 DOI: *https://doij.org/10.10000/IJLMH.119683*

INTERNATIONAL JOURNAL OF LAW MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

Volume 8 | Issue 3

2025

Judicial Analysis of Pre-Grant and Post Grant Opposition of Patent under the Indian Patents Act, 1970: Issues and Challenges

SANTHOSH KUMAR G[1] AND DR. P.R.L. RAJAVENKATESAN[2]

ABSTRACT

The Patents Act, 1970 (as amended in 2005) governs the Indian patent regime, and this judicial analysis explores the complexities of the pre-grant and post-grant patent opposition procedures. This study scrutinizes the grounds for pre-grant opposition and the procedural safeguards in place to prevent frivolous challenges, while also examining the role of the Controller of Patents and the judiciary in adjudicating these disputes. Meanwhile, post-grant opposition permits objections to a patent's validity after it has been issued, usually within a year of the grant. The reasons for post-grant opposition are examined in detail in this analysis, including issues regarding prior art, sufficient disclosure, and deceptive inventor ship claims. The study further examines important judicial precedents that have shaped the interpretation and application of the provisions, highlighting evolving jurisprudence in India. This study provides insight on how to strike a balance between protecting the public interest and safeguarding inventors' rights by examining important cases and the judicial approach of pre- and post-grant opposition. These underscore the importance of a robust opposition system in maintaining the integrity of the patent regime in India, ensuring that the patent system serves as a tool for innovation rather than an instrument for monopolistic practices.

Keywords: *Invention, Inventive Step, Industrial Application, Patent and Novelty.*

I. INTRODUCTION

The patent system in India is governed by the Patents Act, 1970, which provides protection for inventions, encouraging innovation by granting exclusive rights to inventors. An invention, whether a product or process, must satisfy three key criteria: novelty, inventive step, and industrial applicability to qualify for patent protection. The Act excludes certain categories like business methods, algorithms, and medical procedures from patentability. The patent filing process involves filing an application, followed by an examination, and may be opposed before or after the grant. Once awarded, a patent grants the holder the only right to use, sell, or lease

[1] Author is a LL.M. (IPR) Student at VIT School of Law, Vellore Institute of Technology, Chennai India.
[2] Author is Professor of Law at VIT School of Law, Vellore Institute of Technology, Chennai, India.

 [ISSN 2581-5369]

the invention for a period of 20 years. To be eligible for patent protection, an invention—whether it be a technique or a product—must meet three essential requirements: inventive step, novelty, and industrial applicability. Certain categories, such as algorithms, medical treatments, and business methods, are not eligible for patent protection under the Act. An application is submitted, examined, and may be challenged either before or after the patent is granted. For 20 years after it is granted, a patent gives the owner the sole authority to use, sell, or lease the invention.Technical details about the invention must be made public through a patent application in order to obtain a patent. The Patents Act, 1970, which protects inventions and promotes innovation by giving inventors exclusive rights, oversees the patent system in India. The Patents (Amendment) Act, 2005, which brought Indian law into accordance with the TRIPS Agreement under the World Trade Organization (WTO), completely transformed the patent landscape in India.[3] This introduced product patents in sectors like pharmaceuticals and agriculture, ending India's prior focus on process patents. This amendment balanced encouraging innovation with safeguarding public interest, particularly in the pharmaceutical sector, through provisions like Section 3(d), which prevents "evergreening" of patents on minor modifications of known substances. The system aims to balance the interests of inventors, industries, and public welfare.[4]

II. PRE-GRANT AND POST GRANT OPPOSITION IN INDIA

The Indian Patent Act of 1970 provides the public the right to oppose to a patent being granted by filing an objection to the patent office. The Indian patent system relies heavily on opposition methods, such as pre-grant and post-grant objection. In order to guarantee that only inventions that satisfy the stringent requirements of novelty, inventive step, and industrial usefulness are protected, these procedures enable third parties to contest the legality of a patent application or a granted patent. They act as a safeguard on the issuance of pointless or unworthy patents, which can inhibit competition, impede innovation, and create needless market monopolies. Depending on the stage at which the patent was granted, there are two different kinds of opposition processes in existence such as pre-grant opposition which allows the opponent to object to a pending application before a patent is granted and also Post-grant opposition which occurs when a party contests the legality of a previously issued patent.[5] Prior to 2005, the "pre" grant

[3] Patent Laws in India: compliance with the TRIPS Agreement, available at: https://blog.ipleaders.in/patent-laws-india-compliance-trips-agreement/, Last visited on 07/09/2024.
[4] An Overview of Evergreening Patents, Available at: https://www.mondaq.com/india/patent/1318938/an-overview-of-evergreening-patents, Last visited on 08/09/2024.
[5] Pre-Grant Opposition In India, Available at: https://excelonip.com/pre-grant-opposition-in-india/, Last Visited on 07/09/2024.

 [ISSN 2581-5369]

opposition mechanism was the only one that worked, and once a patent was awarded, it could not be challenged. However, in accordance with the TRIPS agreement (Trade-Related Aspects of Intellectual Property Rights), the Indian patent system experienced a major shift on January 1, 2005. India modified its Patent Act to conform to the international agreement, and Section 25 of the Act established a post-grant opposition mechanism[6]. The Patent grant is formally effective from the date when notice of it is officially published.[7] Let discuss the pregrant and post grant opposition in detail.

Through the pre-grant opposition procedure, third parties can contest a patent application prior to its issuance, allowing for public review and assisting in the prevention of patents for unworthy inventions. Similarly, post-grant opposition provides a one-year window after the patent is granted for stakeholders to contest its validity. These mechanisms enhance the transparency and integrity of the patent system, reduce litigation, and promote a balance between the rights of inventors and the public. By enabling challenges to weak patents, the opposition mechanisms help maintain a robust patent landscape, fostering innovation while protecting public interest. Rule 55 of the Patents Rules, 2003 and Section 25(1) of the Indian Patent Act, 1970 establish the legal framework for pre-grant opposition in India. Any individual may submit a written opposition at any point after the patent application is published but before it is granted. Since opposition cannot be made based only on the abstract, a complete specification must be obtained from the official website. The system serves as a protective barrier that confirms the application's legitimacy prior to the patent rights being granted. Making a "representation" is the term used to describe the opposition. Section 25(1) clauses (a) to (k) of the Patents Act, 1970 provide a comprehensive list of grounds for opposing a patent application. Wrongful acquisition, prior publication, prior claim, prior knowledge or usage, obviousness, non-patentable subject matter, inadequate description, and non-disclosure: false disclosure, time limit, biological material, and traditional knowledge are some of these reasons. Even after a patent grant has been formally announced, third parties may still contest it. For this, a "notice of opposition" was employed. The notice must be delivered to the Controller of the appropriate patent office within a year of the date the patent grant was published in the Indian Patent Journal.Unlike pre-grant objection, only a "interested party" may register this type of protest. Section 2(1)(t) of the Patent Act of 1970 defines "person interested" in an inclusive manner. A person doing or assisting with research in the field covered by the patent is included.

[6] Ibid at p.3.
[7] W R CORNISH, TEXT BOOK ON INTELLECTUAL PROPERTY: PATENTS, COPYRIGHT, TRADEMARK AND ALLIED 102 (6th edn, 2007).

 [ISSN 2581-5369]

This phrase may also refer to a company that produces, sells, or funds the patented goods.[8] The invention claimed in the complete specification may be opposed on the grounds that it is claimed in another claim of a complete specification published in India on or after the applicant's claim priority date and has an earlier priority date than the applicant's claim.[9] The process for a post-grant opposition is outlined in Rules 55A to 70 of the Patent Rules, 2003. According to Form 7, the notice of opposition under Section 25(2) must be submitted to the Controller of the relevant office. There are cases for pre-grant and post-grant opposition of patents.

In *UCB Farchim SA V. Cipla Ltd. & Ors*[10], a pharmaceutical company named UCB submitted a patent application for a medication composition. A pre-grant objection was submitted by Cipla Ltd., a generic pharmaceutical manufacturer, against UCB's patent application in accordance with Section 25(1) of the Indian Patents Act, 1970.[11] Cipla argued that the claimed invention lacked novelty and inventive step and was not patentable under the provisions of the Act. UCB challenged the opposition process, arguing that the pre-grant opposition was being misused and that the proceedings were becoming adversarial and protracted. Here, the UCB Farchim contended that the pre-grant opposition process should not be treated as a full-blown litigation and that the Patent Controller should have the discretion to manage the process without turning it into a lengthy adjudication. Cipla, on the other hand, argued that as an opponent, it had the right to present its objections fully and be heard in detail. The core issue revolved around the nature of the pre-grant opposition proceedings—whether they should be treated as purely administrative or as quasi-judicial processes with all procedural safeguards. The court underscored that pre-grant opposition is fundamentally an administrative process rather than a quasi-judicial or judicial one. It is designed to assist the Patent Office in evaluating the patentability of an application before the grant of the patent. The court emphasized that the opposition process should not be treated as a full-fledged adversarial proceeding. The role of the Patent Controller in this process is to consider the opposition arguments and the applicant's responses in a manner that ensures a fair decision without unnecessarily prolonging the proceedings.[12] The court highlighted the purpose of pre-grant opposition is to provide relevant information to the Patent Office that may affect the grant of a patent. The process is intended to be efficient, ensuring that valid objections are considered without converting the proceeding

[8] Opposition Proceedings In India, Available at: https://www.mondaq.com/india/patent/1185948/opposition-proceedings-in-india, Last visited on 08/09/2024.
[9] V K AHUJA, TEXT BOOK ON LAW RELATING TO INTELLECTUAL PROPERTY RIGHTS , 520 (Lexis Nexis Publications, 2nd edn., 2017).
[10] W.P. (C) Nos. 332 of 2010.
[11] AVTAR SINGH, INTELLECTUAL PROPERTY LAW, 262 (Eastern Book Company,1st edn., 2013).
[12] PAUL TORREMANS, HOLYOAK & TORREMANS INTELLECTUAL PROPRETY LAW, 112, (Oxford Publications, 8th edn.,2016).

into a trial-like environment. The Controller has discretion to determine the extent of hearing and evidence required, maintaining a balance between procedural fairness and administrative efficiency[13]. The court emphasized the significance of upholding natural justice principles, especially the right to be heard, while reaffirming the administrative nature of pre-grant objection. The court emphasized that all parties must be given a fair chance to submit their arguments and supporting evidence, even in administrative proceedings. However, the scope of this hearing should be limited and focused, avoiding a lengthy adversarial process that could delay the decision-making. The court analyzed the extent to which natural justice principles should apply in pre-grant opposition. It concluded that while the right to be heard is essential, it must be balanced with the need for efficiency in administrative proceedings.

The Patent Controller has the authority to determine how much evidence and argument is necessary to make a fair decision, without being obligated to conduct a full trial-like proceeding. In an attempt to argue that indigenous peoples should be compensated for the use that is made of their knowledge, the question has been raised as to whether the contribution of indigenous knowledge ought to be recognized as an inventive contribution to the resulting synthetic drugs.[14] The court's judgment in *UCB Farchim SA V. Cipla Ltd.* emphasized the need to strike a balance between procedural fairness and administrative efficiency.[15] It pointed out that pre-grant opposition proceedings should not become unduly adversarial or protracted, as this would defeat the purpose of an efficient patent examination process. The court maintained that the opposition process should enable relevant objections to be considered promptly, ensuring that patent applications are scrutinized without unnecessary delays.[16]

This judgment has influenced how pre-grant opposition proceedings are conducted in India, with an emphasis on maintaining the administrative character of the process while ensuring that parties are treated fairly. It has also guided the Patent Office in handling pre-grant oppositions, emphasizing that decisions should be made efficiently, without compromising on the fairness and transparency required by natural justice principles. This case serves as a crucial judicial precedent that defines the administrative nature of pre-grant opposition under Indian patent law. The court's analysis ensures that while opponents have the right to challenge patent applications, the process remains streamlined and focused, preventing unnecessary delays in the patent

[13] Dr. B L WADEHRA, TEXTBOOK OF LAW RELATING TO INTELLECTUAL PROPERTY, 22 , (Universal Publication,4th edn.,2007).
[14] LIONEL BENTLY & BRAD SHERMAN, TEXTBOOK ON INTELLECTUAL PROPERTY LAW, 472, (Oxford Publication, 2008).
[15] Ibid at p.3.
[16] Appeals against Pre-grant Patent Oppositions and Exhaustion of Remedies, Available at: https://www.lexology.com/library/detail.aspx?g=ae93e2a7-99db-45b4-a154-c55a13bd192d, Last visited on 09/09/2024.

 [ISSN 2581-5369]

granting process. By balancing fairness with efficiency, the ruling has shaped the conduct of pre-grant opposition proceedings, ensuring that the system works effectively to uphold both patent quality and procedural integrity[17]. Pre-grant opposition, according to the Delhi High Court, is an administrative procedure meant to help the Patent Controller determine whether a patent application is legitimate. The court stressed that the opposition procedure is intended to be a chance for third parties to draw the Controller's attention to pertinent facts rather than a full-fledged trial or adjudication.

The court also emphasized that although natural justice principles, such the right to be heard, must be adhered to, the procedure should be effective and not too adversarial. The judgment further clarified that the Controller has the discretion to manage the proceedings and decide the opposition based on the merits of the case without turning the process into a protracted legal battle. In *Hoffmann-La Roche v. Cipla Ltd*[18]**,** The Supreme Court of India addressed important questions pertaining to patent rights and the production of generic drugs in Hoffmann-La Roche v. Cipla Ltd. Erlotinib, an anti-cancer medication sold under the Tarceva brand, was patented by the global pharmaceutical corporation Hoffmann-La Roche. An Indian pharmaceutical company called Cipla Ltd. started producing and marketing a generic form of Erlotinib at a much reduced cost. Cipla was sued by Hoffmann-La Roche for allegedly violating its patent rights. Cipla argued that the patent was invalid and that Hoffmann-La Roche's patent wasn't infringed by its generic version. The dispute concerned whether the patent itself was valid under Indian law and whether Cipla's generic medication was violating the patent[19]. In this case, the Supreme Court of India deliberated on the burden of proof during pre-grant opposition proceedings under the Indian Patents Act, 1970. The case involved Hoffmann-La Roche's patent for the anti-cancer drug Erlotinib and Cipla's challenge to this patent. Cipla filed a pre-grant opposition to Hoffmann-La Roche's patent application for Erlotinib. Through this procedure, interested parties can contest a patent's validity prior to its issuance.[20]. The primary issue in this case was the burden of proof in pre-grant opposition proceedings. The Supreme Court clarified that in a pre-grant opposition, the burden of proof lies on the opponent (Cipla in this case) to establish that the patent application does not meet the requirements for patentability, such as novelty and inventive step[21]. The Court ruled that Cipla, the patent's opponent, needed to back

[17] Ibid at p.3.
[18] 2015 (225) DLT 391 (SC)
[19] Available at: https://legal-wires.com/case-study/case-study-f-hoffmann-la-roche-ltd-anr-petitioners-v-cipla-ltd/, Last visited on 08/09/2024.
[20] Case Analysis on F. Hoffmann-La Roche Ltd. & Anr. v Cipla Ltd, Available at: https://thelawbrigade.com/intellectual-property-rights/case-analysis-f-hoffmann-la-roche-ltd-anr-v-cipla-ltd/, Visited on 09/09/2024.
[21] An Overview On The Roche Vs. Cipla Dispute, Available at: https://blog.ipleaders.in/overview-roche-vs-cipla-

 [ISSN 2581-5369]

up its assertions of invalidity with significant evidence. This involves proving that the patent failed to meet the requirements for invention, novelty, and non-obviousness. The Court underlined that, in light of the existing prior art, the opponent must demonstrate that the patent application was not worthy of being granted. The Supreme Court affirmed Hoffmann-La Roche's patent's validity, reaffirming that the challenger bears the burden of demonstrating a patent's invalidity in pre-grant opposition. This ruling guaranteed that only patents that satisfied the legal requirements would be issued and reaffirmed the strict criteria needed to declare a patent invalid during pre-grant proceedings. The Court ruled that Cipla, the patent's opponent, needed to back up its assertions of invalidity with significant evidence. This involves proving that the patent failed to meet the requirements for invention, novelty, and non-obviousness. The Court underlined that, in light of the existing prior art, the opponent must demonstrate that the patent application was not worthy of being granted. The Supreme Court maintained Hoffmann-La Roche's patent's validity, reaffirming that the challenger bears the burden of demonstrating a patent's invalidity in pre-grant opposition. This ruling guaranteed that only patents that satisfied the legal requirements would be issued and reaffirmed the strict criteria needed to declare a patent invalid during pre-grant proceedings.[22]. The *Hoffmann-La Roche v. Cipla Ltd.* case thus highlighted the procedural and substantive standards required in pre-grant opposition, particularly the significant burden of proof on the challenger to demonstrate patent invalidity. In *Novartis v. Union of India*[23]**,** the Supreme Court of India rendered a significant decision and addressed the interpretation of Indian patent rules with a particular emphasis on Section 3(d) of the Indian Patents Act, 1970. The case, which focused on the patentability of the anti-cancer medication Glivec (Imatinib Mesylate), has important ramifications for Indian pharmaceutical and public health patents. In 1998, the Swiss pharmaceutical company Novartis AG filed for a patent in India for the beta crystalline form of imatinib mesylate, which is sold under the brand name Glivec. Chronic myeloid leukemia (CML) and some other cancers can be effectively treated with this medication. Although imatinib, the drug's core chemical, was already well-known, Novartis applied for a patent on a particular crystalline version of the medication. Novartis's application was denied by the Indian Patent Office on the grounds that Imatinib Mesylate's beta crystalline form did not meet the standards for patentability under Section 3(d) of the Indian Patents Act. The primary issue was whether the beta crystalline form of Imatinib Mesylate qualified for a patent under Indian law, specifically under Section 3(d). Novartis argued that the beta crystalline form was a new invention and should be granted a patent. The

dispute/, Last visited on 09/09/2024.
[22] Ibid at p.7.
[23] AIR 2013 SC 1311.

case required the Supreme Court to interpret what constitutes an "enhancement of known efficacy" under Section 3(d) and whether Novartis's application met this criterion. The case also raised concerns about access to affordable medicines in India. Granting a patent for Glivec would have allowed Novartis to charge higher prices for the drug, making it less accessible to patients who needed it. In its ruling dated April 1, 2013, the Supreme Court denied Novartis's appeal and maintained the Indian Patent Office's and the Intellectual Property Appellate Board's (IPAB) decision to reject the patent application. According to the Court, Novartis was unable to prove that the beta crystalline version of imatinib mesylate significantly improved therapeutic efficacy over the well-known drug. The Court stressed that the term "efficacy" in Section 3(d) refers to therapeutic efficacy, which is a drug's capacity to have the intended therapeutic effect. The Court determined that this criterion was not met by the beta crystalline form.[24]. The Court acknowledged that Section 3(d) was designed to guarantee that only true inventions receive patent protection, thereby promoting access to reasonably priced medications. While Court acknowledged the importance of incentivizing pharmaceutical innovation through patent protection, it also emphasized the need to balance this with public health concerns. The judgment reflected India's commitment to ensuring that life-saving drugs remain accessible and affordable to the public. The judgment was hailed as a victory for public health advocates and patients in India and other developing countries. By denying Novartis's patent, the Court ensured that generic manufacturers could continue to produce and sell affordable versions of Glivec, making it accessible to a larger number of cancer patients. The decision provided clarity on the interpretation of Section 3(d) of the Indian Patents Act, reinforcing the principle that minor modifications to known drugs do not qualify for patent protection unless they demonstrate a significant enhancement of therapeutic efficacy. This interpretation has had a lasting impact on how pharmaceutical patents are granted in India. This case is a landmark ruling that has shaped the landscape of pharmaceutical patent law in India. By rejecting Novartis's patent application, the Supreme Court affirmed the importance of safeguarding public health interests and ensuring that patents are granted only for genuine innovations. The following are the important cases for post-grant opposition. In *Monsanto Technology LLC v. Nuziveedu Seeds Ltd* [25] , Monsanto, a multinational agrochemical and agricultural biotechnology corporation, developed genetically modified (GM) cotton seeds, branded as "Bollgard." These seeds contain a gene (Bt gene) that provides resistance against the Bollworm pest, which is a significant threat to cotton crops. Monsanto granted licenses to various Indian

[24] Indiakanoon, Available at: https://indiankanoon.org/doc/165776436/, Last visited on 09/09/2024.
[25] AIR 2019 SC 559.

seed companies, including Nuziveedu Seeds Ltd., to use this technology in developing their own hybrid seeds[26].However, a dispute arose when Nuziveedu Seeds Ltd. did not agree to Monsanto's revised trait fee, leading to the termination of the license agreement by Monsanto. In response, Nuziveedu continued to use Monsanto's technology, arguing that the patents were not valid under Indian law. Nuziveedu Seeds Ltd. challenged Monsanto's patents, claiming that they failed to meet Indian law's specifications for patentability, namely Section 3(j) of the Indian Patents Act, 1970. This section excludes from patentability "plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties, and species and essentially biological processes for production or propagation of plants and animals."Another key issue was whether Monsanto's Bt gene technology involved an inventive step that was non-obvious to a person skilled in the art. An inventive step is a crucial criterion for patentability, as it ensures that only inventions that are not obvious improvements or advancements over existing knowledge are granted patent protection.

From the Delhi High Court's Single Judge to the Division Bench, the matter was decided at several levels before making its way all the way to the Supreme Court of India. In the initial phase, the Single Judge decided in Monsanto's favor, confirming the patent's legality and acknowledging the technology's patentability under Indian law. The Division Bench reversed the Single Judge's ruling after an appeal. Because the claims in Monsanto's patent concerned a process for creating a transgenic plant—which is not patentable under Section 3(j) of the Patents Act—it was determined that the patent was invalid.[27] Monsanto challenged the Division Bench's ruling before the Supreme Court and the Court did not delve deeply into the substantive issues of patentability or the inventive step. Instead, it referred the matter back to the Delhi High Court for reconsideration, emphasizing that the case required a more thorough examination of the facts and legal issues. The decision of the Division Bench of the Delhi High Court highlighted the complexities in interpreting Section 3(j) of the Indian Patents Act concerning biotechnological inventions. The exclusion of "essentially biological processes" from patentability poses challenges for patenting genetically modified organisms (GMOs) and related technologies in India. The interpretation of this section remains a point of contention, with significant implications for the biotech industry. The case also underscores the importance of the inventive step in determining patentability. While the Bt gene technology represented a significant advancement, the question of whether it involved an inventive step that was non-

[26] Monsanto Technology Llc v. Nuziveedu Seeds Ltd. Thru The Director on 8 January, 2019 https://indiankanoon.org/doc/116548206/.
[27] Ibid at p. 8.

 [ISSN 2581-5369]

obvious to a person skilled in the art remained contentious. The outcome of this case could influence how Indian courts assess the inventive step in future patent disputes, particularly in complex fields like biotechnology. The final resolution of this case is likely to have far-reaching implications for the biotechnology and seed industries in India. A decision that restricts the patentability of GMOs could discourage innovation and investment in agricultural biotechnology. Conversely, a more liberal approach to patentability could lead to monopolistic practices, with significant implications for farmers and food security. It raises critical questions about the patentability of biotechnological inventions under Indian law and the standard for assessing inventive steps. The *Enercon v. Aloys Wobben*[28] is a significant judgment in the context of Indian intellectual property law, particularly regarding patent disputes. The case also sheds light on procedural safeguards and principles of natural justice in judicial and quasi-judicial proceedings. Aloys Wobben, a German inventor, held several patents related to wind energy technology. Enercon (India) Ltd., the Indian subsidiary of the German company Enercon GmbH, was involved in a dispute with Aloys Wobben over the validity and infringement of several patents. The conflict between Enercon and Aloys Wobben began with disputes over patents, eventually leading to multiple legal proceedings in Indian courts and patent offices. The crux of the issue was the validity of several patents held by Aloys Wobben, which Enercon (India) Ltd. challenged. The case touched upon several critical issues, with a particular focus on procedural safeguards and the principles of natural justice in patent-related litigation. Enercon (India) Ltd. filed revocation petitions against Aloys Wobben's patents before the Intellectual Property Appellate Board (IPAB) under the Patents Act, 1970. The challenge was based on the grounds that the patents lacked novelty and inventive step, among other reasons. The key issue here was whether the IPAB followed the principles of natural justice during the revocation proceedings, especially in terms of giving both parties a fair opportunity to present their cases[29]. Fairness in judicial and quasi-judicial processes is largely dependent on the natural justice principles, especially the rule against bias (nemo judex in causa sua) and the right to be heard (audi alteram partem). In this case, questions were raised about whether the IPAB's procedures adhered to these principles. The case also highlighted the need for clear procedural safeguards in patent litigation, particularly concerning the timeliness of hearings, the opportunity to present evidence, and the impartiality of the adjudicating body. The case reached the Supreme Court of India, where the court addressed the procedural issues and the broader principles of natural justice. The Supreme Court emphasized that in patent litigation, especially

[28] (2014) 3 SCC 366.
[29] Casemine, Available at: https://www.casemine.com/judgement/in/574990ccadd7b016e0f04960, Last Visited on 09/09/2024.

in revocation proceedings, procedural safeguards are critical. This includes ensuring that both parties have a fair chance to present their cases and that the tribunal or adjudicating body is free from bias.[30] The court emphasized how crucial natural justice is to guaranteeing a fair and just decision- making process. The court noted that any decision made in violation of natural justice principles could be overturned for that reason alone. In order to guarantee that all procedural safeguards were observed and that both parties had an equal opportunity to present their cases, the Supreme Court remanded the case to the IPAB for reconsideration This case is a landmark decision in terms of emphasizing procedural safeguards and natural justice in patent litigation. The case serves as a reminder that in complex and technical disputes like those involving patents, ensuring fairness in the adjudicative process is as important as the substantive issues at hand. The judgment highlights the need for procedural safeguards in IP litigation, where the stakes are high and the subject matter is often complex. Ensuring that the parties have sufficient time to prepare, present evidence, and argue their cases is crucial. The principle of natural justice is fundamental to any legal proceeding. The court's insistence on adherence to these principles in this case reinforces the idea that justice should not only be done but should also be seen to be done. This is particularly important in quasi-judicial proceedings like those before the IPAB. The decision in this case sets a precedent for future patent litigation in India, emphasizing the importance of procedural fairness. This is likely to influence how patent cases are handled by courts and tribunals, ensuring that parties are given a fair hearing and that decisions are made impartially. This case is significant for its emphasis on procedural safeguards and natural justice in patent litigation. The Supreme Court's decision serves as a reminder that the fairness of the process is just as important as the outcome. This case is likely to influence how future patent disputes are adjudicated in India, ensuring that the principles of natural justice are upheld in all proceedings. In *Merck Sharpe & Dohme Corp v. Glenmark Pharmaceuticals Ltd*[31], Indian patent law that addresses important issues regarding the assessment of novelty, patent infringement, and the balancing of public interest in the context of pharmaceutical patents. A patent was owned by the multinational pharmaceutical corporation Merck Sharpe & Dohme Corp. (Merck) for the medication sitagliptin, which is sold under the "Januvia" brand. Type 2 diabetes is treated with the anti-diabetic drug sitagliptin. The Indian generic pharmaceutical company Glenmark Pharmaceuticals Ltd. had been charged by Merck of violating its patent by producing and selling a generic form of sitagliptin under the brand names "Zita" and "Zita-Met." The central issue was whether Merck's patent for Sitagliptin

[30] Ibid at p.4.
[31] 2015 (64) PTC 417 (Del).

was valid under Indian patent law. Glenmark challenged the patent, arguing that it lacked novelty and was obvious in light of prior art. Novelty is a fundamental requirement for patentability, meaning that the invention must be new and not disclosed in any prior art. Glenmark contended that the Sitagliptin patent did not meet this criterion. Maintaining the public's access to reasonably priced medications while also safeguarding patent rights was another crucial concern. Glenmark argued that its generic version of Sitagliptin was priced significantly lower than Merck's patented drug, making it more accessible to patients in India. The case raised important questions about how to reconcile the rights of patent holders with the public interest in affordable healthcare[32]. The Delhi High Court heard the matter and issued a landmark ruling that addressed the validity of the patent as well as issues of public interest. The court determined that the innovation satisfied the criteria of novelty and non-obviousness, upholding Merck's patent.The court found that Sitagliptin was a new and inventive chemical entity, not disclosed in any prior art. Therefore, Merck's patent was valid and enforceable under Indian patent law. The Delhi High Court granted an interim injunction against Glenmark, restraining it from manufacturing and selling its generic versions of Sitagliptin (Zita and Zita-Met) pending the final resolution of the case. The court emphasized that Glenmark's activities constituted prima facie infringement of Merck's patent rights. The court stressed the necessity to protect patent rights in order to promote innovation in the pharmaceutical sector, even as it recognized the significance for providing the general people with affordable medications. The court noted that balancing these competing interests is challenging but necessary. The decision to grant an injunction was based on the court's determination that Merck had a valid patent and that Glenmark's actions undermined the incentives for innovation[33]. This case highlights the ongoing tension between patent protection and public health in India, especially in the pharmaceutical sector. The court's decision underscores the importance of novelty and non-obviousness as criteria for patentability. In this case, the court found that Sitagliptin was a novel and inventive compound, affirming the patent's validity. This decision is significant for pharmaceutical companies seeking patent protection for their innovations in India, as it demonstrates that Indian courts are willing to uphold patents if the criteria are met. The case also illustrates the delicate balance between patent rights and public interest. While the court granted an injunction in favor of Merck, it acknowledged the importance of making life-saving medications affordable and accessible to the public. The judgment suggests that Indian courts

[32]Glenmark restrained from manufacturing and selling its anti-diabetes drugs.Available at:https://www.scconline.com/blog/post/2015/10/08/glenmark-restrained-from-manufacturing-and-selling-its-anti-diabetes-drugs/, Last visited on 09/09/2024.
[33] Ibid at p.3.

are aware of the broader social implications of patent enforcement, especially in a country where access to affordable healthcare is a critical issue. The decision in *Merck v. Glenmark*[34] has significant implications for both innovator pharmaceutical companies and generic manufacturers. For innovator companies, the case reinforces the value of strong patent protection in India. For generic manufacturers, the decision serves as a reminder that patent challenges must be based on solid legal grounds, particularly when arguing lack of novelty or obviousness. This case serves as a precedent in Indian patent law, particularly in cases involving the pharmaceutical industry. It reinforces the idea that patents, once granted, are presumed valid unless successfully challenged based on clear evidence of lack of novelty or non-obviousness. It is a landmark case that addresses critical issues in patent law, particularly the assessment of novelty and the balance between patent rights and public interest. The court's decision to uphold Merck's patent and grants an injunction against Glenmark emphasizes the importance of protecting innovative pharmaceutical products while also recognizing the need for affordable access to medicines. Future patent litigation in India, especially in the pharmaceutical industry, would be significantly impacted by this case. In the *Novartis AG v. Union of India* case, which concerned the cancer medication Glivec, the court's interpretation of Section 3(d) was the most noteworthy. Novartis argued that the beta-crystalline form of imatinib mesylate had greater stability and bioavailability than the original medication and filed for a patent for it.[35]. According to the Supreme Court of India, Novartis's patent application was rejected because the beta-crystalline form of imatinib mesylate was a "new form of a known substance" and did not satisfy Section 3(d) standards for greater therapeutic efficacy. The Court ruled that improvements in bioavailability or other physicochemical properties did not constitute enhanced therapeutic efficacy. The ruling emphasized that a novel formulation of a well-known drug must show a notable advancement in the management of an illness or medical condition in order to be eligible for patent protection.[36]. The Novartis decision is a landmark ruling clearly emphasized the intent of Section 3(d) to avoid evergreening. The Court made it clear that patent protection would only be granted for genuine innovations that provide real therapeutic benefits, rather than for minor modifications to existing drugs. This interpretation set a high bar for pharmaceutical companies seeking to patent new forms of known substances, effectively

[34] 2015 SCC OnLine Del 10225.

[35] Mondaq, Section 3(D) Of Indian Patents Act 1970: Significance And Interpretation, Available at: https://www.mondaq.com/india/patent/295378/section-3d-of-indian-patents-act-1970-significance-and-interpretatio, Last visited on 09/09/2024.

[36] India Corporate Law , Available at: https://corporate.cyrilamarchandblogs.com/2024/02/act/#:~:text=The%20court%20highlighted%20the%20three,use%20of%20a%20known%20substance,Last visited on 09/09/2024.

curbing evergreening practices. The Novartis decision has been cited in several subsequent cases, with courts continuing to apply the principles established by the Supreme Court to prevent evergreening.[37] In *Bayer Corporation v. Union of India*[38], Bayer attempted to obtain a patent for a novel version of its cancer medication, sorafenib. Citing Section 3(d), the Controller of Patents denied the application, and the courts upheld the judgment. The ruling reinforced that minor changes to a known drug, without any significant improvement in therapeutic efficacy, would not qualify for patent protection. In *Sun Pharmaceuticals v. Bristol-Myers Squibb* [39] Dasatinib, a well-known medication, had a novel polymorph that Bristol-Myers Squibb was attempting to patent. The appeal upheld the Patent Office's decision to reject the application under Section 3(d). The ruling emphasized that merely discovering a new polymorph without demonstrating enhanced therapeutic efficacy did not meet the criteria for patentability under Section 3(d).According to courts' consistent interpretation of Section 3(d), any new formulation of a well-known medication must demonstrate enhanced clinical efficacy, not only enhanced stability or bioavailability.[40] By setting a high standard for patentability, courts have ensured that companies cannot obtain patent extensions for trivial modifications to existing drugs. Section 3(d) serves as a critical tool in achieving this balance, ensuring that patents are granted only for substantial advancements in treatment, rather than for incremental changes that do not benefit patients. The judicial interpretation of Section 3(d) of the Indian Patents Act has been pivotal in preventing evergreening and ensuring that patent protection is granted only for genuine innovations that enhance therapeutic efficacy. The landmark *Novartis AG v. Union of India* case set a strong precedent, establishing that minor modifications to known substances do not warrant patent protection unless they offer significant therapeutic benefits. Subsequent rulings have reinforced this interpretation, contributing to a patent system that promotes innovation while safeguarding public health and access to affordable medicines[41]. The following cases where principles of natural justice in opposition proceedings/principle of audi alteram partem has been emphasized. The natural justice principle plays a crucial role in opposition proceedings under the Indian Patents Act, 1970. These principles, including the right to be heard or the Audi Alteram Partem and the Rule against bias or Nemo Judex In Causa Sua, ensure that opposition proceedings are conducted fairly and impartially. Courts have repeatedly

[37] Ibid at p. 2.
[38] (2014) 5 SCC 618.
[39] 2015 SCC OnLine Bom 4532.
[40] India: The implications for patent owners of section 3(d),Available at: https://www.managingip.com/article/2a5ceo2rx2jynjz4loagw/india-the-implications-for-patent-owners-of-section-3d, Last visited on 09/09/2024
[41] Ibid at p. 2.

emphasized the importance of these principles in safeguarding the rights of both the patent applicant/patentee and the opponent, ensuring that decisions are made transparently and justly. The principle of Audi Alteram Partem mandates that all parties involved in a legal proceeding should be given an opportunity to present their case. In the context of patent opposition proceedings, this principle ensures that both the applicant/patentee and the opponent are allowed to submit their arguments, present evidence, and respond to any claims made against them. In *Ajanta Pharma Ltd. v. Allergan Inc.*[42], the Delhi High Court stressed that the Board must act impartially and independently. The court pointed out that the recommendation of Board is based solely on the merits of the case, without any external influence. *Mylan Laboratories Ltd. v. Union of India* **[43],** the High Court of Delhi highlighted the need to balance the speed of the pre-grant opposition process with the natural justice principle. The court held that while pre-grant opposition should be resolved expeditiously, this should not come at the cost of denying the applicant a fair hearing. In M*/s Wockhardt Ltd. v. Torrent Pharmaceuticals Ltd.* [44], the Bombay High Court set aside a decision in a post-grant opposition due to procedural irregularities that violated the right to be heard. After making sure that each party had an equal chance to make their case, the court ordered the Patent Office to re-evaluate the opposition. The Bombay High Court noted that prolonged delays in post-grant opposition proceedings could significantly impact the commercial interests of the patent holder, who may be unable to fully exploit their patent rights during the pendency of the opposition. The court underscored the need for the Patent Office to expedite opposition proceedings to minimize the commercial uncertainty. *Telefonaktiebolaget LM Ericsson v. Competition Commission of India* [45],in this case, the High Court of Delhi held that the Controller's discretion must be exercised judiciously, particularly in complex cases involving significant legal and technical issues. The court noted that the Controller should base decisions on sound reasoning, taking into account the evidence presented by both the applicant and the opponent. In *Hindustan Unilever Ltd. v. Tata Chemicals Ltd.* [46], the High Court of Delhi noted that the Controller should not dismiss the Board's recommendations lightly. In this case, the Court held that if the Controller chooses to depart from the Board's recommendation, the reasons for doing so must be clearly stated and must withstand judicial scrutiny. The High Court of Delhi further ruled that the Patents Act, 1970 and followed by the Rules mandate a fair and impartial hearing in post-grant opposition. The court emphasized that the Controller of Patents must provide clear and cogent reasons for

[42] (2019) 2 SCC 284.
[43] 2018 SCC OnLine Del 10457.
[44] 2016 SCC OnLine Bom 2448.
[45] 2016 (65) PTC 609 (Del).
[46] 2008 (36) PTC 67 (Del).

 [ISSN 2581-5369]

accepting or rejecting the opposition. Courts have emphasized the importance of adhering to statutory timelines in post-grant opposition proceedings. In *Hindustan Unilever Ltd. v. Tata Chemicals Ltd*[47] the Delhi High Court highlighted that delays in post-grant opposition could undermine the certainty and enforceability of patents, affecting the business operations of both the patent holder and the opponent. The court stressed that the statutory timelines should be respected to ensure fairness in the process.

III. CONCLUSION AND SUGGESTIONS

India's legal system has known for ensuring the rights of intellectual while striking a balance balance between private as well as public interest during udicial examination of pre-grant and post-grant patent proceedings. Through numerous cases as cited above , various High Courts and Supreme Court in India held that the burden of proof in pre-grant opposition proceedings always rest with opponenets like *Hoffmann-La Roche v. Cipla Ltd*[48]., lies with the opponent to show that the patent application is inadequate based on predetermined statutory criteria. By avoiding the issuance of patents that do not meet the necessary standards of originality and novelty, this rigorous review guarantees that only genuine innovations are protected. Post-grant opposition proceedings, highlighted in cases like ***Novartis AG v. Union of India***[49], play a crucial role in maintaining the quality of granted patents. The focus on Indian Patents Act Section 3(d), which mandates significant improvements in therapeutic efficacy for minor modifications, underscores the judiciary's commitment to preventing "evergreening" and ensuring that patents do not unjustly restrict access to essential medicines. This process allows for the correction of potentially erroneous grants and reinforces the importance of substantive review in patent law. Overall, the evolving judicial perspective on patent proceedings reflects a balanced approach that aims to protect genuine innovations while safeguarding public access and preventing monopolistic practices. It is an appropriate to note here that Indian courts have emphasized procedural fairness and the need to prevent abuse of patent rights, thereby fostering a legal environment that supports both innovation and equitable access to vital resources.

*****

[47] *Id.*
[48] 2015 (225) DLT 391 (SC).
[49] AIR 2013 SC 1311.