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CURTAILING ACCESS TO MEDICINES: DRAWBACKS OF DRAFT PATENTS (AMENDMENT) RULES,2023

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ABSTRACT

Patent opposition has been an important tool in the arsenal of civil societies and generic companies ensuring increasing access of medicines to the public. Indian Patent law provides for two-tier opposition mechanism: pre-grant opposition where an application for patent has been published but a patent has not been granted, and post-grant opposition can be filed after grant of patent but before expiry of one month. The present paper critically examines the role of patent opposition to safeguard access to medicines in India. It further examines how patent opposition serves as an important mechanism to ensure quality of pharmaceutical patents in the country. Undeserving patents, granted without effective opposition mechanisms, may lead to monopolies, and restrict competition, negatively impacting medicine availability and affordability. The paper explores the impact of patent opposition on medicine access, emphasizing its potential to enhance availability and affordability of medicines. Through legal analysis, case studies, and policy evaluations, the paper aims to provide an in-depth understanding of how patent opposition contributes to safeguarding medicine access, and try to find solution to challenges posed to these provisions from activists supporting stronger patent rights. Following the introduction, paper is divided into four parts. Part 1 discusses patent opposition mechanism under Indian Patent Law. Part 2 covers international agreements and national regulations governing patent opposition. Part 3 focuses on impact of patent opposition on medicines access with special focus on recent ruling of Indian Patent Office in rejection of secondary patent to the bedaquiline drug. Part 4 examines the proposed changes in patent opposition provisions, and how it might play a role in shaping the future of medicine accessibility to public in India.

Keywords: Patent Opposition, Access to Medicines, Patent Quality and Pharmaceutical Patents

1. INTRODUCTION

The last few decades have seen significant advancements in medical and pharmaceutical research that have improved both the quality of life and the treatment of diseases. However, access to these medicines is often restricted to specific segments of the population. The most vulnerable people cannot access the newer, better forms of medications that are on the market, despite their promise to treat a wide range of deadly, infectious, and non-communicable diseases. This is because the drugs are extremely expensive.[i] The monopoly rights granted to pharmaceutical products for incentivizing the inventor is one such cause for high cost of medicines. Public health is inherently a global challenge and assumes high priority for international cooperation.[ii]

In a developing country like India, where access to medicine can affect a large number of lives, the status of relationship between pharmaceutical patents and public health has for long been a subject of debate. Hitherto, India has

done a good job in balancing the interests of pharmaceutical innovation with the obligation of ensuring affordable medicines to its large population.

Patent Opposition has been one of the various key mechanisms, through which India has been able to safeguard access to medicines. Originally, prosecution framework provided opportunity for opposition only after grant of patent. In 2005, India streamlined its patent opposition system to provide two types of opposition- (a) pre-grant opposition against published application and post-grant opposition against a granted patent.[iii] As a result, under section 25(1), "any person" may now oppose a published patent application by submitting a representation to the Patent Office. This is commonly referred to as a "pre-grant opposition." According to section 25(2), only "person interested" may file an opposition to a granted patent within 12 months of grant. Typically, this is referred to as a "post-grant opposition." Grounds for opposition are same in both cases. By allowing stakeholders to oppose grant of patents that can potentially impede access to essential medicines, Indian patent opposition system has been a vital instrument in furthering public health goals.

Over the years, India has been pressurized by the developed countries for amending its patent opposition provisions in favor of patentee. The office of United States Trade Representative in its annual Special 301 Report has kept India in Priority Watch List for last many years. The most prominent concern of the US is "…confront(ing) costly and time consuming pre- and post-grant oppositions, long waiting periods to receive patent grants, and excessive reporting requirements."[iv] Under such prevailing conditions, on August 22, 2023, Ministry of Commerce and Industry proposed to change the opposition process and timelines.[v] Stakeholders have been claiming that proposed amendments, if accepted, would leave Patent Opposition provisions as a toothless tiger. These proposed changes have ignited discussions among policymakers, pharmaceutical companies, public health advocates, and legal experts regarding their implications for innovation, affordability, and access to healthcare.

In this paper, author undertake a comprehensive examination of patent opposition provisions and their role in safeguarding access to medicines in India. The author also analyses relevant patent opposition cases and their impact on access to medicines. Furthermore, author also examines the proposed changes and their potential ramification for access to medicines.

2. INTERNATIONAL FRAMEWORK

Unlike other industries, in pharmaceutical industries major share of revenue is spent on research and development. Hence, Patent opposition mechanism is often seen as impediment to enjoyment of monopoly rights by pharmaceutical companies. However, this patent opposition mechanism is in consonance with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

Firstly, the objective of the TRIPS Agreement itself states that the intellectual property rights should be protected and enforced in such a way that it benefits both producers and users of technological knowledge.[vi] Further, it also gives autonomy to its members, that while formulating or amending their law and regulations, they may adopt measures consistent with the other provisions of TRIPS Agreement, to protect public health and nutrition.[vii]

Secondly, the TRIPS Agreement requires that the granting or registration of the right must be done within a reasonable period of time.[viii] It also requires that the opposition procedures shall be governed by the general principles.[ix] Article 41.2 of the TRIPS Agreement mandates that the procedure concerning the enforcement of intellectual property rights shall be fair and equitable. Such procedure "shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays."[x]

Many countries like India, Australia, New Zealand, Pakistan and Israel have provided pre-grant opposition mechanism in their patent laws.[xi] Out of these countries, India has been able to leverage most out of pre-grant oppositions. Post-grant opposition is provided by almost every nation.

3. PATENT OPPOSITION IN INDIA

The Indian Patents Act provides opposition opportunity at two stages.

1) Where an application for a patent has been published but a patent has not been granted, any person, may, in writing, oppose with the controller against the grant of patent.[xii] The representation may be filed at any time

before the grant of patent.[xiii] The Patents Rules, 2003, provide that the patent office cannot grant a patent within six months from the date of publication. Thus, for filing the pre-grant opposition, minimum time that a person gets is six months from the date of publication.[xiv] "Any person" may file a representation for pre-grant opposition in India.[xv] Both natural person and legal person can file an opposition representation. Even a person who neither resides nor carries on business in India, may file for opposition proceedings by giving security for the costs of proceedings, if required by the controller.[xvi] The liberty to file pre-grant opposition by "any person" has been viewed with suspicion for potential misuse. Intellectual Property Appellate Board observed, "to curb the filing of pre-grant opposition by benami applicants, 'any person' filing the pre-grant opposition must submit his valid Aadhar Card/ Voter id Card/ Passport/ Driving Licence to authenticate his identity."[xvii] It also sought modification of E-filing system at Indian Patent Office, and rejection of all pending pre-grant opposition filed without proof of identity if same is not submitted within 15 days from period of such communication.[xviii]

The burden of proof does not lie upon the opponent in pre-grant opposition proceedings. The reason for not imposing burden of proof on the opponent is, because opponent is not made a party to the proceedings. Therefore, if the opponent omits to submit reply statement or evidence, it does not have any effect on the proceeding.[xix] For the same reasons hearing the opponent is not necessary in pre-grant opposition proceedings. The opponent while making the representation of opposition has to make a request for hearing too, if he desires so.[xx]

The opposition can be filed on any of the eleven grounds provided in Section 25(1). The list of grounds for opposition is exhaustive and includes inventions obtained wrongfully[xxi], prior publication[xxii], prior claiming[xxiii], publicly known or used in India before filing[xxiv], obviousness and clearly does not involve any inventive step[xxv], non-patentable subject matter[xxvi], insufficient disclosure[xxvii], failure to disclose information under section 8 of the Act[xxviii], failure to file the patent application within 12 months of filing the first application in convention country[xxix] and non-disclosure or wrongful disclosure of the source or geographical origin of the biological material as used in the invention[xxx]. The usual practice is several grounds provided under section 25(1) are raised, but only few of them are debated during hearing. Those grounds which are not debated in the opposition proceedings are held to be withdrawn.[xxxi]

After perusing the applicant's and the opponent's statement and supporting evidence, the parties' submissions, and, a hearing with the parties (only on prior request), the Controller may refuse to award a patent on the application, reject the representation, or demand that the entire specification and supporting documents be amended to his satisfaction before the patent is granted.[xxxii]

2) Once the patent has been granted, 'any person interested' has another opportunity to oppose such grant.[xxxiii] Such opposition has to be made before the expiry of one year from the date of publication of grant of a patent.[xxxiv] The opposition prior to grant of patent under section 25(1) is wider in scope than post-grant opposition as in the latter only the person aggrieved can oppose the grant of patent.[xxxv] Grounds for opposition are same as in pre-grant opposition. The notice of opposition has to be sent to the Controller in duplicate at the appropriate office.[xxxvi] The Controller shall, on receipt of notice, constitute a three-member Opposition Board and nominate one member as its Chairman.[xxxvii] Any examiner appointed under section 73 of the Patents Act, 1970 shall be eligible to be appointed as member of Opposition Board.[xxxviii] However, if such examiner has dealt with the patent application during the patent grant proceeding, shall be ineligible to be appointed as a member of the Opposition Board.[xxxix] Both opponent and the patentee are required to furnish statement and evidence to each other.[xl] Regarding the requirement of evidence, the Controller ruled that, "the requirement of evidence to be filed is optional. If the opponent is successful in providing obviousness on the basis of documents in combination with the common general knowledge, then additional evidence may not be required."[xli]

If the patentee does not express willingness to contest or leave his reply and the evidence within the period of two months from the date of receipt of copy of the written statement and Opponent's evidence, patent shall be deemed to be revoked.[xlii]

After all the evidence has been presented, and the Opposition Board's recommendation has been received, or at any other time the Controller may think fit, on giving at least 10 days prior notice, fix date and time for such hearing.[xliii]

The Controller shall order either to maintain or to amend or to revoke the patent.[xliv] The decision of the Controller can be appealed by both the parties within three months from the date of such decision, order or direction.[xlv]

4. PATENT OPPOSITION AND ACCESS TO MEDICINES IN INDIA

Patent opposition has been indispensable for civil societies and aggrieved persons in their quest for ensuring access to medicines. Successful patent opposition has resulted in increasing the patent quality and also promoting generic competition in the drug market. Generic competition is the only strategy that has been shown to reduce drug prices over the long term.[xlvi] .

Drug access mechanisms are important in country like India because of its large population and poverty levels.[xlvii] Also, India has one of the highest levels of Out-of-Pocket-Expenditures on healthcare.[xlviii] These factors should be kept in mind while examining the impact of patent opposition provisions in India.

The paper will discuss 4 oppositions cases including the latest Bedaquiline case. These cases relate to drugs which are needed by large population and successful opposition has positively impacted access to medicines. Over the years, stark changes have been noticed in grounds for challenges as well. Earlier the opposition was made mostly on grounds of patentability.[xlix] Now, the oppositions are "based on more complex arguments like lack of inventive step, obvious to try, anticipatory disclosures etc."[l]

- **Novartis AG v. Union of India**[li]

This is the most cited patent opposition case, and has been taken up to the highest court of the land. In 1998 Novartis AG filed for patenting its invention 'Crystal Modification of a N-Phenyl-2-Pyrimidine-amine derivative'. The drug was invented from Beta crystalline form of "Imatinib mesylate", and was used to treat cancer.[lii] Interestingly, Novartis' lab research had shown results that the Imatinib and Imatinib Mesylate salt had no difference in level of efficacy.[liii] Pre-grant opposition were filed by the Cancer Patients Aid Association, India, M/s Natco Pharma Limited, M/s Cipla Limited, M/s Ranbaxy Laboratories Limited, India.[liv]

The contentions of opponents were mainly based on two grounds (a) S. 3(d) and (b) requirement of non-obviousness for an invention to be patentable. After considering the representation and hearing the parties, the Controller refused to grant patent to Novartis. The Controller had refused to grant patent after Novartis could demonstrate only 30% improvement in bioavailability of Imatinib Mesylate in the beta-crystalline form over Imatinib free base.[lv]

The refusal to grant patent by the Controller, laid the foundation for legal battles which have wide impact over Indian pharmaceutical patent landscape. Firstly, the Novartis drug went off patent 15 years earlier than it was scheduled to be, thus ensuring access to medicine to public at large. Secondly, the 'efficacy in pharmaceutical inventions' jurisprudence and the methodology to determine non-obviousness while evaluating pharmaceutical inventions was developed by the courts. Lastly, the Supreme Court emphasized that "there cannot be a difference between what is disclosed in the patent specification versus what is claimed in the patent' claims."[lvi]

- **Valganciclovir Patent**

Valganciclovir was a modification of drug by Swiss company Roche, Ganciclovir (approved in 1988). This anti-viral drug was useful in preventing infections that may occur after an organ transplant and other infection in patients suffering from acquired immunodeficiency syndrome (AIDS).[lvii] In 2007, the Chennai patent office had granted patent to Roche for 'L-valinate ester of Ganciclovir' (brand name: Valcyte), without hearing the pre-grant opposition filed by civil society groups.[lviii]

A fierce Patent Opposition battle ensued with two oppositions under s 25(1) of the Patents Act, 1970, and one post-grant opposition under s 25(2). The first pre-grant opposition was filed by the two organizations- Indian Network for People Living with HIV/AIDS(INP+) and Tamil Nadu Networking People with HIV/AIDS (TNNP+).[lix] Their opposition was rejected by the Controller. Aggrieved by the Controllers' decision, opponents challenged the Controller's decision at Madras High Court. The Madras High Court sought the Patent Office to review its decision.[lx] Meanwhile, Roche moved to the Supreme Court challenging the Madras High Court order. Following the Supreme Court's order to dispose the case by 31st January, 2009, the Patent Controller again disposed the case.[lxi] Consequently, patent was granted to Roche.

Various NGOs and generic companies filed post-grant opposition on the ground that, Valcyte lacked enhanced efficacy and was hit by section 3 (d) of the Patents Act, 1970. Another argument was that, 'L-valinate ester of Ganciclovir'

was an obvious invention. This post-grant opposition is also relevant because an important question that, who all are included under the ambit 'interested party' under section 25(2) was answered by the Controller.

The Controller, revoked the patent granted to Roche, and ensured the access to medicines. Further, the scope of 'person interested' was also widened by the Controller, by including non-manufacturing entity like civil society groups in section 25(2). The Controller, on the orders of Intellectual Property Appellate Board (IPAB), revisited its earlier order. Finally, on 1st July 2015, the Controller revoked the Valcyte patent once again.[lxii]

- **Combivir & Trizivir Opposition**

These two cases are mentioned together because in both cases, the applicant abandoned the patent application after pre-grant opposition. Combivir, a Glaxo brand product, is developed by combining two existing drugs: Lamivudine and Zidovudine. This drug was useful for treatment of HIV infection. Indian Network for People Living with HIV/AIDS and the Manipur Network of Positive People together filed a pre-grant opposition in March 2006, claiming Combivir was not a novel invention.[lxiii] In August, 2006 Glaxo withdrew its patent application.[lxiv]

Similarly, in 2007, once again Glaxo voluntarily withdrew its patent application for the drug named Trizivir.[lxv] Trizivir was combination of three drugs Lamivudine, Zidovudine (both were constituent drugs in Combivir too) and abacavir sulfate. The pre-grant opposition was filed by Cipla Limited at Kolkata Patent Office. The patent application was withdrawn with a statement, "the company's move is in public interest and is part of its policy of routine review of patent applications."[lxvi]

These two cases repose the faith in utility of patent opposition provisions in ensuring access to medicines. It should be noted that how a single withdrawal of patent application led to abandonment of other linked applications, ultimately benefiting public.

- **Bedaquiline Pre-grant Opposition**

In March, 2023, the Controller rejected claim for secondary patent on Johnson and Johnson's tuberculosis drug Bedaquiline. Two pre-grant oppositions[lxvii] were filed six years apart, on the grounds of lack of novelty, lack of inventive step, lack of enhanced therapeutic efficacy, and for the formulation being a mere admixture.[lxviii] The Controller, in its decision held that there was no sufficient evidence that "combination of fumarate salt of Bedaquiline along with TWEEN 20 would show significant enhancement of the known efficacy or improved therapeutic efficacy over the known efficacy of the composition of Bedaquiline on the treatment of a patient."[lxix] Moreover, the claimed drug did not show synergistic effect of claimed formulation, hence was merely an admixture and not patentable under section 3(e) of the Patents Act.[lxx] Theoretically, there is no need to investigate whether an invention is new, non-obvious, and suitable for industrial application if it may be rejected under Section 3(d) on its face.[lxxi] Nevertheless, the controller also took note of the three patent applications of Janssen, where the documents indicated, composition of fumarate salt of Bedaquiline and held the invention lacked inventive step.

It is important to note, that India has largest number of tuberculosis patients in the world, and around 25% of the worlds drug resistant tuberculosis cases.[lxxii] It is necessary to control the menace of such disease by ensuring that the access to such drugs is not hampered by ulterior practices of pharmaceutical corporations. Patent opposition is one such mechanism through which third parties can protect their right to health.

Notably, Johnson & Johnson announced that it would not be enforcing patents for Bedaquiline in 134 low and middle-income countries.[lxxiii] Ukraine and Belarus implored the company to drop its patent on Bedaquiline in their company, post rejection of its secondary patent in India. Public Health Activist have hailed the refusal to grant patent to fumarate salt of Bedaquiline, as "initial crack in J&J's patent shield"[lxxiv] and one of the reasons for taking the drug off patent.

5. PROPOSED CHANGES TO PATENT OPPOSITION MECHANISM IN PATENT RULES, 2003

Indian Patent Opposition provisions are one of the most unique and effective mechanism for promoting public health and access to medicines. In August, 2023, Ministry of Commerce and Industry, published the Draft Patent (Amendment) Rules, 2023 (hereinafter Draft Rules). The Draft Rules proposes various amendments to patent opposition procedure in Patent Rules, 2003, *inter alia*. One of the reasons for such amendment is said to tackle delay in grant of

patent[lxxv] but patent law experts and activists view some provisions of Draft Rules as an attempt to weaken the patent opposition mechanism.

The Draft Rules proposes various changes to Rule 55 of the Patent Rules, 2003.

- Draft Rules proposes that on receiving the representation of pre-grant opposition, "the Controller shall first decide the maintainability of the representation".[lxxvi] The current rules allowed 'any person' to file the pre-grant opposition. This amendment gives arbitrary, unchecked power to the Controller to decide who has the right to file a pre-grant opposition.[lxxvii] The Draft Rules do not even provide grounds on which the Controller shall decide maintainability of the pre-grant opposition.
- Further, the rule proposes that once the representation is found to be maintainable, examination of the subject application should be expedited in accordance with the Rule 24C of the Patents Rules, 2003.[lxxviii] The problem here arises that, without easing the overburden of patent offices and providing extra resources, any attempt to expedite examination would result "in a situation where it is preferable to take the quick and easy method forward, rather than one where time and energy is to be spent on carefully checking opposition claims."[lxxix]
- Additionally, the Draft Rules insert Rule 55(6), which states, "After considering the representation and submission made during the hearing if so requested, the Controller shall proceed to either reject the representation and granting the patent or accepting the representation and refusing the grant of patent on that application, ordinarily within 3 months from completion of above proceedings."[lxxx] This insertion appears to be in conflict with Rule 55(5) of Patents Rules, 2003 which provides that after considering the statements and evidence by the parties, the Controller may grant the patent or refuse to grant the patent or order amendment of specification within one month. The careful reading of the proposed sub-rule, suggests that the period of three months is provided only when the Controller, grants the patent or refuses the patent and does not include when only amendment of specification is ordered. However, the intention of increasing time period without amending Rule 55(5) still does not make sense.
- The Draft Patent Rules, also propose to charge fee for filing a patent opposition. There is no requirement of fee for opposing a patent at present. The fee for opposition shall be dependant on the aggregate amount that has been paid by the patent applicant.[lxxxi] "The minimum fee can range from INR 20,100 for individuals to INR 40,000."[lxxxii] Proposing such high fees merely for filing opposition representation is indirectly an attempt to discourage individuals, civil society organizations and patient association from opposing the ill-motivated patents.

6. CONCLUSION

The patent opposition mechanism of Indian Patents Act, 1970 is one of the most effective tools for meeting public health demands of a developing nation like India. A successful patent opposition leads to earlier launch of generic version of the expensive patented drugs, and ensuring access to medicine to the public. As noted earlier, with the passing years, the opposition scenario has also changed considerably. The patent oppositions in India, have shifted from Section 3(d) straightforward arguments to more intricate ones.[lxxxiii]

The pre-grant opposition provision, provides comparatively cheaper and less formal process than post-grant opposition. The pre-grant opposition is an opportunity to maintain the high quality of patents granted and ensure that the problem of low-quality patents is addressed at the examination stage only.

Post-grant opposition is equally important mechanism by which third party's knowledge and expertise about the patented product can be used by the Patent Office, to reverse any mistake committed in granting a patent. It is a less complex process than patent litigation. Patent litigation is costly, formal and cumbersome process. Moreover, in the patent litigation, often the civil society organizations and individuals are pitted against the pharmaceutical corporations with deep pockets, patent opposition is more convenient recourse to clinch access to medicines for public.

The patent opposition provisions are often criticised for delaying the grant of patent and increasing the cost for the inventor. India has been pressurised by the developed countries to amend its patent opposition provisions in favour of pharma giants. The Draft Patent Rules, 2023 is seen as an attempt to weaken the opposition provisions under the guise of providing solution for pendency of application and delay in granting of patent. It is worth noting, that the Patent Rules,

2003 had prescribed time limit for pre-grant opposition proceeding. The delay is probably result of lack of fund and resources at disposal of Patent Offices. Ideally, to tackle the delay of patent grants, authorities should focus on providing more trained patent examiners and other resources.

A miniscule number of patent opposition are filed in India, annually but they are relevant because they challenge commercially viable drugs, which are often too expensive. The government should aim to facilitate the opposition proceeding instead of discouraging third parties.

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[vii] Agreement on Trade Related Aspects of Intellectual Property Rights, 1995, art. 8.
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[ix] Agreement on Trade Related Aspects of Intellectual Property Rights, 1995, art. 61.4.
[x] Agreement on Trade Related Aspects of Intellectual Property Rights, 1995, art. 41.2.
[xi] Standing Committee on the Law of Patents, Eighteenth session Geneva, May 21 to 25, 2012 OPPOSITION SYSTEMS AND OTHER ADMINISTRATIVE REVOCATION AND INVALIDATION MECHANISMS
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[xiii] Id.
[xiv] The Patents Rules, 2003, r 55(1A).
[xv] The Patents Act,1970 No. 39, Acts of Parliament, 1970 §. 25(1) (India).
[xvi] Id. §. 150
[xvii] Anaghaya Million Pharma LLP v. Nippon Soda Co. Ltd. And Ors., (29.12.2020- IPAB): MANU/IC/0074/2020.
[xviii] Id.
[xix] Anglo Operations Ltd. v. AIA Engineering Pvt. Ltd., (1995) 690/DEL/95, 10.
[xx] The Patents Rules, 2003, r 55(1).
[xxi] The Patents Act,1970 No. 39, Acts of Parliament, 1970 §. 25(1)(a) (India).
[xxii] Id. §. 25(1)(b)
[xxiii] Id. §. 25(1)(c)
[xxiv] Id. §. 25(1)(d)
[xxv] Id. §. 25(1)(e)
[xxvi] Id. §. 25(1)(f)
[xxvii] Id. §. 25(1)(g)
[xxviii] Id. §. 25(1)(h)
[xxix] Id. §. 25(1)(i)
[xxx] Id. §. 25(1)(j)
[xxxi] FEROZE ALI KHADER, THE TOUCHSTONE EFFECT: IMPACT OF PRE-GRANT OPPOSITION ON PATENTS 116 (LexisNexis Butterworths, 2009).
[xxxii] The Patents Rules, 2003, r 55(5).
[xxxiii] The Patents Act,1970 No. 39, Acts of Parliament, 1970 §. 25(2) (India).

[xxxiv] Id.
[xxxv] J Mitra and Co. Pvt. Ltd. v. Assistant Controller of Patents and Design, 2008 (10) SCC 368.
[xxxvi]The Patents Rules, 2003, r 55A.
[xxxvii] The Patents Act,1970 No. 39, Acts of Parliament, 1970 §. 25(3)(b) (India),The Patents Rules, 2003, R 56 (1).
[xxxviii] The Patents Rules, 2003, r 56 (2).
[xxxix] The Patents Rules, 2003, r 56 (3).
[xl] The Patents Rules, 2003, r 57, 58.
[xli] Boehringer Ingelheim Pharma GMBH and Co. v. Cipla Ltd., 558/DEL NP/2003, 15.
[xlii] The Patents Rules, 2003, r 58(2).
[xliii] The Patents Rules, 2003, r 62(1).
[xliv] The Patents Act,1970 No. 39, Acts of Parliament, 1970 §. 25(4) (India).
[xlv] The Patents Act,1970 No. 39, Acts of Parliament, 1970 §. 117A (2) & (4) (India),
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[lii] https://www.mondaq.com/india/patent/826478/a-study-on-novartis-ag-v-union-of-india
[liii] Rathod, *supra* note 47, at 156.
[liv] *Supra* note 51.
[lv] Rathod, *supra* note 47, at 156.
[lvi] *Ibid* at 157.
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[lxxvii] *Supra* note 75.

[lxxviii] *Supra* note 76.

[lxxix] S. P. Barooah, *Draft Patent Amendment Rules- Increasing Efficiency of Granting Patent Monopolies While Forgetting the Reason for Allowing Them in the First Place* Spicy IP, https://spicyip.com/2023/09/draft-patent-amendment-rules-increasing-efficiency-of-granting-patent-monopolies-while-forgetting-the-reason-for-allowing-them-in-the-first-place.html.

[lxxx] *Supra* note 76.

[lxxxi] *Supra* note 75.

[lxxxii] *Ibid*.

[lxxxiii] Rathod, *supra* note 47, at 176.