

INTERIM-RELIEF FOR DRUG PATENTS AMONGST THE DISARRAY OF INDIAN PATENT LITIGATION

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Abstract

The Indian Patent Act of 1970 lacks specific provisions for interim relief, such as interim injunctions in patent infringement cases, although Section 108(i) addresses "Reliefs in suit for infringement." Patentees typically seek injunctive relief to halt alleged infringers or restore the status quo, necessitating specific injunctive provisions and a robust judicial infrastructure for Intellectual Property (IP) matters. Judicial discretion governs the administration of interim injunctions, weighing factors like public interest and economic impact, with flexibility incentivizing patent protection. However, the Civil Procedure Code of 1908's interim relief clause lacks the strength to address patent innovations, evident from the backlog of cases in Indian civil courts. Immediate interim injunctions play a vital role in patent protection, especially as delays in legal proceedings can result in substantial losses for patent holders, discouraging innovation. In cases involving medication patents, efficient handling is crucial to safeguard public health and ensure adequate access to medicines. This paper aims to explore legal gaps in interim relief procedures for drug patent infringement cases, highlighting associated health sector challenges and proposing remedies to address these gaps.

Keywords: Drug Patents, Interim Relief, Indian Patent Law, Civil Procedure Code and Health Sector.

1. Introduction

The Intellectual Property Rights Appellate Board has been abolished on April 4th, 2021. This has had a direct impact on the enforcement of the Patent Act specially for those essential goods and services that determine overall public health, welfare and safety in the country. For example, Drug Patents. It has been noticed that this recent change has many adverse effects such as: Delayed adjudication, Lack of specialised expertise, time

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inefficiency, inconsistency in decisions, adjudication process becoming more cost heavy, discouraged innovation, increase case backlogs and an overall negative impact of innovation and market competition.

1.1. Evolution of Indian Patent Law Pertaining to Drug Patents

Article 300-A of the Indian Constitution guarantees the right to property, stating that no one shall be dispossessed of 'property' unless with the sanction of law.¹ A Patent is a property owned by the inventor, and the issuance of a patent is constitutionally protected. The state has instructions, known as the Directive Principles of State Policies, that direct the government to promote public health and to prohibit the ingestion of intoxicating beverages and hazardous substances, barring if the same is used for nutritious purposes as under Article 47 of the Indian Constitution that covers medical purposes as well.²

The British Administration introduced the concept of Patents through India's Act VI of 1856 which was based of the British law on patents.³ It had a period of 14 years of exclusive privileges extended to the inventors. In 1911, the Indian Patents and Designs Act⁴ was enacted which introduced patent administration in India through the Controller of Patents and Designs. In 1947, the necessity for a law that would look into national interests, strengthening local businesses and boosting manufacturing was met. Commissions were formed to investigate the feasibility of patent law in the current socioeconomic environment. The Bakshi Tekchand Committee in 1949 was appointed on January 10, 1948 via a resolution to examine Indian patent laws to ensure that the patent system is more conducive to national interests.⁵

A second committee headed by Justice Rajagopal Ayyangar was appointed in 1959 to review the law on patents in India w.r.t the socioeconomic conditions prevailing at that time. The recommendations given by these committees were the background on which India enacted its first independent law with respect to patents - The Patents Act, 1970. It expressly prohibited the patentability of pharmaceutical products but allowed for

¹ Constitution of India, art. 300A.

² *Id.* at art. 47.

³ Linda L. Lee "Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India" 23(1) *Berkeley Technology Law Journal* 289 (2008).

⁴ The Indian Patent and Design Act, 1911 (Act II of 1911).

⁵ World Intellectual Property Organization, "An International Guide to Patent Case Management for Judges" 249 (2023).

patents on processes for making pharmaceutical compounds.⁶ This law can be credited for the exponential growth of the Pharma Industry in India, a deliberate choice of the government to provide leverage to the local drug manufacturing industry and in the decades since, helped earn the distinction of “the pharmacy of the world”.

In 1991, the Indian economy was liberalised, and our markets were opened to the rest of the globe. India joined the World Trade Organisation in 1995, and in order to realise the benefits of the WTO framework, India had to comply with the WTO’s intellectual property standards outlined in the TRIPS. The government amended the Indian Patent Act, 1970 to conform with TRIPS regulations, which meant that the scope of patenting was ‘expanded to food, medicines and agrochemicals’, which was not the case prior to TRIPS.

2. TRIPs and Drug Patents

The enactment of the Patent Act, 1970, prohibited patents on products useful as medicines, and food and expanded the scope of compulsory licensing. This led to the exponential development of the Indian Generic Drugs Industry, a deliberate decision of the government. India’s Patent law have been the subject of criticism and discussion, especially in the pharmaceutical industry. Minimum requirements for several types of intellectual property, including patents, are outlined in the TRIPS agreement, and overlooked by the World Trade Organisation (WTO). The Patent Protection Policy of India has drawn criticism from certain nations and multinational companies, particularly with regard to its treatment of pharmaceutical patents.⁷

The way India has used the flexibilities granted by TRIPS to safeguard public health has been a major point of controversy. TRIPS enables member nations to enact the policies required to safeguard public health and advance universal access to medications. India has implemented policies like mandatory licencing and limitations on specific types of patents to lower the cost and increase accessibility to necessary medications.⁸ Critics contend that India’s strategy might be interpreted as not entirely complying with some

⁶ *Ibid.*

⁷ World Trade Organization, “TRIPS — Trade-Related Aspects of Intellectual Property Rights”, available at: https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited on January 15, 2024).

⁸ *Ibid.*

TRIPS interpretations, particularly in regards to specific patentability requirements and the awarding of exclusive rights to medical advances. However, supporters of India's strategy stress how crucial it is to strike a balance between the interests of Public Health and Intellectual Property Rights.⁹

In *Bishwanath Prasad Radhey Shyam v. HM Industries*,¹⁰ the Apex Court stated that "The object of patent law is to encourage scientific research, new technology and industrial progress. Grant of exclusive privilege to own, use or sell the method or the product patented for a limited period, stimulates new inventions of commercial utility".¹¹ Initially, India opposed the inclusion of patents and the broader aspect of Intellectual Property rights in GATT. It was viewed by the developing countries alike that the GATT framework was a deliberate imposition of strong IPR rules by having market access on the line.¹² By 1989, India reversed its anti-TRIPS stance and agreed for further deliberation on patent protection while maintaining that the extent of protection should depend on the economic prowess of a member country - implying that a uniform application of patent protection is not viable on the date the agreement is signed. India is often credited for the TRIPS multi-year Transition periods. India became a member of WTO effective from 1st January, 1995 on signing the Uruguay Round Agreements in 1994 which obligated India to amend its domestic laws to be in compliant with the TRIPS Agreement. India was given a transition period of 10 years, i.e. until 2005 to implement on the conditions of the agreement. Article 27(1) of TRIPS outlines the fundamental provision defining the extent of patentability. It stipulates that member nations are obligated to ensure that patents are accessible for all inventions, encompassing both products and processes across various technological fields, provided they meet standard criteria such as novelty, utility and non-obviousness.¹³ This was a far cry from what the Patents Act, 1970 provided for. It had the option of patents only for method or process patents.

⁹ Nanki Arneja, "Breaking Myths: Pharmaceutical Patenting in India", *Lexology* 1-2 (2019).

¹⁰ AIR 1982 SC 1444.

¹¹ *Ibid.*

¹² Janice M. Mueller, "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation", 68(3) *University of Pittsburgh Law Review* 505 (2007).

¹³ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art. 27(1).

The push given by TRIPS has transformed India's patent laws, three amendments over the transition period were made to the Patents Act, 1970. "*India had to set up a mailbox facility, which accepted pharmaceutical product patent applications filed during the transition period. It is commonly referred as pipeline protection*".¹⁴

An ordinance was passed by the President in 1994 but it lapsed. In another case the Upper House did not pass the bill before the dissolution of parliament in 1996. The US initiated a Dispute resolution process against India for failing to fulfil its obligations. The WTO held that India failed *its obligation under Article 70.8(a) of the agreement*.¹⁵ An implementation bill was passed by the Upper House of the parliament in 1998, there had been no further development beyond that. It was in 1999 that the Patents (Amendment) Act, 1999 was enacted. It inducted the mailbox procedure and gave it retroactive to 1995.

2.1. The Patents Amendment Act, 2002

The next in line of the amendment lot during the transition period brought in many important changes but the most talked of is the extension of patent term from, 5 years from sealing or 7 years for the processes for drugs and foods from the date of the patent, for all other type of patents- 14 years from date of patent to 20 years. It provided that the term of all Indian patents would henceforth expire twenty years after their application filing date.¹⁶ Another important step was the recognition in the Act, of the nation's accession to two leading international intellectual property treaties, both administered by the United Nations affiliated World Intellectual Property Organization (WIPO).¹⁷

India also complied with the Paris Convention for the protection of Industrial Property, and, henceforth was to abide by the national treatment principle which was also present in TRIPs in Article 3, which, forbids any type of discrimination against applicants from outside India, the concept of equal treatment irrespective of the nationality. It also

¹⁴ *Supra* note 3 at 293.

¹⁵ World Trade Organization, "India — Patent Protection for Pharmaceutical and Agricultural Chemical Products", available at: www.wto.org/english/tratop_e/dispu_e/cases_e/ds50_e.htm (last visited on January 03, 2024).

¹⁶ Andy McDonnell and Stephen Traynor, "France Bans Analytics of Judges' Decisions", Lexology, available at: <https://www.lexology.com/library/detail.aspx> (last visited on January 06, 2024).

¹⁷ World Trade Organization, "Overview: a Navigational Guide", available at: https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited January 06, 2024).

had the priority principle which meant that foreigners who had already filed an application for patent in their country be granted a 12-month period in which an application for the invention filed in their home country be continued/granted in India as well. Another development during this period was the signing of the Patent Cooperation Treaty, in 1998.

2.2. The Patents (Amendment) Act, 2005

In the final leg of the compliance with TRIPS agreement marathon, the most difficult part was to provide full recognition of patent-eligibility for pharmaceutical products. The definitions of various terms were amended, e.g. ‘inventive step’, ‘patent’. It amended the list which had those innovations which cannot be patented (non-patentable subject matter). Another introduction was in the levels of opposition- pre-grant and post-grant.

It is worth noting that Section 3, Provisional Measures Article 50 of TRIPs created provisions enabling judicial authorities to have the authority to order prompt and effective provisional measures (a) to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods. These provisions allow adoption and execution of measures “*audi alteram partem*” i.e. “the other part not having been heard” or “not in the presence of the other or opposing party”.

As it is binding on TRIPs signatories to align their national enactments with standards at least that of TRIPs, logically laws governing IP ought to have been amended to include provisions of interim injunction in specifics but Indian scenario relies heavily on equivalent provisions in Civil Procedure Code i.e., CPC.

3. Interim Relief and CPC

The Patent Act 1970 does not contain any provision for interim relief. Thus, interim relief even in the case of patent infringement cases refers to Order 39 Rule 1 and 2 and Section 151 of the Civil Procedure Code 1908.¹⁸

¹⁸ The Code of Civil Procedure, 1908 (Act No. 5 of 1908).

Order 39 Rule 1

In instances where a temporary injunction may be warranted, if it is demonstrated through affidavit or other means that:

(a) any property under contention in a lawsuit is at risk of being wasted, harmed, or transferred by any party involved in the suit, or wrongfully sold under a decree's execution, or

(b) the defendant threatens or plans to relocate or dispose of their assets to defraud creditors,

(c) the defendant threatens to unlawfully dispossess the plaintiff or cause harm to the plaintiff concerning any disputed property in the suit,

the Court has the authority to issue a temporary injunction to prevent such actions or enact other measures aimed at halting or preventing the waste, damage, transfer, sale, relocation or disposal of the property, or the plaintiff's dispossession, or any harm to the plaintiff related to the disputed property until the suit is resolved or further directives are issued.¹⁹

Order 39 Rule 2

In cases seeking to prevent the defendant from engaging in contract breaches or any other form of harm, regardless of whether compensation is sought in the suit, the plaintiff has the option, at any point following the initiation of the suit, to petition the Court for a temporary injunction to prohibit the defendant from committing the alleged breach or harm, or any similar breaches or harms stemming from the same contract or pertaining to the same property or right. The Court, by decree, may issue such an injunction, imposing terms regarding its duration, accounting, provision of security, or other relevant conditions, as deemed appropriate by the Court.²⁰

Section 151

Saving of inherent powers of Court - The inherent powers of the Court shall not be constrained or altered by any provision in this Code. The Court retains the authority to

¹⁹ The Code of Civil Procedure, 1908 (Act No. 5 of 1908), Order 39 Rule 1.

²⁰ *Id.* at Order 39 Rule 2.

issue orders deemed necessary to serve the interests of justice or to prevent the misuse of the Court's processes.²¹

However, these provisions were framed keeping in mind tangible forms of property and hence, application of them over intangible property like Patents can become formidable to implement. The Supreme Court has therefore by its various past judgements established a formal judicial standard upon the fulfilment of which Court can make exercise their judicial discretion in Patent Infringement cases. These are:²²

3.1. Establishment of Prima Facie Case

As the Indian statutory bodies are deeply influenced by English Law. The interpretation of 'prima facie case' can be witnessed in the case of *American Cyanamid Co. v. Ethicon Ltd.*²³ The reconsideration in this case extended the scope of what might be considered prima facie to be the establishment of a mere triable issue or legitimate disagreement. The assessment of the relative strengths of the plaintiffs' cases was reduced to the status of a minor tie-breaking criterion used to resolve the balance of convenience in favour of one of the litigants. The goal was to allow more cases to qualify for interim relief. This was a positive step towards improving the interim relief mechanism for patents in cases of drug infringement. In the case of *F. Hoffman-La Roche Ltd. v. Cipla Ltd.*²⁴ The Delhi High Court confirms to the precedent set by the above case.

3.2. Irreparable Damages

It denotes any harm that is too severe to be adequately repaired by damages. If damages are the only relief available to the plaintiff, even if the plaintiff wins the case in court, he will not be restored to a position as was before the harm took place.

3.3. Balance of Convenience

The expression 'balance of convenience' in favour of the plaintiff relates to the fact that if an injunction is not given and the lawsuit is finally decided in favour of the plaintiffs, the plaintiffs will win. If an injunction is granted but the complaint is ultimately dismissed, the plaintiff would suffer less trouble than the defendants. Although it is

²¹ *Id.*, at s.151.

²² Ashutosh Kumar, "Patent Protection through Interim Injunctions: Adding Sting to the Enforcement of Indian Patent Law" 20(2) *National Law School of India Review* 217-219 (2008).

²³ [1975] A.C. 396.

²⁴ 2015 SCC OnLine Del 13619; (2015) 225 DLT 391 (DB), (2016) 65 PTC 1 (DB), (2015) 4 Civ LT 500.

referred to as the balance of convenience, it may be perceived more as the balance of inconvenience, and the plaintiffs must show that their inconvenience is higher than the defendants' inconvenience. The plaintiffs will suffer if the inconvenience is equal. In the case of *F. Hoffman-La Roche Ltd. v. Cipla Ltd.*²⁵ the application for an interim injunction was denied on the grounds that the balance of convenience was not in favour of the plaintiff, due to the harm caused to the public interest.²⁶

However, in *Sterlite Technologies Ltd. v. ZTT India Ltd.*,²⁷ decided in year 2019, the Delhi High Court enumerated that “*the life of a patent is limited and further considering then the time taken in determination, whether there is infringement of patent, non-grant of interim injunction often results in, the defendant, even if ultimately found to have infringed the patent, till the said determination, continuing to reap fruits of infringement*”.²⁸ Therefore, the Hon'ble Court granted interim relief even though there was an absence of prima facie case.

Nonetheless in a judgement recited on the same year the Delhi High Court restored to its original mindset and decided that the general principle must be followed while, deciding in case of interim relief. In the *Natco Pharma Ltd. v Bayer Healthcare Llc.*²⁹ case, the court emphasized the importance of deciding on interim injunctions based on merit, rather than establishing a blanket rule for granting them, as such grants could potentially be sought for malicious motives. With this perspective, the court reverted to the three-rule principle for requesting interim injunctions.³⁰

Three rule principle or three factor principle enumerates (i) Prima facie case in favour of the litigant seeking the injunction, (ii) the reasonable chance of irreparable damage being done to the litigant seeking the injunction if the injunction is not granted and (iii) the damaging effects of the injunction being minimal for the other litigants so that the 'balance of convenience' lies in favour of the litigant seeking the interim

²⁵ *Ibid.*

²⁶ *Supra* note 5 at 14.

²⁷ 2019 SCC OnLine Del 8833.

²⁸ *Ibid.*

²⁹ 2019 SCC OnLine Del 9164, (2019) 263 DLT 622 (DB).

³⁰ *Natco Pharma Limited v. Bayer Healthcare Llc.*, available at: <https://indiankanoon.org/doc/52483234/> (last visited January 06, 2024).

injunction as key principle factors in deciding whether interim injunction should be granted or not.³¹

4. Problems Caused Due to the Existing Gaps

There are no provisions pertaining specifically to patent law or any other form of intellectual property in either the General Principles or the Civil Procedure Code. Property is not defined anywhere in the Civil Procedure Code. However, the Code does define “movable property” under Section 2(13). Since most patents are regarded as movable property, civil lawsuits can be brought against them in accordance with the CPC. Order 39 Rule 1 and 2 were created keeping in mind tangible property and a majority of the cases and precedents of this order discuss the same. Given that patents are intangible assets and that there are several gaps between tangible and intangible property, the failure to fully implement this directive with regard to patents has led to a number of significant issues:

4.1. Tedious Litigation Process in India

Justice delayed is justice denied, Patent infringement cases serve as an epitome to this quote. Innovations amounting to Patentable inventions come into existence after years of hard work and significant capital or financial investments. Therefore, it is extremely unfair and unjust when such a patent holder is involved in the tedious litigation process of patent infringement. The process not only costs them more money and time, but it also damages their reputation greatly. Additionally, patents only provide exclusive rights for a period of 20 years from the date of application, after which they fall into public domain. Lengthy court proceedings eat up a significant amount of time that the patent holder could have spent enjoying these rights.³²

This shows insufficient acknowledgement of value of patents in defining future and a lack of respect for the patent holders. This silence on absence of specific prompt injunctive provisions in Intellectual Property (IP) laws only discourage citizens from engaging in innovating. Therefore, economies that do not have the support of a strong system of legal protection for patents tend to suffer from slow technological progress and limited economic growth. Interim reliefs are a viable option in such cases however, the

³¹ *Supra* note 22 at 217.

Patent Act has no provision for interim relief and one has to rely heavily on somewhat broad, vague procedures (as discussed above) illustrated in the CPC albeit those procedures primarily relate to tangible property making it tougher to prove a prima facie case or balance of convenience. A creation of specific interim relief or interim injunction provisions in IP Laws may lead to rise in a greater number of patent infringement cases receiving interim relief.

4.2. Difficult to Establish Prima Facie Case and Balance of Convenience:

Due to the Code's propensity for tangible property, the laws are presented in such a manner that the fulfilment of two prerequisite principles — establishing a prima facie case and the balance of convenience to obtain temporary relief is challenging. Since intellectual property rights are a distinct type of right in different domain of rights, whose application and utilisation are extremely limited and delicate, it can be tricky to gather sufficient evidence to support the aforementioned two. To be able to monitor patent interim relief proceedings justly and fairly, there is need to enact more detailed and specific provisions in IP laws, more specifically in The Patents Act of India.

4.3. Health Industry Suffers

Absence of specific provisions in IP laws, more specifically in The Patents Act and relying heavily on provisions on heterogeneous code or different set of Laws such as CPC, results in not only monetary loss for the patent holder, but also creates a climate of distrust and abilities of apex body to freely and fairly respect international agreements. It provides an opportunity to raise disputes in international forums against India. India has already been criticised for negating their health sector, if this gap between in patent law continues to exist, this will further push India towards the negative title it has incurred. One may experience lesser influx of capital in innovation of drugs mainly from overseas enterprises and the ones who may be experience unworthy delays in Patent Litigations related to infringement.

4.4. Proposed Remedies

4.4.1. *Set Up Separate Court or Tribunal*

On April 2021 the Central Government abolished the Intellectual Property Appellate Board, which was formed in 2003,³³ as their absence does not contravene TRIPs, but it must be supported by broadening the judicial base and creating broader forums for judicial processes, may be by appointing more judges or creating more benches specifically dealing in IP matters. India's intellectual property rights sector is expanding and will continue to expand. As the world becomes more digitalised, the value of such rights for the growth and development of our economy becomes increasingly important. As a result, participation in such rights should be promoted. As more people become interested in IPRs, the need for a dedicated place to deal with these rights becomes more critical, allowing matters involving them to be settled promptly and efficiently. Intellectual Property rights need speedy justice to prevent the wastage of time and money to promote confidence in Indian Judicial system.

4.4.2. *Make Separate Laws for Patent Interim Relief*

A separate provision should be added in the Patents Act itself that illustrates a procedure specific to Patents to get an interim relief. Patents are specific and quite distinct from tangible property which is more prominently discovered by the Civil Procedure Code. They, therefore, require a separate and focused law to allow justice to be delivered more efficiently and accurately.

4.4.3. *Commencement of Exclusive Rights Upon Patent Application and Subsequent to Final Infringement Decision*

The time to enjoy exclusive rights starts from the date of application for patent and continues only after Final Decision on Infringement Matter. This suggestion may seem far-fetched but, it ensures fairness and justice. Specific provisions of Interim relief in IP Laws more specifically in The Patents Act of India and their swift execution would enable patentee to enjoy his exclusive right reasonably uninterrupted for a period of 20 years barring intermittent period till patentee secures interim relief. Thus, patentee will

³³ Nalini Sharma, "Scrapping of the IP tribunal: The Good, the Bad and the Ugly", available at: <https://www.indiatoday.in/india/story/scrapping-of-the-ip-tribunal-the-good-the-bad-and-the-ugly-1790112-2021-04-12> (last visited September 11, 2023).

have satisfactorily enjoyed fruits of his efforts during his life and during the validity of patent.

5. Conclusion

Although Intellectual property laws of India at par with TRIPs exist in India for over decade now, Intellectual Property rights are a relatively new, and hence still provides scope to further improve Indian Intellectual Property laws, more specifically the Patents Act of 1970, to have or to include apt and adequate provisions related to interim relief to be provided to patentee in case of an infringement. Interim relief for drug patents is one example of a legal gap. Patents, which are intangible properties, are scrutinised and governed by specific enactment, The Patents Act of 1970 relies heavily on provisions of the Civil Procedure Code, 1908 for administration of relief to patentee in case of infringements of patents. One may say that a code primarily designed to govern tangible property is applied to intangible property and this dichotomy creates a specific need to have a self-reliant Intellectual Property enactment. The significant contrast in characteristics between these two attributes is the reason for delay in arriving at verdicts or court orders in infringement proceedings. Creation of specific interim relief measures with full-fledged infrastructure as referred in Section 3, Provisional Measures Article 50 of TRIPs in Intellectual Property Laws more specifically in The Patents Act of India, would raise image of India on international platforms, reduce suffering of country's healthcare sector, and may lead to rise in the country's general development. It would also unblock or eliminate ambiguity about outcomes of legal processes and promote or foster innovation driven industrial climate.

It is high time to update the Patents Act, 1970 to include succinct provisions that describe the process to gauge interim-relief in cases of Patent infringement, and establish separate courts to decide infringement cases to swiftly arrive at court decisions. Creating an enactment with apt provisions will enable patentee and other litigant/s to put forth their point and improve visibility of quickly getting a verdict or court order in reliable finite time. Thus, establishing a statute with adequate provisions governing interim relief in cases of patent infringement and separate court will aid in expediting the process and delivering the justice.