what is obvious, first of all, because biological processes are rather complicated. This has greatly posed a challenge in the award of patents regarding biotechnological innovations in India. The assessment of non-obviousness mainly comes into operation by the patent examiners in Indian affairs significantly. The patent authorities assess if the claim made regarding the invention provides an enhanced technical contribution. But, in biotechnology, the difference between an inventive step and an obvious improvement is not always clear-cut. This subsection examines patent examination and the difficulties that examiners encounter when handling biotechnology cases.⁵

In biotech patents, the examiners cannot rely only on biology to consider the prior art, but there is the element of technology which is continually advancing. Indian examiners make it challenging for them to explain the difference between the direct application of known biological methods and the novelty in areas such as gene therapy/ bioengineering.

Several judgments have been made in India to define non-obviousness in the biotech industry. For instance, the case of **Novartis AG v Union of India**⁶ discussed the non-obviousness of pharmaceutical compounds, which is related to biotechnology. This section describes this case and others to show how the Indian courts apply the inventive step in biotech.

It is argued that the Indian judiciary has, in most instances, adopted a stringent approach to meet the requirement of non-obviousness, especially in pharmaceutical and biotechnological inventions. Judges dismiss several inventions where prior art seems to be developed only slightly, so an element of novelty or progress of technology is usually expected by the courts when granting a patent.⁷

⁵ P Narayanan, *Patent Law* (4th edn, Eastern Book Company 2017)

⁶ *Novartis AG v Union of India* (2013) 6 SCC 1 (SC)

⁷ Bhaven N Sampat and Kenneth C Shadlen, 'Indian pharmaceutical patent prosecution: The changing role of Section 3(d)' (2018) 13(4) PLoS ONE <<https://doi.org/10.1371/journal.pone.0194714>> accessed 06 September 2024

In biotechnology, very many innovations are developments based on the existing biological methods or techniques. One of the most important aspects to consider to evaluate patentability is to decide whether that advance is an incremental one or a new invention, if you will. This section also looks at how Indian law treats between obvious discoveries and obvious inventions, particularly in light of the inventive step. While enhancement of an existing biological process may provide enhancement in its functionality or its field of use, Indian Taiwanese courts and the Patent Offices demand that such enhancement should have a technical and/or economic relevance. For instance, if a researcher has come up with a technique on DNA sequencing that is only slightly faster than previous techniques, it will not qualify for non-obviously.

In India, the Indian Patents Act has a Section, specifically **Section 3(d)**⁸, a provision in acts and laws to avoid or not allow patents on certain types of inventions, particularly when it is merely a new form of a known substance but with lesser efficacy. This clause has been very important in declining the patenting of biotechnological products. This section brings perspectives of Section 3(d) in the Google biotech patents. Section 3(d) can be applied to exclude many inventions found in the field of biotechnology, for instance, new uses of known bioactive compounds. This has resulted in several well-known scenarios whereby patents were not granted for sustaining innovations, especially in the biotechnology field with specific reference to the pharmaceutical industry.

India's patent law on non-obviousness is often compared with international standards, particularly those of the U.S. and European Union. This section compares India's approach to non-obviousness in biotechnology with those of these major jurisdictions, focusing on key legal differences and their implications.⁹ A comparative analysis of India's non-obvious patent law with the counterpart laws of other countries, especially that of the US and the European Union, is done. This section undertakes a comparison of India's approach to non-obviousness in biotechnology with that of these major jurisdictions, with reference made to the basics of legal disparities involved.

⁸ The Patents Act 1970, s 3(d)

⁹ Shamnad Basheer, 'India's Tryst with TRIPS: The Patents (Amendment) Act 2005' (2005) 1(3) Indian Journal of Intellectual Property Law <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=764066> accessed 06 September 2024

This paper discusses how, although non-obviousness standards are almost identical between the United States and Europe, Indian law interferes with incremental innovations by using Section 3(d). This makes it more difficult for biotech companies to patent their inventions in India than in these other jurisdictions. Less developed countries such as India need to pay attention to these changes affecting the biotechnology industry due to the application of the non-obviousness standard together with Section 3(d). This section analyses how these laws impact innovation, research, and investment in Indian biotechnology, especially in pharmaceutical and agricultural biotechnology.

THE ROLE OF JUDICIAL INTERPRETATION IN NON-OBVIOUSNESS

In our assessment of India's non-obviousness standard in the biotechnology patents, it emerges that the judiciary has a critical duty of interpreting such aspects. Courts, on the other hand, are required to decide a given case based on the legal provisions. This subclass provides an insight into some of the important legal precedents that have shaped the non-obviousness of Indian biotechnology patents.

During the initial years of biotechnology patent filings, Indian courts were often put to the test to decipher the technology embodied in a biotechnological innovation. This section describes the early case law approaches of non-obviousness in the biotechnological context. Novartis decision is one of the landmark judgments of Indian patent law, especially for the pharmaceutical and biotechnology industry. The following section focuses on the effects of this decision on non-obviousness and the effect on patents of biotechnological innovations.¹⁰

CHALLENGES IN APPLYING THE NON-OBVIOUSNESS STANDARD TO BIOTECHNOLOGICAL INVENTIONS

Indeed, some experts refer to biotechnology as a 'knowledge-driven' field with a growing pace of innovation and research. As seen before, the use of non-obviousness as a standard in this particular context can be rather difficult to assess. This subclass emphasises the challenges that are unique to disclosing the non-obviousness of inventions in the field of biotechnology because such inventions tend to be presented in a step-by-step manner.

¹⁰ *Ibid*

Patenting of biotechnological inventions is closely related to natural biological phenomena, an aspect that makes application of the patent law a little challenging. The progress in knowing the interactions of biological systems often results in steps, which are sometimes hard to distinguish between obvious and innovative. This section offers an introduction to why biotechnology is special and why it is more challenging to assess non-obviousness in this industry.

Another characteristic that makes biotechnology different from other fields of technology is that it has to do with life, genes, and proteins that may be already available in society. This has given rise to critical issues as to what can be considered an invention or new and useful art, as well as other issues, such as whether finding new uses or applications for a natural phenomenon satisfies the standard of non-obviousness.

One of the difficult challenges that entail biotechnological patents is the doctrine of the obvious. This principle is a restatement of the non-obviousness requirement averring that any invention is patentable only if it was not obvious to try based on the prior art available to the person skilled in that area of technology. This section gives an insight into how this doctrine has been adopted by Indian courts, especially in biotechnological inventions, particularly in genetics and pharmaceuticals. The inventions in biotechnology, for instance, stem from systematic experiments that are carried out and although the results may not always be predictable, they are expected given prior experiments. This can render many of the advancements in biotechnology to appear as something that is 'worth a try' and therefore, unable to be patented even though they call for a great deal of effort and creativity.

In general, biological systems are random and therefore, it is hard to rely on the highly rational structure of the assessment of non-obviousness. This section analyses the advantages and the disadvantages of patent seekers at the fact that biological processes are unpredictable. It can help make some inventions less conspicuous while at the same time making it harder to easily distinguish them as genuinely inventive. Currently, Indian courts and patent examiners are faced with the question of whether the unpredictability in the field of biotechnology means

an inventive step. For example, although the result of manipulating a gene may be something one did not foresee, the process of manipulating a gene may still be deemed obvious.¹¹

Another global but mostly **US case is In Re Kubin**¹², which has shaped the biotech patent legislation not only in India but in the entire world. The decision reaffirmed the obvious-to-try doctrine in biotechnology, especially concerning gene sequences. This section also shows how some Indian courts may look at such matters and the consequences it may hold for Indian patent law. In *In Re Kubin*, the court decided that even if the isolated gene sequence is arrived at through a process that seems to be implemented, the findings of the prior study may not be original. It shows the problem that biotech innovators have to solve when they employ their skills to create new products out of existing knowledge.

JUDICIAL TRENDS

1. **Novartis AG v Union of India & Ors**¹³ -

Facts: This case revolved around Novartis AG, a pharmaceutical company that took the lawsuit when the patent application for the beta-crystalline form of the imatinib mesylate, an anti-cancer drug known in the market as Gleevec, was rejected. The first concern was whether the drug was a new invention or merely an alteration of a known drug that affected the non-obviousness criterion.

Decision: According to the highest court of India, the decision of the Patent Office and the Intellectual Property Appellate Board (IPAB) was justified, which is why Novartis' application failed to meet Section 3(d) of the Patents Act, 1970 with regards to non-obviousness. The Court stressed that the innovation consisted of gradual modifications of the known compound and its therapeutic efficacy is not significantly better than the efficacy of the prior arts drugs.

Significance: This case also supported the use of Section 3(d) to stop the patenting of small

¹¹ F. Scott Kief, 'Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science - A Response to Rai and Eisenberg' (2000) 95(2) Northwestern University Law Review
<https://scholarship.law.gwu.edu/cgi/viewcontent.cgi?article=1749&context=faculty_publications> accessed 06 September 2024

¹² *In Re Kubin* [2009] 561 F.3d 1351

¹³ *Novartis AG v Union of India & Ors* (2013) 6 SCC

extensions of known drugs if they do not provide a greater therapeutic efficacy, it emphasised non-obviousness so the patenting does not prolong the life of patents on existing drugs.

2. Merck Sharp & Dohme Corp. v Glenmark Pharmaceuticals Ltd¹⁴ -

Facts: Here, Merck Sharp & Dohme Corp. tried to sustain its patent of the drug sitagliptin, an anti-diabetic one, against Glenmark Pharmaceuticals. The legal battle hinged on establishing whether Glenmark's version of sitagliptin breached Merck's patent, especially based on the non-obviousness of Merck's patented invention.

Decision: The Delhi High Court observed that the sitagliptin of Merck was protected with a patent and fulfilled the test of non-obviousness. It pointed out that the invention was not a mere improvement from the existing inventions and it involved steps that were not easily discernible from the state of the art.

Significance: The ruling in this case meant the continuation of the recognition of the patenting of new biopharmaceuticals in India, giving the invention the test of non-obviousness. It also explains how Indian courts approach the inventive step in connection to pharmaceutical patents.

3. Roche Products (India) Pvt. Ltd. v Cipla Ltd. (2008)¹⁵ -

Facts: Roche products attempted to prevent Cipla from introducing their version of the product, especially Erlotinib, which is an anti-cancer drug that Roche had patented. The crux of the problem was whether the Erlotinib patent fulfilled the non-obviousness criteria since Erlotinib was developed from existing compounds.

Decision: Non-obviousness requirement the Delhi High Court upheld the decision in favour of Roche, stating that the patent was valid. The Court concluded that Erlotinib meant significant and nonobvious development in the case of cancer therapy compared to previous known techniques.

Significance: This case, thus, emphasised a point for evidencing a non-obvious inventive step justifying patent protection in the pharmaceutical realm and established a benchmark to assess the inventive value proposition of biotechnological inventions.

¹⁴ *Merck Sharp & Dohme Corporation & Anr v Glenmark Pharmaceuticals Ltd* (2015) 6 SCC 161

¹⁵ *Roche Products (India) Pvt Ltd v Cipla Ltd* (2008) 6 SCC 362

4. **In Re: Patents Act, 1970 (S. 3(d))¹⁶ -**

Section 3. Indian Patents Act 1970 reads as - the Act that defines and provides legal status to inventions, including a procedure to regulate patents in India, such as the requirements and fundamentals for protecting patents and inventions in India.

Facts: This was a general case on the patentability under Section 3(d) of the Patents Act 1970 given a new form of a new substance that does not have casting efficacy. Since the amendment of Section 3(d), different parties have criticised it as having a very narrow scope.

Decision: The Hon'ble Supreme Court of India has ruled that Section 3(d) does not violate the provisions of international patent law and its purpose was not to deny patents on obvious combinations but against the grant of patents on small improvements. The Court further noted that non-obviousness should be accompanied by an outline of greater improvement in efficacy.

Significance: This case gave some more light on how Section 3(d) is to be implemented and it strengthened the yardstick that is used to test for non-obviousness under Indian patent law, especially in the pharmaceuticals and biotechnology industries.

5. **Biocon Limited v The Controller of Patents (2020)¹⁷ -**

Facts: Biocon opposed the decision made by the controller to refuse patent protection for a novel biopharmaceutical product. The main concern of the dispute was whether the claimed invention was non-obvious and whether it could meet the requirements of the patent law in light of the prior art.

Decision: The Board, IPAB upheld its decision of granting a patent to Biocon's invention, stating that the invention was not obvious and it has improved the state of the art over prior art through an Inventive Step.

Significance: They recognised the use of non-obviousness to the preservation of complicated biopharmaceutical inventions and the necessity of proving the existence of an all-inclusive inventive step.

¹⁶ The Patents Act 1970, s 3(d)

¹⁷ *Biocon Limited v The Controller of Patents* (2020) 2 SCC 500

CONCLUSION

This conflict comes to the spotlight in the context of biotechnological inventions because of the push to encourage innovation while preventing patent monopolies. On the one hand, there is a need for patent protection in these costly and high-risk to encourage research and development in this sector. However, adopting overly broad or lenient standards for patenting is likely to result in the monopolisation of basic biological techniques that hinder progress in the advancement or even development of new technologies. This makes non-obviousness both a fundamental and a rather controversial aspect of the biotechnology patent law.

This paper examines the change in the non-obviousness standard in biotechnology to outline the trends, case laws, and legal provisions that formed the basis of the current laws. Concerning the non-obviousness requirement, it analyses the problems that arise in the framework of the protection of biotechnological inventions and reviews the changes that could contribute to a more appropriate balance between the incentives for further development of innovations and the opportunities to utilise the results of development in the field of biotechnological progress.

In this case, there is a need to run parallel with biotechnological advances to address issues of patent protection. This subclass is concerned with the possibilities of modification of the non-obviousness standard in Indian patent law: the goal is to develop the conditions for further biotechnological research while protecting the public interest in the availability of certain technologies.

One modern problem of the patent law regulating biotechnology is how to provide stimulus for inventors, first of all, within the framework of the invention's subject matter, yet avoid the creation of monopolies as to basic biological functions. This section examines the proposed changes to the Indian patent regime that could sustain research in the biotech industry while safeguarding the public.

In influencing non-obviousness, one potential reform is that there is a need for better-defined rules when establishing such inventions in biotechnology, especially where a substance occurs in nature. According to this, the examination authorities would be able to better evaluate inventive steps if they offered more apparent standards.