

**AN EVALUATION OF THE INDIAN LEGISLATIVE FRAMEWORK FOR PATENT
OPPOSITION MECHANISM: MERITS AND DEMERITS OF THE PROCEDURAL
SAFEGUARD**

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ABSTRACT

Patent opposition refers to the ways in which it is possible to challenge the validity of a patent both during the pendency of a patent application and after the grant of a patent. Patent opposition proceedings provide the first opportunity for third parties to challenge the validity of patents. These are in-house proceedings because they are instituted within the Patent Office. Since 2005, India has provided a detailed legislative framework for challenging the validity of patents in a cost-effective manner. Patent opposition proceedings provided under the Patents Act can be classified into two distinct categories: pre-grant opposition (before the patent is granted) and post-grant opposition (after the patent is granted). This study supports India's decision to provide a less formal ex-parte pre-grant opposition procedure. Opposing a patent before the grant is an easier option as compared to the post-grant opposition because at this stage there is no burden of proof on the opponent. As the patent is yet to be granted at this stage, the pre-grant opposition does not involve the issuance of interim orders or injunctions. Pre-grant opposition helps patent offices to make more informed decisions because third parties, especially competitors having technical expertise in the field of invention, bring additional information to the attention of the controller. This paper also supports India's approach of providing the additional safeguard of a more formal inter-parties post-grant opposition procedure. This paper also highlights certain lacunae in India's opposition procedures and argues that India's patent opposition model lacks clarity and legal certainty.

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I. INDIA MADE THE RIGHT CHOICE BY PROVIDING PRE-GRANT OPPOSITION PROCEDURE

The pre-grant opposition mechanism provided under section 25(1) of the Patents Act, 1970 and rule 55 of the Patents Rules, 2003, is not designed to make the opponent a party to the proceedings.¹ The role of an opponent in pre-grant opposition proceedings is to help or aid the Controller by providing information in the form of grounds of opposition and supporting evidence. The Controller can, therefore, make a more informed decision on the patent application in the light of the information supplied by the opponent.

In India, 'Any person' can file a representation for pre-grant opposition before the Controller.² The scope of 'Any person' includes not only natural persons but also legal persons like associations and corporations. The scope of 'Any person' also includes foreign opponents who neither reside nor carry on business in India.³ A representation for opposition can be filed free of charge,⁴ at any time after an application for a patent has been published,⁵ but a patent has not been granted.⁶ The potential opponents have a time period of at least six months to file a representation for the opposition because, under the rules, no patent shall be granted before the expiry of a period of six months from the date of publication of the patent application.⁷

The pre-grant opposition can be filed on the grounds provided in section 25(1) which provides an exhaustive list of grounds of pre-grant opposition by specifically stating 'but on no other ground'.⁸ Normally, several grounds available under section 25 are raised and a few of

¹ (Patents (Amendment) Ordinance 2004 provided for pre-grant representation under § 25. Section 25(2) of the Ordinance specifically stated that 'the person making a representation referred to in that sub-section shall not become a party to any proceedings under this Act only for the reason that he has made such representation'. Though § 25 was amended under the Patents (Amendment) Act 2005 to provide for pre-grant opposition proceedings and new provision was silent on whether or not the pre-grant opponent is a party to the proceedings, the previous provision can still be used to show the intent of the legislature).

² The Patents Act, 1970, No. 39, Acts of Parliament, 1970, § 25(1) (India). (Prior to 2005, only any 'person interested' was allowed to initiate pre-grant opposition. The provision was amended in 2005 to remove the condition of 'interested' for filing this type of opposition).

³ *Id.* §150.

⁴ (No fee has been stipulated for instituting pre-grant opposition proceedings under the Patents Act and the Patents Rules).

⁵ The Patents Act, 1970, No. 39, Acts of Parliament, 1970, §11A (India).

⁶ *Id.* §25(1). (Prior to the 2005 amendment, pre-grant opposition was allowed within four months from publication of the acceptance of a complete specification).

⁷ Patents Rules, 2003, r. 55(1A) (India).

⁸ The Patents Act, 1970, No. 39, Acts of Parliament, 1970, §25(1) (India).

them are debated during the hearing. The grounds not debated during the hearing are considered as withdrawn even if the opponent does not withdraw the grounds in writing or orally.⁹

It is important to note here that the Patents Act and the Patents Rules do not contain any provision that imposes the burden of proof on the opponent in pre-grant opposition proceedings. According to the Indian Evidence Act, whoever seeks to rely on the existence of certain facts must prove that those facts exist. The burden of proof lies on the person who is bound to prove the existence of facts.¹⁰ In other words, the burden of proof lies on that person who would fail if no evidence at all were given on either side.¹¹ The burden of proof has not been imposed on the opponent in pre-grant opposition proceedings possibly because of the fact that she is not a party to the proceedings. If the opponent fails to submit reply statement and evidence, it does not make any difference as the same is not required in the pre-grant opposition.¹² The role of the opponent is just to bring valuable information to the notice of the Controller.

Hearing the opponent is not mandatory in pre-grant opposition proceedings. If the opponent wants to be heard, she may include a request for hearing in her written representation for opposition.¹³ But the opponent does not enjoy a legal right to be heard because she is not a party to the proceedings.¹⁴ The Controller considers the opponent's request for hearing only if she is satisfied with the merit of the opposition.¹⁵ Even if the Controller is satisfied and she grants the opponent an opportunity to be heard, the hearing is informal because the Patents Act and the Patents Rules do not provide details on procedure or formalities of hearing in pre-grant opposition proceedings.

One of the grounds of invoking patent opposition proceedings in India, under sections 25(1)(f) and 25(2)(f), is that 'the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act'.¹⁶ This ground of patent opposition links the Indian opposition proceedings with section 3(d) which provides a notable exception to patentability in India. As noted above, section 3(d) excludes trivial

⁹ FERROZ ALI KHADER, *THE TOUCHSTONE EFFECT: THE IMPACT OF PRE-GRANT OPPOSITION ON PATENTS* 116 (LexisNexis Butterworths, 1st ed. 2009).

¹⁰ Indian Evidence Act, 1872, No. 1, Acts of Parliament, 1970, §101.

¹¹ *Id.* §102.

¹² *Anglo Operations Ltd. v. AIA Engineering Pvt. Ltd.*, 690/DEL/95, 10.

¹³ Patents Rules, 2003, r 55(1) (India).

¹⁴ *M/s Schering Corporation v. M/s Cadila Healthcare Ltd.*, IN/PCT/2000/00434/CHE, 3.

¹⁵ Patents Rules, 2003, r 55(3) (India).

¹⁶ The Patents Act, 1970, No. 39, Acts of Parliament, 1970, §25(1)(f) (India).

modifications of known substances from patent eligibility in India unless they satisfy the condition of ‘enhanced efficacy’.¹⁷ Moreover, under sections 25(1)(e) and 25(2)(e), patents can be opposed on the ground of obviousness or lack of inventive step. This ground links the Indian opposition proceedings with section 2(ja) which defines inventive step and adds additional requirements of ‘technical advance’ and ‘economic significance’ to the inventive step threshold. Sections 3(d) and 2(ja) are, therefore, very important components of the Indian patent opposition proceedings.¹⁸ This nexus of two distinct TRIPS flexibilities is a distinctive feature of the Indian patent opposition model. India, therefore, used its procedural mechanisms of patent opposition to reinforce its heightened patentability requirements.

Pharmaceutical Research and Manufacturers of America (PhRMA) has criticized India for applying narrow patentability standards and reinforcing its higher standards through patent opposition.¹⁹ PhRMA claims that India’s opposition mechanism is a source of restrictive standards for patentability. PhRMA argues that India’s opposition proceedings create uncertainty relating to the patentability of inventions.²⁰ The lack of clear rules guiding pleading and evidentiary standards during opposition proceedings creates uncertainty and causes a delay in the introduction of new inventions by delaying patent examination and patent prosecution.²¹ PhRMA further argues that long patent examination delays cause significant damage. The value of patents granted with unreasonable delays is reduced given the fact that the term of a patent begins on the date of filing of a patent application. Backlogs, therefore, undermine incentives to innovate and undermine investment in future research activity.²² Consequently, backlogs hinder timely patient access to valuable new treatments and cures.²³

In response to PhRMA’s criticism, it is argued that the Member States have legitimate flexibility to adopt patent opposition procedures in their national patent laws. Art. 62 (4) of the TRIPS Agreement condones the use of opposition procedures.²⁴ This study specifically supports

¹⁷ *Id.* §3(d).

¹⁸ Muhammad Zaheer Abbas, *Conflicting Interests, Competing Perspectives and Policy Incoherence: COVID-19 Highlights the Significance of the UN High-Level Panel Report on Access to Medicines*, 31 *AUSTL. INTELL. PROP. J.*, 30 (October 2020).

¹⁹ *Pharmaceutical Res. and Manufacturers of America (PhRMA)*, SPECIAL 301 SUBMISSION 85 (2018), <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-2018-Special-301-Submission.pdf>.

²⁰ *Id.* at 87.

²¹ *Id.*

²² *Id.* at 90.

²³ *Id.* at 90.

²⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, Art. 62(4), 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 TRIPS Agreement].

India's policy decision of providing pre-grant opposition procedure as a pre-emptive safeguard against evergreening²⁵ of drug patents and grant of low-quality patents in general. As noted by Jeffrey D. Sachs, 'If governments would do their job in setting up the right rules, major international companies would play a vital role in solving problems'.²⁶ Corporations, especially brand-name drug companies, rely heavily on exclusive rights in order to maximize their profits. Absence of proper safeguards enhances the likelihood of corporations getting low-quality patents or deliberately engaging in the practice of pursuing low-hanging fruits through evergreening of drug patents. In either case, the public interest is seriously undermined. Governments need to set up the right rules to regulate international companies. India has made the right policy choices by making it difficult for corporations to acquire low-quality patents and by making it easier for third parties to challenge questionable patents.

More precisely, India's approach is in line with Peter Drahos' argument that patent quality issues need to be addressed at the examination stage. If examination of the prior art is done properly, then the chances of poorly-granted patents are much lesser and it reduces the probability of patent litigation. Drahos uses the concept of 'patent social contract' between the inventor and society to justify the existence of the patent system. Under this social contract, society is willing to grant exclusive rights to innovators who deliver socially valuable and non-obvious inventions. In his 2010 book, Drahos notes that:

The patent social contract is not a contract aimed at the grant of more and more patents, but rather at the diffusion of more and more significant inventions. Under the patent social contract, society cannot be taken to be contracting for obvious inventions since by definition these are already available to society in the storehouse of skills of the workers skilled in the relevant arts. Instead, society is contracting for the delivery of non-obvious inventions.²⁷

²⁵ (In order to qualify for patent protection, an invention is required to be novel, non-obvious and useful in the sense of being capable of industrial application. This is a universal standard required under the TRIPS Agreement. It is argued that instead of channeling their efforts towards genuine R&D for development of novel and effective drugs, the originator companies attempt to find loopholes in the existing regulatory framework and play safe by adopting different tactics or strategies to prolong their period of exclusivity by exploiting those loopholes. See GAURAV DWIVEDI, SHARANABASAVA HALLIHOSUR & LATHA RANGAN, 'EVERGREENING: A DECEPTIVE DEVICE IN PATENT RIGHTS' (2010), 32(4) *Technology in Society* 328.

²⁶ JEFFREY D. SACHS, *THE END OF POVERTY: HOW WE CAN MAKE IT HAPPEN IN OUR LIFETIME* 358 (The Penguin Press, 2005).

²⁷ PETER DRAHOS, *THE GLOBAL GOVERNANCE OF KNOWLEDGE: PATENT OFFICES AND THEIR CLIENTS* 78-79 (Cambridge Univ. Press, 2010).

By referring to ‘patent social contract’, Drahos highlights the public mission of patent offices to secure society’s entitlements under the social bargain.²⁸ He links the issue of patent quality to the patent social contract. In his view, ‘improving patent quality is very much about improving the quality of invention that the patent system serves to disclose to the public’.²⁹ He argues that patent offices ‘steer away from the ... rigorous analysis of the link between invention and prior art’.³⁰ Drahos stresses that ‘someone has to check that the patentee is delivering his side of the bargain’.³¹ It is clear from the context that the ‘someone’ is a patent office in general and a patent examiner in particular. The ‘someone’ is unlikely to be the courts as Drahos contends that the courts are not best suited to address the patent quality issues. In his 2008 article, he clearly asserts that ‘[r]elying on patent litigation as a tool to weed out invalid patents will not work in developing countries’.³² Drahos, therefore, has a very clear argument that the best way to address patent quality issues is at the examination stage.

Carlos Correa is another prominent academician who expressed his dissatisfaction over the patent examination standards. He is of the view that:

*“The rights conferred by patents are based on partial and often imperfect determinations. The examination process does not allow patent offices to reach definitive judgments on patentability. There is uncertainty regarding the validity of patents as well in the boundaries of what is protected under individual patents.”*³³

Correa supports the use of pre-grant opposition procedures as a measure to improve the quality of patent examination. He contends that ‘[p]re-grant opposition mechanisms help examiners to improve the analysis they undertake, as third parties can bring to their attention precedents that may not have been identified’.³⁴ He adds that pre-grant opposition procedures ‘lead to the granting of more solid patents while avoiding the creation of rights over developments that are not really inventive’.³⁵

²⁸ *Id.* at 38.

²⁹ *Id.* at 79.

³⁰ *Id.* at 78.

³¹ *Id.* at 33.

³² *Id.* at 173.

³³ Carlos M. Correa, *Patent Examination and Legal Fictions: How Rights Are Created on Feet of Clay in KRITIKA: ESSAYS ON INTELL. PROP.* 62.

³⁴ Carlos Correa, *Guidelines for the Examination of Pharmaceutical Patents: Developing A Public Health Perspective* 24 INTERNATIONAL CTR. FOR TRADE AND SUSTAINABLE DEV (January 2007).

³⁵ *Id.*

Joseph E. Stiglitz advocates the quicker and less costly opposition procedure integrated within the examination process. He particularly appreciates the information gathering function of opposition procedures. The opposition procedure, in Stiglitz's view, 'functions as a device that elicits and examines relevant information that the opposing parties possess and have every interest to communicate'.³⁶ Stiglitz considers this information 'particularly important in a situation in which the quality of direct information gathered by the examiners in patent offices has seriously deteriorated'.³⁷

To cancel a patent that already exists is risky and cumbersome because it mobilizes political capital. Pre-grant opposition proceedings are less risky because of a 'prevention is better than cure approach', as low-quality patents do not make it to grant if opposed successfully at the stage of examination. As noted by Michael A. Carrier, '[o]ne way to reduce the number of invalid patents is to ensure that they are not granted in the first place'.³⁸ Once a patent is granted, '[i]t may be difficult for the Patent Office, which sets out procedures and enforces standards for issuing patents, to turn around and revoke patent claims in a post-grant opposition proceeding immediately after allowing them'.³⁹ It might be difficult for the Patent Office to concede that the patent application was improperly examined, and the patent should not have been granted. Moreover, if a considerable number of post-grant oppositions are successful, questions may be raised about the examination process of the Patent Office, a prospect not desired by the Patent Office. Pre-grant opposition is, therefore, a perfectly timed proceeding as it does not require the Patent Office to reverse its previous decisions.

This study argues that third parties should not be left with only the option of court litigation to challenge questionable patents. Relying on patent litigation alone to weed out invalid patents is not an economically and practically efficient approach because of several reasons. First, the costs of accessing justice through litigation are prohibitively high. To challenge the validity of a patent before judicial courts after its grant is a costly and time-consuming procedure involving substantial financial burden for parties to the patent litigation.⁴⁰ The cost is high because patent

³⁶ Claude Henry and Joseph E. Stiglitz, *Intellectual Property, Dissemination of Innovation and Sustainable Development*, 1 GLOBAL POL'Y 246 (October 2010).

³⁷ *Id.*

³⁸ Michael A. Carrier, *Post-Grant Opposition: A Proposal and a Comparison to the America Invents Act*, 45 UC DAVIS L. REV. 109 (November 2011).

³⁹ Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17(2) BERKELEY TECH. L. J. 777 (April 2002).

⁴⁰ Kristof Roos et al., *Patent Related Barriers to Market Entry for Generic Medicines in the European Union: A Review of Weaknesses in the Current European Patent System and their Impact on Market Access of Generic Medicines* 5(4) J. OF GENERIC MED. 260 (2008).

litigation is complex and the stakes are usually high.⁴¹ In cases where a drug patent is wrongly granted, the title holder innovative drug companies, with superior financial resources, enjoy a major advantage because the cost of patent litigation is ‘nearly prohibitive to many companies or institutions that are not financially well off’.⁴² The small and medium-sized generic firms and the general public may be reluctant to take the risk of waging costly and cumbersome multi-year patent battles.⁴³ The prolonged trial and appeal processes seriously disincentivize interested third parties from using patent litigation to invalidate a patent.⁴⁴

Second, invalidating granted patents in a judicial court is particularly cumbersome because of a presumption of validity. In most of the jurisdictions, granted patents enjoy a legal ‘presumption of validity’. To rebut the presumption of validity, not only does the burden of proof lie on the party challenging the issued patent but also, the standard of proof is high.⁴⁵ The evidence presented before the court to support the assertion of invalidity of a granted patent must be ‘clear and convincing’.⁴⁶ The titleholder enjoys a major advantage when the validity of a granted patent is challenged in a court as persuading the courts to overrule an errant determination would be an uphill battle for challengers of patent validity.

Third, reliance on patent litigation to invalidate low-quality patents is negatively impacted by the public good problem. A court ruling invalidating a patent is a public good. As noted by Eric Williams, ‘a party that successfully challenges a patent’s validity cannot exclude competitors from benefiting from the successful attack’.⁴⁷ The U.S. Supreme Court ruled in 1971 that a party successful in challenging a patent cannot block competitors from relying on the court’s decision.⁴⁸ A free-riding problem develops because the challenging infringer bears all the costs of litigation costs while all potential infringers can benefit from a successful challenge without

⁴¹ Paul R. Gugliuzza, *Quick Decisions in Patent Cases*, 106 GEO. L. J. 630 (April 2018).

⁴² Qin Shi, *Reexamination Opposition, or Litigation-Legislative Efforts to Create a Post-Grant Patent Quality Control System* 31(4) AIPLA Q. J. 435 (October 2003).

⁴³ *Supra* note 16.

⁴⁴ *Supra* note 42.

⁴⁵ FED. TRADE COMM’N, *TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY: A REPORT BY THE FEDERAL TRADE COMMISSION* 8 (2003).

⁴⁶ ADAM B. JAFFE AND JOSH LERNER, *INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT* 192-193 (Princeton University Press, Oxfordshire, 3rd ed. 2007).

⁴⁷ Eric Williams, *Remembering the Public’s Interest in the Patent System—A Post-Grant Opposition Designed to Benefit the Public*, B.C. INTELL. PROP. AND TECH. F. 8 (November 2006) <http://bcipf.org/wp-content/uploads/2011/07/27-EricWilliamsIPTF2006.pdf>.

⁴⁸ *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 350 (1971).

sharing the financial burden of court proceedings.⁴⁹ Consequently, the public good phenomenon discourages ‘challenges from competitors that know they can free-ride on another party’s success’.⁵⁰

Fourth, judges are inadequately equipped with the knowledge of technology. Patent documents are written in a highly technical language. It is argued that ‘judges are poorly equipped to read patent documents and construe technical patent claims’.⁵¹ With limited technical knowledge, judges or juries might face serious difficulties ‘when it comes to evaluating competing testimony about the originality of a technical accomplishment’.⁵² Patent cases are not only technically sophisticated but also technology changes from case to case.⁵³ Kimberly A. Moore noted that ‘judges are not ... capable of resolving these issues with sufficient accuracy’.⁵⁴ Judges are ill-equipped to deal with these technically complex issues because ‘most judges have no special knowledge, education or training in the technology that is at issue in a patent case’.⁵⁵ Pre-grant patent opposition not only takes advantage of the Controller’s technical expertise but also preserves judicial time and prevents unnecessary backlog in the judicial system. More importantly, in contrast to courts, which can only uphold or invalidate a patent, patent opposition offers increased flexibility as the patent office can confirm the patent, cancel it, or require it to be amended. It can compel an applicant to narrow the contested claims.⁵⁶

This study supports India’s approach of providing pre-grant opposition procedures because the best way to address the issue of low-quality patents is within the patent office at the examination stage. India complemented its pre-grant opposition procedures with a more formal post-grant opposition. I support this additional safeguard because some low-quality patents may be improperly granted or slip through. Post-grant opposition proceedings provide a quicker, cheaper, and easier option to reverse the issuing mistakes as compared to costly, protracted, and cumbersome patent litigation which unjustifiably favours holders of patents because of a strong presumption of validity.

⁴⁹ MICHAEL A. CARRIER, *INNOVATION FOR THE 21ST CENTURY: HARNESSING THE POWER OF INTELLECTUAL PROPERTY AND ANTITRUST LAW* 210 (Oxford University Press, 2011).

⁵⁰ *Id.*

⁵¹ Doug Lichtman and Mark A. Lemley, *Rethinking Patent Law’s Presumption of Validity*, 60 *STAN. L. REV.* 67 (October 2007).

⁵² *Id.*

⁵³ Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 15 *HARV. J. OF LAW AND TECH.* 30 (September 2001).

⁵⁴ *Id.* 38.

⁵⁵ Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 *MICHIGAN L. REV.* 374 (May 2000).

⁵⁶ *Supra* note 49.

II. THE ADDITIONAL SAFEGUARD OF A MORE FORMAL INTER-PARTES POST-GRANT OPPOSITION PROCEDURE

Post-grant opposition proceedings in India provide for an inter-partes procedure where the opponent is a party to the proceedings. The rights of the opponent are, therefore, not dependent on the discretion of the Controller. As compared to pre-grant opposition procedures, post-grant opposition procedures are more formal and detailed. As these proceedings are instituted after the grant of the patent, unlike pre-grant opposition, they are not an extension of the patent application procedure.

Before going into details of post-grant opposition proceedings, it is important to note that neither the principle of *res judicata* nor the doctrine of *stare decisis* is applicable to post-grant opposition proceedings in India.⁵⁷ Logically speaking, as the opponent is not a party to the proceedings in the pre-grant opposition, the principle of *res judicata*, which bars further proceedings between the ‘same parties’ on the same subject matter,⁵⁸ should not apply to post-grant opposition proceedings in India. The Controller held in *Shogun Organics Ltd. v. Endura SPA* case that the doctrine of *stare decisis* is also not applicable to the post-grant opposition proceedings because the claims disputed in pre-grant and post-grant opposition are different.⁵⁹ In post-grant opposition proceedings, the granted claims of the impugned patent are challenged by the opponents whereas in pre-grant opposition the claims as filed are challenged.⁶⁰

Filing a notice of opposition in a prescribed manner is the first step in initiating post-grant opposition proceedings. Notice of post-grant opposition can be filed to the Controller by ‘any person interested’.⁶¹ For maintainability of post-grant proceedings, the opponent’s nature of interest needs to be within the ambit of section 2(1)(t) of the Patents Act which defines ‘person interested’. The notice of opposition can be filed ‘[a]t any time after the grant of patent but before the expiry of one year from the date of publication of grant of a patent’⁶² in the official

⁵⁷ *Shogun Organics Ltd. v. Endura SPA*, 2014 SCC IPAB 6 (India).

⁵⁸ The Code of Civil Procedure 1908, §11 (India).

⁵⁹ *Shogun Organics Ltd. v. Endura SPA*, 2014 SCC IPAB 6 (India).

⁶⁰ *Id.*

⁶¹ The Patents Act, 1970, No. 39, Acts of Parliament, 1970, §25(2) (India).

⁶² *Id.*

journal. Unlike the pre-grant opposition, post-grant opposition proceedings cannot be instituted free of charge. The opponent is required to pay the prescribed fee.⁶³

The post-grant opposition can be filed on the grounds provided in section 25(2) which provides an exhaustive list of grounds of pre-grant opposition by specifically stating ‘but on no other ground’.⁶⁴ The additional grounds added to the opposition after the prescribed time limit are not allowed.⁶⁵

Along with the notice of opposition, the opponent shall send a written statement of opposition in duplicate setting out the nature of the opponent’s interest, the facts upon which she bases her case, the relief sought and evidence, if any.⁶⁶ In *Boehringer Ingelheim Pharma GMBH & Co. v. Cipla Ltd.* case, an important question was raised whether the requirement of evidence to be filed under rule 57 is optional or mandatory.⁶⁷ The patentee argued that it is a well-settled principle in patent law that it is the challenger who has to discharge the onus through the filing of verifiable evidence while dealing with invalidity grounds.⁶⁸ The patentee further argued that under section 79 of the Patents Act, the evidence before the Controller shall be given by way of affidavit.⁶⁹ The patentee, therefore, asserted that in the ‘absence of having filed evidence by way of affidavit, the oral arguments made by the opponent’s legal counsel before the Controller at the hearing cannot take the place of evidence or pleadings’.⁷⁰

The opponent, on the other hand, contended that under rule 57, the filing of evidence is not mandatory and the ‘decision about its filing is left to the opponent and the merits of the documentary evidence supporting the written statement’.⁷¹ The opponent contended that ‘the Controller is a creature of the patent law’ who is appointed to the position due to her technical qualifications and she determines the patentability of an invention without hiring the services of an expert.⁷² The expert affidavit is, therefore, not necessary if sufficient documentary evidence has been provided.⁷³ The Controller ruled that ‘the requirement of evidence to be filed is optional. If the opponent is successful in proving obviousness on the basis of documents in

⁶³ *Id.*

⁶⁴ (The grounds of filing pre-grant opposition and post-grant opposition are similar in India).

⁶⁵ *M/s F. Hoffmann LA Roche AG v. M/s Ranbaxy Laboratories Ltd. and Others*, 959/MAS/1995, 27.

⁶⁶ Patents Rules, 2003, r 57 (India).

⁶⁷ *Boehringer Ingelheim Pharma GMBH and Co. v. Cipla Ltd.*, 558/DEL NP/2003, 15.

⁶⁸ *Id.*

⁶⁹ *Id.* at 16.

⁷⁰ *Id.* at 19.

⁷¹ *Id.*

⁷² *Id.* at 24.

⁷³ *Id.* at 23.

combination with the common general knowledge, then additional evidence may not be required'.⁷⁴ The evidentiary standards in post-grant opposition proceedings are, therefore, less strict as compared to patent litigation.

On receipt of notice of opposition, the Controller is required to notify the patentee⁷⁵ and constitute an Opposition Board.⁷⁶ The language of rule 56 of the Patents Rules suggests that the constitution of the Opposition Board is a mandatory requirement and it is not dependent on the discretion of the Controller. The Controller is, however, not bound by the recommendations of the Board.⁷⁷

On the completion of the presentation of evidence from both parties and on receiving the recommendation of the Opposition Board, the Controller fixes a date and time for the hearing of the opposition in the exercise of her discretionary powers under the rules. The Controller gives the parties at least ten days' notice of such hearing and may require members of the Opposition Board to be present at the hearing.⁷⁸ If either party to the proceedings desires to be heard, she needs to inform the Controller by a notice.⁷⁹

After hearing the party or parties desirous of being heard, the Controller decides the opposition and notifies her decision to the parties. The Patents Act and the Patents Rules do not prescribe a time limit for the Controller to decide the opposition after completion of the proceedings. Both the patent holder and the opponent have a right to appeal the decision of the Controller in the post-grant opposition proceedings because the opponent is a party to the proceedings and enjoys all rights and privileges.⁸⁰ The appeal can be made to the Intellectual Property Appellate Board (IPAB) within three months from the date of the Controller's decision.⁸¹

India has, therefore, supplemented its less formal pre-grant opposition proceedings with more formal post-grant opposition proceedings where the opponent is a party to the proceedings and gets a proper opportunity to make her case and to appeal the decision if not satisfied with the Controller's decision. This study supports India's approach of providing this additional safeguard

⁷⁴ *Id.* at 76.

⁷⁵ The Patents Act, 1970, No. 39, Acts of Parliament, 1970, §25(3)(a) (India).

⁷⁶ *Id.* §25(3)(b).

⁷⁷ Patents Rules, 2003, r 62(5) (India).

⁷⁸ *Id.* r 62(1).

⁷⁹ *Id.* r 62(2).

⁸⁰ The Patents Act, 1970, No. 39, Acts of Parliament, 1970, §117A (2) (India).

⁸¹ *Id.* § 117A(4).

because for third parties, especially civil society organizations, administrative post-grant proceedings are a far more viable option to challenge the validity of questionable patents as compared to costly and cumbersome patent litigation.

III. INDIA'S PATENT OPPOSITION MODEL LACKS CLARITY AND LEGAL CERTAINTY

A. Lack of Clarity Regarding Date of Grant of Patent

The date of grant of patent is crucial when it comes to filing a pre-grant or post-grant opposition. The Patents Act, under section 25(1), confers an unrestricted and complete right on any member of the public to file pre-grant opposition any time after the publication of a patent application and before the grant of the patent but the date of the grant of patent remains controversial. This controversy or confusion regarding the date of grant of patent is rooted in the fact that there is no statutory provision in the Act, and/or in the Rules framed thereunder, regarding the date of grant of a patent.

The grant procedure in India comprises of the following four stages: (a) Grant by controller on patent file; (b) According of serial number to the patent; (c) Entry of grant in the register of patent and issuance of letter of patent; and (d) Publication of grant under section 43(2) of the Patents Act.⁸² The grant procedure completes with the completion of these four stages.⁸³ There is a difference between 'in order for grant of patent' and 'grant of patent'. This distinction was highlighted in *Pfizer Products Inc. v. Natco Pharma Ltd.* case.⁸⁴ The patent applicant agitated the issue of considering the opposition proceeding only under post-grant opposition because of the fact that the patent application was found 'in order for grant of patent' before the pre-grant opposition was filed. The patent applicant argued that 'in order for grant of patent' by the Controller is equivalent to 'grant of patent' and therefore no pre-grant opposition should be allowed and letters patent should be issued to the patent applicant.⁸⁵ The Controller concluded that section 43 has clearly distinguished between a patent that has been found to be 'in order for grant of patent' and the 'grant of patent'. The time gap between these two activities is actually allowed by the law to complete the official formalities.⁸⁶ In the instant case, the opposition was taken as pre-grant opposition because section 25(1) clearly defines the time limit for opponents

⁸² *Supra* note 9, 112.

⁸³ *Id.*

⁸⁴ *Pfizer Products Inc. v. Natco Pharma Ltd.*, 537/DEL/1996.

⁸⁵ *Id.*

⁸⁶ *Id.*

to file a pre-grant opposition up to grant of a patent and the patent could not be granted in this case before the pre-grant opposition was filed.⁸⁷

Another issue related to grant of patent was raised in *M/s Tibotec Pharmaceuticals Ltd. v. M/s Cipla Ltd.* case where the patent applicant submitted that the patent is granted by ‘the letter of notification of grant’ by the Patent Office to the patent applicant and not by ‘the issuance of the Patent Certificate’.⁸⁸ The applicant argued that the date of issuance of the letter of notification of grant is the date of grant of a patent after which pre-grant procedures cease to apply. After this date, any opposition has to be made as a post-grant opposition. The applicant cited the case of *Nokia Mobile Phones (UK) Ltd. Application* (19961 RPC 733) where it was held by the Court that the Patent Office did not have the power to withdraw an application once notification of grant had been issued.⁸⁹ The applicant argued that the issuance of Patent Certificate was merely an evidence of the grant. The applicant referred to the ruling of the Honourable Supreme Court of India in various matters where it has time and again held that ‘[w]e must always remember that procedural law is not to be a tyrant but a servant, not an obstruction but an aid to justice. It has been wisely observed that procedural prescriptions are the hand-maid and not the mistress, a lubricant, not a resistant in the administration of justice’.⁹⁰ The applicant submitted that non-issuance of Patent Certificate, which is merely a procedural formality, ought not to take away a substantive right that accrued to the applicant for patent upon grant.⁹¹

The opponent, on the other hand, argued that letter of the grant was not issued under any statutory obligation and was merely a good gesture from the Patent Office to intimate the applicant that the application has been found in order for grant. The opponent further argued that there were several instances where the Patent Certificate was directly issued without the issue of such a letter.⁹² The Controller, in his decision, referred to section 43 which stipulates that ‘where an application for a patent has been found to be in order for grant of the patent ... The patent shall be granted as expeditiously as possible to the applicant ... with the seal of the patent office and the date on which the patent is granted shall be entered in the register’.⁹³ The Controller also referred to Rule 74 which provides that ‘[t]he patent certificate shall ordinarily be

⁸⁷ *Id.*

⁸⁸ *M/s Tibotec Pharmaceuticals Ltd. v. M/s Cipla Ltd.*, India, 1647/DELNP/2000, 3.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

issued within seven days from the date of grant of a patent under section 43'.⁹⁴ The Controller identified following three activities for a final grant of Patent: (a) Application must be found in order of grant; (b) Seal of Patent Office must be put or Letters Patent should be generated; and (c) Date of the grant must be entered in the register.⁹⁵

The Controller noted that there may be a time lag in the application found in order of grant and finally grant of patent. In the case at hand, the letter issued by the Patent Office stated: 'Your above Application for patent has been found in order for grant. However, the Patent Certificate will be issued only after processing of the Application under Section 11(a) and completion of the statutory limit and disposal of pre-grant opposition, if any'.⁹⁶ The Controller held that the opponent had a right to file pre-grant opposition because the patent had not been granted and there were further conditions that needed to be fulfilled.⁹⁷

To make things easier, the Controller noted in *Sanofi Synthelabo v. Glenmark Pharmaceuticals Ltd.* case that both pre- and post-grant oppositions are linked to the public notification process.⁹⁸ The pre-grant opposition 'can be filed only after the notification of the application in the Patent Office Journal and the post-grant opposition can be filed only after the notification of the grant in the Patent Office Journal'. The public is aware of the grant only when the grant of a specific patent has been notified in the Patent Office Journal. Only after the notification of the grant, the public becomes conscious that the option of pre-grant opposition has been lost.⁹⁹

The issue of the distinction between grant and publication was raised again in the *M/s SKC Ltd. v. M/s Mandalapu Nageshwara Rao* case.¹⁰⁰ The Controller noted that under section 25(2), post-grant opposition can be filed '[a]t any time after the grant of patent but before the expiry of a period of one year from the date of publication of the grant of patent'.¹⁰¹ The Controller noted that it is clear from the wording of section 25(2) that the grant of patent and publication of the said grant are altogether different activities. Since the post-grant opposition under section 25(2) can be filed after the grant of a patent but before completion of one year from the date of publication of the said grant, this means that the total time to file a post-grant opposition is one year plus 'some days'. The phrase 'some days' means the time period between the grant and the

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Sanofi Synthelabo v. Glenmark Pharmaceuticals Ltd.*, 414/KOL-NP/2004, 9.

⁹⁹ *Id.*

¹⁰⁰ *M/s SKC Ltd. v. M/s Mandalapu Nageshwara Rao*, 1544/DELNP/2004, 5.

¹⁰¹ The Patents Act, 1970, No. 39, Acts of Parliament, 1970, §25(2) (India).

publication thereof. The said 'some days' are actually required for technical preparation of the grant publication in the official journal.¹⁰² The Controller observed that if the intention of the legislature was to make the date of publication as the date of grant of patent, then the prescribed time period for filing a post-grant opposition should have been one year from the date of publication.¹⁰³

It is clear from these cases that India's patent laws and rules lack clarity regarding date of grant of patent. Parties have repeatedly contested this issue during proceedings. Addressing this question during proceedings results in unnecessary delays and adversely impacts the speed efficiency of the Indian patent opposition model.

B. Lack of an Exhaustive Definition of 'Person Interested'

Notice of post-grant opposition can be filed by 'any person interested'.¹⁰⁴ 'Persons interested' has been defined in the Patents Act as 'person interested includes a person engaged in, or in promoting, research in the same field as that to which the invention relates'.¹⁰⁵ Interpretation of this provision has been an issue in several cases because the section does not provide any exhaustive definition of the phrase 'person interested' but it gives a very wide meaning of the same. A person engaged in, or in promoting research in the same field has a very wide meaning. The interest may vary from case to case. Moreover, this definition of 'person interested' does not differentiate between a natural person and a legal entity to file the post-grant opposition under the Act. The definition is wide enough to include both a natural person and a juridical person or a legal entity like a company or an organization.

There are a number of cases in India where patentee challenged the eligibility of the opponent to file post-grant opposition. In *Shogun Organics Ltd. v. Endura SPA* case, the patentee argued that the opponents did not qualify the definition of 'Persons interested'. The opponents manufactured and sold mosquito repellents whereas the invention in question, related to the process of manufacturing d-trans Allethrin. The fact that said chemical was used by the opponents in their mosquito repellents did not make them 'Persons interested' in the process of manufacturing d-trans Allethrin because the manufacture of an end product is different from the manufacture of chemical/active ingredient used in the end product.¹⁰⁶ The opponents, on the

¹⁰² M/s SKCLtd. v. M/s Mandalapu Nageshwara Rao, 1544/DELNP/2004, 5.

¹⁰³ *Id.*

¹⁰⁴ The Patents Act, 1970, No. 39, Acts of Parliament, 1970, §25(2) (India).

¹⁰⁵ *Id.* § 2(1)(t).

¹⁰⁶ *Id.*

other hand, contested this assertion and referred to the book *Patent Law*.¹⁰⁷ In the context of the *locus standi* of person interested, the author of this book cited the case of *Merron's Appln*¹⁰⁸ wherein it was observed that there are following three clear grounds upon which an opponent can establish *locus standi* to oppose: (a) the possession of patents relating to the same matter as the application opposed; (b) a manufacturing interest; and (c) a trading interest.¹⁰⁹ The Controller agreed with the citation quoted from Narayanan's book. The Controller noted that '[p]atents are for development of technology and are one of the major driving forces of trades and industries. Therefore, a person need not be a researcher alone in order to oppose a patent'.¹¹⁰ The Controller further noted that '[i]t would be sufficient, if he is manufacturer or trader of the same substances or of substances which are derived from the substances of impugned patent'.¹¹¹ The Controller rejected the argument of the patentee and held that the opponents are qualified as 'Persons interested' within the meaning of the Patents Act 1970.

The question of *locus standi* was also raised in *M/s. Lambda Eastern Telecommunications Ltd. v. M/s. ACME Telepower Pvt. Ltd.* case. In this case, the Controller observed that 'the definition is inclusive in nature. Any person including an organization that has a manufacturing or trading interest in the goods connected with the patented article or who has a financial interest in manufacturing such goods or who possesses patents related to the same subject, is considered a person interested'.¹¹²

The same question was raised again in *M/s F. Hoffmann La Roche AG M/s Ranbaxy Laboratories Ltd. and Others* case,¹¹³ where DNP+ opposed an HIV drug patent arguing that an organization representing persons living with HIV is included in the ambit of 'person interested' as defined in the Patents Act.¹¹⁴ The patentee, on the other hand, argued that DNP+ was not a 'person interested' within the meaning of section 2(1)(t) of the Patents Act as DNP+ had no manufacturing, trading or research interest in the invention.¹¹⁵ The Controller referred to the *Ajay Industrial Corporation v. Shiro Kansa* case¹¹⁶ in which the Court had observed that 'a person interested ... must be a person who has a direct, present and tangible commercial interest or

¹⁰⁷ PARAMESWARAN NARAYANAN, *PATENT LAW* ¶ 8 to 13 (183 Eastern Law House, Kolkata, 1985).

¹⁰⁸ *Merron's Appln.* (1944) 61 R.P.C. 92 (C.-G.)

¹⁰⁹ *Endura Spa of Viale Pietramellara v. Manaksia Ltd.*, 897/MUM/2007, 10.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *M/s F. Hoffmann La Roche AG v. M/s Ranbaxy Laboratories Ltd. and Others*, 959/MAS/1995.

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Ajay Industrial Corporation v. Shiro Kansa*, AIR Del 496, (1983).

public interest which is injured or affected by the continuance of the patent on the register'.¹¹⁷ The Controller held that DNP+ was a 'person interested' as its public interest was affected or injured by the continuance of the patent on the register.

The *Sankalp Rehabilitation Trust* case involved a detailed discussion on whether or not a non-governmental or non-profitable organization qualifies as a 'person interested'. The counsel for the Respondent submitted that the 'person interested' might be a person in business or a person who might be a potential infringer. The counsel argued that the Indian legislature had specifically confined *locus standi* to 'person interested' for filing a post-grant opposition.¹¹⁸ To support this argument, the counsel referred to section 2(1)(t) of the Act.¹¹⁹ The counsel also referred to the observations of the Delhi High Court which had observed that 'the legislature appears to have consciously denied to a third party a further statutory remedy of a post-grant opposition in the event of such third party not succeeding in the pre-grant stage'.¹²⁰

The counsel further contended that the 'interest' needs to be a genuine commercial interest.¹²¹ The counsel contended that a non-profitable organization working for the benefit of drug users could not be said to have any interest in the nature as required by the Patents Act.¹²² The counsel submitted that a wide interpretation of the words 'person interested' would mean that any person making a very broad claim of acting in the arena of public health would be entitled to maintain a post-grant opposition. The counsel further submitted that the consideration of public interest could not be accepted because there were several safeguards inbuilt in the Patents Act to protect the public interest.¹²³ He argued for a narrow interpretation of the words so that only a person with a real, tangible and clearly perceived interest in the patent could be allowed to maintain the post-grant opposition.¹²⁴

In response, the counsel for the Appellant submitted that the Appellant was a community-based organization that provided care, support, and treatment for drug users. The counsel argued that the Appellant was definitely a 'person interested' because the patent in question was in respect of a prohibitively expensive medicine for Hepatitis-C which was out of reach of the

¹¹⁷ *Id.*

¹¹⁸ *Sankalp Rehabilitation Trust v. F. Hoffmann La Roche AG and Others*, (2012) SCC OnLine IPAB 167 (India).

¹¹⁹ *Id.*

¹²⁰ *UCB Farchim CA v. Cipla Ltd. and Ors*, 42 PTC 425 (Del.) (2010), 3-4.

¹²¹ (The UK Court of Appeal held in *Globe Industries Corporation's Patent* [1977 RPC 563] that not only should the interest be a commercial interest, it must be a genuine interest and there must be an existence of real prejudice).

¹²² *Sankalp Rehabilitation Trust v. F. Hoffmann La Roche AG and Others*, (2012) SCC OnLine IPAB 167 (India).

¹²³ *Id.*

¹²⁴ *Id.*

community for whom the Appellant worked.¹²⁵ The counsel submitted that the word ‘interested’ needed to be construed so as to mean an opponent having an interest in the grant of a particular patent. The counsel argued that in the entire Patents Act there was a public interest element and such construction was more protective of public interest.¹²⁶

The IPAB observed that in *Ajay Industrial Corporation v. Shiro Kanao*,¹²⁷ the Delhi High Court had held that ‘a person interested within the meaning of section 64 must be a person who has a direct, present and tangible commercial interest or *public interest which is injured or affected by the continuance of the patent on the register* (Emphasis added).¹²⁸ The IPAB also quoted the decision of the Central Intellectual Property and International Trade Court of Thailand in *AIDS Access Foundation and Others v. Bristol-Myers Squibb and Another*¹²⁹ in which it was held that ‘the injured parties from the grant of a patent are not limited to the manufacturers or the sellers of medicine protected by the patent. The patients or those in need of the medicine are also interested parties to the grant of the patent’.¹³⁰

The Board reasoned that a common-sense approach must be taken to construe the interest that the opponent has in opposing the grant of a patent:

*In the present case... The continuance or removal of the patent will definitely affect the interest of the community for whom the appellant claims to work. The appellant has challenged the patent on several grounds, if the challenge succeeds, the monopoly will be broken. This is something the appellant is interested in, since it will bring the drug within the reach of the community for whom it works.*¹³¹

The Board reasoned that ‘public interest is a persistent presence in intellectual property law and will not melt into thin air, nor dissolve’.¹³² The Board held that the Appellant, who worked for a community which needs the medicine, was definitely a ‘person interested’. The Board noted that:

¹²⁵ *Id.* at 5.

¹²⁶ *Id.*

¹²⁷ *Ajay Industrial Corporation v. Shiro Kanao*, AIR Del 496 (1983).

¹²⁸ *Sankalp Rehabilitation Trust v. F. Hoffmann La Roche AG and Others*, (2012) SCC OnLine IPAB 167. (India).

¹²⁹ [Central Intellectual Property and International Trade Court of Thailand], Black Case No. Tor Por 34/2544, Red Case No. Tor Por 93/2545, (2002) (Thailand).

¹³⁰ *Sankalp Rehabilitation Trust v. F. Hoffmann La Roche AG and Others*, (2012) SCC OnLine IPAB 167. (India).

¹³¹ *Id.* at 10.

¹³² *Id.*

*The interest should not be a fanciful interest. ... In the present case, the appellant claims that it is a society which works for the community ... The continuance or removal of the patent will definitely affect the interest of the community for whom the appellant claims to work.*¹³³

It is clear from these cases that interpretation of ‘person interested’ has been an issue in India and it has caused unnecessary delays in several cases.

C. Lack of Clarity About the Withdrawal of Patent Opposition

Whether or not the withdrawal of opposition can be allowed in post-grant opposition proceedings is an important question of law. This question was raised in the *Virgin Atlantic Airways Ltd. v. Jet Airways (India) Ltd.* case.¹³⁴ The opponent and the patentee arrived at a settlement and in consequence thereof, the opponent wanted to withdraw the notice of post-grant opposition. To answer this question of law, the Controller relied on some important orders. The Controller referred to *Rajendra Prasad Gupta v. Prakash Chandra Mishra and Ors.*¹³⁵ In this case, the Court held that ‘Section 151 (Code of Civil Procedure, 1908) gives inherent powers to the court to do justice – it has to be interpreted to mean that every procedure is permitted to the court for doing justice unless expressly prohibited, and not that every procedure is prohibited unless expressly permitted’.¹³⁶

In *Narsingh Das v. Mangal Dubey* case,¹³⁷ the Court observed that ‘Courts are not to act upon the principle that every procedure is to be taken as prohibited unless it is expressly provided for by the Code, but on the converse principle that every procedure is to be understood as permissible till it is shown to be prohibited by the law. As a matter of general principle, prohibition cannot be presumed’.¹³⁸ Relying upon above-mentioned orders, the Controller ruled that there is no express provision in the Patents Act and Rules for prohibiting the withdrawal of notice of post-grant opposition by the parties. There is no bar on considering withdrawal of post-grant opposition proceedings.¹³⁹ The Controller, however, noted that requests for withdrawal of notice of opposition have to be filed along with a Petition. Post-grant opposition proceedings are quasi-judicial proceedings and merely sending a plain letter to the Patent Office stating the intention of

¹³³ *Id.* at 11.

¹³⁴ *Virgin Atlantic Airways Ltd. v. Jet Airways Ltd.*, 500/CHENP/2004.

¹³⁵ *Rajendra Prasad Gupta v. Prakash Chandra Mishra and Ors*, 2 SCC 705 (2011).

¹³⁶ *Id.*

¹³⁷ *Narsingh Das v. Mangal Dubey*, ILR 5 All 163 (1882).

¹³⁸ *Virgin Atlantic Airways Ltd. v. Jet Airways Ltd.*, 500/CHENP/2004, 4.

¹³⁹ *Id.* at 6.

withdrawal of the opposition proceedings cannot be considered as cognisable.¹⁴⁰ Since the Patents Act/Rules do not prescribe a specific petition for withdrawal of opposition, the opponent submitted a miscellaneous Petition along with the prescribed fee.¹⁴¹

D. The Key Term ‘Enhanced Efficacy’ is Not Defined

Sections 25(1)(f)/25(2)(f) and 25(1)(e)/25(2)(e) link the Indian opposition proceedings with India’s unique substantive threshold provisions like sections 3(d) and s 2(ja). Section 3(d) excludes trivial modifications of known substances from patent eligibility in India unless they satisfy the condition of ‘enhanced efficacy’.¹⁴² The important term, efficacy, is not defined in the Indian patent laws or patent office guidelines. There are no guidelines or clear legal standards to understand what constitutes ‘enhanced efficacy’.

In *Novartis v CIPLA Ltd.*, a pre-grant opposition filed on July 5, 2005, the opponent argued that the alleged invention did not meet the patentability standards under section 3(d) of the Patents Act because it was only a polymorphic form of the known substance with no enhancement of known efficacy as the specification stated that all its pharmacological effects were also found with the free base.¹⁴³ In response to arguments of the opponent regarding ‘enhanced efficacy’, the agent of the patent applicant asserted that Beta-crystalline form of Imatinib Mesylate was not a mere discovery, but an invention.¹⁴⁴ The Controller ruled that subject matter of patent application was not patentable under section 3(d) of the Act. The patent application did not claim a new substance. It was only a new form of a known substance and failed to prove any significant enhancement of known efficacy.¹⁴⁵ The Controller reasoned that mere 30% difference in bioavailability might be due to the difference in the solubility in water.¹⁴⁶

Novartis AG, aggrieved by the decision, appealed to the Madras High Court and contended that Beta-Crystalline form of Imatinib Mesylate was not a mere discovery of a new form of a known substance but an invention because the beta-crystal form could not be achieved without human intervention and ingenuity as there was nothing in the prior art to suggest how to make this new form.¹⁴⁷ On November 13, 2007, IPAB was directed by the Madras High Court to

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 7.

¹⁴² The Patents Act, 1970, No. 39, Acts of Parliament, 1970, §3(d) (India).

¹⁴³ *Novartis AG v. Cipla Ltd.*, (2015) 64 PTC 488 (India).

¹⁴⁴ *Id.* at 4.

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Novartis AG v Union of India and Others*, (2013) 6 SCC 1 (India).

constitute a special bench to hear the Novartis' appeal. The IPAB upheld the decision of the Controller and found that Novartis' patent application did not meet the patentability standards set under s 3(d) of the Patents Act.¹⁴⁸ The Board stated that the Madras High Court had already defined the term 'efficacy' as 'therapeutic effect in healing a disease or having a good effect on the body' keeping in view the intent of the legislature to prevent 'evergreening' of pharmaceutical patents.¹⁴⁹ The Board observed that bioavailability was not the same as therapeutic efficacy because therapeutic efficacy was different from the advantageous property of a drug.¹⁵⁰ The demonstration of a 30% increase in bio-availability of the subject compound by the patent applicant did not establish actual enhancement of known efficacy.¹⁵¹

Novartis AG, aggrieved by the decision, approached the Supreme Court of India and filed a special leave petition, under Art. 136 of the Constitution of India,¹⁵² to appeal the decision of the IPAB. Novartis AG contended that Glivec or Beta-Crystal form of Imatinib Mesylate was without precedent because prior to Glivec, no other form of Imatinib Mesylate had shown efficacy in Chronic Myeloid Leukemia.¹⁵³ Novartis AG further contended that the scope of the term 'efficacy' could not be narrowed down to only mean clinical efficacy. The enhanced efficacy could be demonstrated by various technical features of a new form.¹⁵⁴ Furthermore, Novartis argued that in the field of pharmacology, with 20-25% increase in bio-availability, a substance is not considered bioequivalent with another compound under comparison and cannot, therefore, be termed as the 'same substance' because enhanced bio-availability leads to enhanced efficacy.¹⁵⁵

The Supreme Court noted that 'efficacy' means 'the ability to produce a desired or intended result' and in the case of a medicine, the test of efficacy can only be 'therapeutic efficacy'.¹⁵⁶ The Court observed that the explanation to section 3(d) required the derivative to 'differ significantly in properties *with regard to efficacy* (Emphasis added)' which in the case of

¹⁴⁸ *Id.* at 10(v).

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² (Art. 136 of the Constitution of India deals with special leave to appeal by the Supreme Court. It provides that '(1) Notwithstanding anything in this Chapter, the Supreme Court may, in its discretion, grant special leave to appeal from any judgment, decree, determination, sentence or order in any cause or matter passed or made by any court or tribunal in the territory of India. (2) Nothing in clause (1) shall apply to any judgment, determination, sentence or order passed or made by any court or tribunal constituted by or under any law relating to the Armed Forces').

¹⁵³ *Novartis AG v Union of India and Others*, (2013) 6 SCC 1 (India).

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

medicine was its therapeutic efficacy.¹⁵⁷ As regards the issue of 30% increase in bioavailability, the Court reasoned that just increased bioavailability alone might not necessarily lead to an enhancement of therapeutic efficacy.¹⁵⁸ On April 1, 2013, the Supreme Court ruled that the Beta-Crystalline form of Imatinib Mesylate failed the test of section 3(d).¹⁵⁹ It is important to note that it took nearly eight years, from July 5, 2005, to April 1, 2013, to determine what constitutes efficacy under section 3(d).

Section 2(ja) adds additional requirements of ‘technical advance’ and ‘economic significance’ to the inventive step threshold. The important terms, ‘technical advance’ and ‘economic significance’, are also not defined in the Indian patent laws or patent office guidelines. In order to make patent validity challenges time-efficient and in order to minimize the chances of arbitrary use of powers by patent examiners in terms of interpreting ss 3(d) and 2(ja), India should provide guidelines or clearer legal standards to understand what constitutes ‘enhanced efficacy’, ‘technical advance’ and ‘economic significance’.

IV. CONCLUSION

India’s pre-grant opposition procedures provide a less formal and less costly means of gathering crucial information from third parties. The pre-grant opposition mechanism provided under section 25(1) of the Patents Act 1970 and rule 55 the Patents Rules 2003, is not designed to make the opponent a party to the proceedings.¹⁶⁰ The Patents Act and the Patents Rules do not contain any provision that imposes the burden of proof on the opponent in pre-grant opposition proceedings.¹⁶¹ More importantly, India’s pre-grant opposition proceedings have a ‘prevention is better than cure approach’ because low-quality patents do not make it to grant if opposed successfully at the stage of examination. The best way to address the issue of low-quality patents is, therefore, within the patent office at the examination stage.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* at 188.

¹⁵⁹ *Id.* at 195.

¹⁶⁰ (Patents (Amendment) Ordinance 2004 provided for pre-grant representation under s 25. Section 25(2) of the Ordinance specifically stated that ‘the person making a representation referred to in that sub-section shall not become a party to any proceedings under this Act only for the reason that he has made such representation’. Though s 25 was amended under the Patents (Amendment) Act 2005 to provide for pre-grant opposition proceedings and new provision was silent on whether or not the pre-grant opponent is a party to the proceedings, the previous provision can still be used to show the intent of the legislature).

¹⁶¹ *Anglo Operations Ltd. v. AIA Engineering Pvt. Ltd.*, 690/DEL/95, 10.

India complemented its pre-grant opposition procedures with a more formal inter-partes post-grant opposition. India's post-grant opposition proceedings are, however, less costly¹⁶² and less cumbersome as compared to patent litigation. The requirement of evidence to be filed is optional.¹⁶³ This study supports this additional safeguard because some low-quality patents may be improperly granted or slip through. Post-grant opposition proceedings provide a quicker, cheaper, and easier option to reverse the issuing mistakes as compared to costly, protracted, and cumbersome patent litigation which unjustifiably favours holders of patents because of higher evidentiary requirements.

This study found that India's patent opposition model lacks clarity and legal certainty. The date of grant of patent is crucial when it comes to filing a pre-grant or post-grant opposition. There is no statutory provision in the Patents Act or in the Patents Rules regarding the 'date of grant' of a patent.¹⁶⁴ Notice of post-grant opposition can be filed by 'any person interested'.¹⁶⁵ India's patent laws and rules do not provide an exhaustive definition of 'person interested'. Consequently, there are a large number of cases in India where patentee challenged the eligibility of the opponent to file post-grant opposition.¹⁶⁶ The Patents Act and Patent Rules are also completely silent on whether or not the withdrawal of notice of post-grant opposition by the parties can be allowed.¹⁶⁷

Sections 25(1)(f)/25(2)(f) and 25(1)(e)/25(2)(e) link the Indian opposition proceedings with India's unique substantive threshold provisions like section 3(d) and section 2(ja). India requires 'enhanced efficacy' for patent eligibility under section 3(d) of the Indian Patents Act.¹⁶⁸ The important term, efficacy, is neither defined in the Indian patent laws nor in the patent office guidelines. There are no guidelines or clear legal standards to understand what constitutes 'enhanced efficacy'. Furthermore, section 2(ja) defines inventive step as 'a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art'.¹⁶⁹

¹⁶² Patents Rules, 2003, Entry 9 of First Schedule (India).

¹⁶³ *Boehringer Ingelheim Pharma GMBH and Co. v. Cipla Ltd.*, 558/DELNP/2003, 76.

¹⁶⁴ *M/s Tibotec Pharmaceuticals Ltd. v. M/s Cipla Ltd.*, 1647/DELNP/2000, 2009, 3.

¹⁶⁵ The Patents Act, 1970, No. 39, Acts of Parliament, 1970, §25(2) (India).

¹⁶⁶ See, for instance, *Endura Spa of Viale Pietramellara v. Manaksia Ltd.*, 897/MUM/2007, 10; *M/s F. Hoffmann La Roche AG v. M/s Ranbaxy Laboratories Ltd. and Others*, 959/MAS/1995; *Sankalp Rehabilitation Trust v. F. Hoffmann La Roche AG and Others*, (2012) SCC OnLine IPAB 167. (India).

¹⁶⁷ *Virgin Atlantic Airways Ltd. v. Jet Airways Ltd.*, 500/CHENP/2004.

¹⁶⁸ The Patents Act, 1970, No. 39, Acts of Parliament, 1970, §3(d) (India).

¹⁶⁹ *Id.* §2(ja).

The important terms 'technical advance' and 'economic significance' are not defined in the Indian patent laws or patent office guidelines.