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PRELIMINARY INJUNCTION IN PATENT INFRINGEMENT SUITS

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ABSTRACT

An injunction order is the most beneficial and equitable remedy for any person whose rights are being infringed. The most important of all the types of injunctions is the one granted during the preliminary stages, so as to minimize the damages the person could have suffered during the course of the trial. By extension of the same logic, a preliminary injunction in patent infringement cases is the most coveted preliminary remedy sought by the patent holder. The grant of a preliminary injunction works greatly to the benefit of the patentee to ensure that there is no continued violation of his/her rights till such time that the court passes a judgment. However, a balance has to be struck in cases where the product of the accused, although infringing a patent, seems to be in favour of the public needs, and granting an injunction will only hamper the citizens at large.

In the following article, the authors have made a humble attempt to study and analyze the grant of preliminary injunctions in patent infringement cases with the primary focus on public interest. They have approached the article in a threefold manner. It begins with an overview of patent infringement and its remedies followed by an analysis of the influencing factors in a preliminary injunction. The authors then proceed to a discussion of the factor of public interest and its relevance in certain patent infringement cases, through a study of landmark judgments and a brief comparison with the United States law. Lastly, the authors have concluded this paper with original recommendations and conclusions.

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I. INTRODUCTION

Patent infringement is the commission of a prohibited act with regard to a patented invention devoid of the patent holder's permission. A patent granted under the Indian Patents Act 1970, confers exclusive rights to the patentee to restrict third parties from creating, using, offering for sale, selling, or importing the patented invention for the same purposes.[1] This prevents third parties from commercially exploiting the patented invention till the aforesaid patent is operative. It is imperative to protect the rights of the patentee from the threats of undue exploitation of the patent, assigning of license to others, as well as for modifications in an existing invention. Under Section 108 of the Patents Act, 1970, the patentee has two remedies, that is, injunction and damages, in the event that the patent is infringed.[2] While damages can only be awarded after a fair determination of the rights and liabilities of the parties, there must be something to restrict the continued infringement of the patent till the court comes to a conclusion. This is where a preliminary injunction assumes importance. Patent systems ordinarily authorize courts to order the defendant to refrain from continuing infringing conduct in the coming years.[3]

An infringement analysis entails two steps. The first step is asserting the validity of the patent claimed to be violated. The second step is linking the claims to the device alleged of infringing.[4] An injunction to prevent the alleged infringer from infringing a patent is the most common kindof relief wanted and granted in infringement proceedings. Injunction is an equitable remed y and is thus at the discretion of the court to be granted. In cases where the court considers that an injunction would be disproportionate, it may refuse to grant one. A preliminary injunction is temporary and stops the alleged infringement until the dispute can be heard at trial.[5]

II. PRELIMINARY INJUNCTION IN PATENT INFRINGEMENT SUITS

Injunctions form an essential aspect of the scheme of remedies available to patentees against their infringers. The Patents Act, 1970 explicitly provides for such an injunctive relief,[6] in the form of preliminary and permanent injunctions. The courts in the USA also grant injunctions to

[1] The Patents Act, 1970, No.39, Acts of Parliament, 1957, §48 (India).
[2] The Patents Act, 1970, No.39, Acts of Parliament, 1957, §108 (India).
[3] Rafal Sikorski, *Patent Remedies and Complex Products*, 23 J. PAT. OFF. SOC'Y 460 (1941).
[4] DR. ELIZABETH VERKEYS, LAW OF PATENTS, 395(Eastern Book Company 2nd ed., 2012).
[5] Gujarat Bottling Co. Ltd. v. Coca Cola Co, AIR 1995 SC 2372 (India).
[6] *Supra* note 2.

preclude infringement of the rights of a patent holder.[7] Injunction exists as a remedy against infringement of patent because of the nature of patent rights, that is, the right to exclude. The legal fraternity strongly believes that the courts must not hesitate in using their equity powers once the validity of a patent has been established.[8]

One important aspect, which makes a preliminary injunction extremely vital to a patent suit, is the stage at which it is granted, or denied. The decision whether an interlocutory injunction will be granted or not is taken at a time when the existence of the legal right claimed by the plaintiff and its alleged violation, both are uncertain and contested.[9] Therefore, if a further loss to the plaintiff is to be prevented, and injustice mitigated, the courts grant a preliminary injunction during the period of uncertainty before trial. Order 39[10] of the Code of Civil Procedure, 1908 deals with temporary injunctions, and the factors necessary to be proven by the plaintiff are as follows:

A. Prima facie case

B. Irreparable injury

C. Balance of convenience

A mere glance at these factors and the ones stated above show that the requirements of preliminary injunction in patent infringement suits are almost similar. In order to better understand this concept, we will now be going into the details of these factors.

A. Prima facie case

In patent cases, the burden of showing a prima facie case to receive an injunction is a very heavy one. In order to prove a reasonable likelihood of success of the application, the party applying for the injunction has to establish, to a substantial degree, that the patent in question is valid and infringed.[11] However, there is no predefined standard for what constitutes as *prima facie,* which might lead to confusion and ambiguity. Over the years, courts have given varying interpretations to this term to bring some sort of objectivity to it. The initial trend among the High Courts was to ensure that the case is not a frivolous or a vexatious one,[12] or that there indeed existed a

[7] 35 U.S.C. § 283 (1926).
[8] Smith International Inc. v. Hughes Tool Co., 718 F 2d 1573 (Fed. Cir. 1983).
[9] Gujarat Bottling Co. Ltd. v. Coca Cola Co., AIR 1995 SC 2372 (India).
[10] The Code of Civil Procedure, 1908, No.39, Acts of Parliament, 1993, §39 (India).
[11] H.H. Robertson Co. v. United Steel Deck Inc., 820 F 2d 384 (Fed. Cir. 1987).
[12] Rajesh Kumar v. Manoj Jain, (1998) 47 DRJ 353 (India).

serious question to be tried and resolved.[13] A few years later, the Supreme Court held that the applicant must establish that at the conclusion of the trial, s/he would, in all probability, be entitled to relief.[14] In the opinion of the authors, this was a much stricter requirement as this would require taking some evidence on record and by the time it is proved, the plaintiff might have already suffered irreparable harm. It is relevant to mention that the Patents Act, 1970 does not guarantee a presumption of validity in favour of the patent[15] and this view is also consistent with the opinion of the Supreme Court.[16] In *Bilcare Ltd. v. Supreme Industries Ltd.,*[17]while adjudicating upon an application for a preliminary injunction in favour of the patentee-plaintiff, the court opined that it is imperative to first determine the validity of the patent. If the patent is relatively new, a mere challenge is considered sufficient to refuse the injunction whereas if the patent is an old one and being worked, it is often presumed to be valid.[18] The courts also deny preliminary injunction if the defendant raises a counterclaim towards the validity of the patent.

In *B. Braun Melsungen AG v. Rishi Baid,*[19] the court denied granting a preliminary injunction on the ground that registration of patent *per se* does not entitle the patentee to an injunction. The fact that there was a serious challenge to the validity of the patent, by the defendant's claim of the prior art, also heavily influenced the court's decision. Therefore, at present, the courts mostly apply this standard while determining *prima facie* cases;[20] that the patentee must show unchallenged possession and enjoyment of the patent for a minimum of six years.[21] However, there is no need to prove an actual case of invalidity at this stage as vulnerability is the issue at preliminary stage and validity is the issue at trial.[22] The authors believe that this 'six-year' standard is counterproductive and unreasonable. This is because registration of a patent goes through immense scrutiny, examination, pre-grant opposition and post-grant opposition. Therefore, to still doubt the validity of a patent in a patent infringement suit runs contrary to the entire process undertaken by the Controller General of Patents, and also to the interests of a patentee. Therefore, the courts must relax the rule of not granting injunctions in cases where the patent is relatively new.

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[13] Supreme General Films Exchange Pvt. Ltd. v. Durgaprasad Jannath Tiwar, AIR (1984) Bom 131 (India).
[14] Colgate Palmolive Ltd. v. Hindustan Unilever Ltd., (1998) 1 SCC 720 (India).
[15] The Patents Act, 1970, No. 39, Act of Parliament, 1993, § 13 cl.4, (India).
[16] Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries, AIR (1982) SC 1444.
[17] Bilcare Ltd. v. Supreme Industries Ltd., MIPR (2007) 13 (India).
[18] *Id.*
[19] B. Braun Melsungen AG v. Rishi Baid, (2009) SCC Del 868 (India).
[20] V. Manika Thevar v. Star Plough Works, AIR (1965) Mad 327 (India).
[21] NRDC v. Delhi Cloth & Heneral Mills Co. Ltd., AIR 1980 (Del) 132 (India).
[22] Helifix Ltd. v. Blok-Lok Ltd., 208 F 3d 1339 (Fed. Cir. 2000).

B. Irreparable Injury

The presence of a prima facie case is not sufficient for a patentee to receive injunction unless s/he proves the likelihood of an irreparable injury.[23] The court has to be satisfied that non-interference by the Court will result in an irreparable loss to the person seeking the injunction and that once such loss occurs, s/he cannot be compensated in damages.[24] When the validity of a patent and its alleged infringement is sufficiently proved, the court often presumes irreparable damage.[25] Irreparable loss or injury, however, does not necessarily refer to the physical possibility of repairing the harm, rather the material sense of it. This metaphorical and material injury becomes particularly important in patent cases, more so than other cases of injunction, such as a property dispute. The authors intend to illustrate this via two case laws. In the landmark case of *Merck Sharp and Dohme v. Glenmark Pharmaceuticals,*[26] a division bench of the Delhi High Court reversed the decision of a single judge who denied granting of preliminary injunction. While restraining Glenmark from making, using or selling MSD's popular anti-diabetic drug, the division bench held that when a strong case of infringement is made out, the court must be really mindful of the rights of the parties. Moreover, the argument that decline of preliminary injunction is justified on the ground that the patent holder can later be compensated monetarily if the case is decided in his favour, does not hold efficacy in patent cases. This is because a piercing analysis of the market forces reveals that in cases of patent infringement, the damage can be irreparable because infringement may lead to a cutback in price by virtue of the infringer not having any research and development costs to recover. Therefore, most revenue becomes profit for the infringing party and the patent holder might not survive the financial setback during the preliminary period.

Indivior Inc. v. Dr. Reddy's Laboratories, S.A.,[27] was a suit for infringement of Indivior's Suboxone Film, a formula that helped in reducing opioid dependency. Although the preliminary injunction was vacated on appeal, the ground for it was different from the matter in consideration here. In the dissenting opinion, Judge Newman stated that entry of another generic drug by the defendant would impair research and development of Indivior, causing it to lose market share and business opportunities, damage its reputation, and decrease Suboxone Film's advantageous formulary status. These grounds, according to the learned judge, were valid evidence to prove

[23] M/s Best Sellers Retail Pvt. Ltd. v. M/S Aditya Birla Nuvo Ltd., AIR (2012) SC 2448 (India).
[24] Dalpat Singh v. Prahlad Singh, AIR (1993) SC 276 (India).
[25] Verkeys, *supra* note 4.
[26] Merck Sharp and Dohme v. Glenmark Pharmaceuticals, (2015) 63 PTC 257 (India).
[27] Indivior Inc. v. Dr. Reddy's Laboratories, S.A., (Fed. Cir. 2018).

irreparable damage. Therefore, in patent infringement suits, the standard of irreparable damage is distinct from ordinary suits of injunction.

C. Balance of Convenience

Before passing a preliminary injunction, the court has to look into the balance of hardships between the applicant and the defendant that will be caused if the preliminary injunction is or is not granted. The party who is likely to suffer greater harm, will have the balance of convenience in its favour and will influence the court's decision. The apex court has observed that a preliminary injunction is granted to mitigate the risk of injustice to the plaintiff, if the balance of convenience is in his/her favour in the initial stages.[28] While discussing the balance of convenience in detail, the Delhi High Court has, in the case of *Franz Xaver Huemer v. New Yash Engineers*[29] laid down instances as to when the scales will tip in favour of the plaintiff. The court opined that product quality plus price, loss of employment, and public interest in the product are factors that might go against the plaintiff. Whereas factors like short period of time left for the expiry of the plaintiff's patent, the parties being of equal size, may go in the plaintiff's favour.

D. Public Interest

The factor of public interest has been recognized by the Indian courts by incorporating it into the analysis of balance of convenience as well as a separate factor. In a case involving patent infringement, whether or not there exists an element of public interest is primarily a question of fact that must be adjudicated upon on a case-to-case basis.[30] With respect to patent injunctions, public interest mostly comes into play pertaining to affordability and access to drugs as well as the commercial working of the patent in Indian Territory, although there may be other factors involved too. The reason why this is a vital element is because patents are a result of large-scale investments for the patentees and at the same time are critical for purposes like public health and economic growth. Thus, the court has to be very mindful and cautious while weighing the scales. Following is an analysis of the judicial approach of public interest in patent injunctions.

[28] Hindustan Petroleum Corp. Ltd. v. Sriman Narayan, (2002) 5 SCC 760 (India).
[29] Franz Xaver Huemer v. New Yash Engineers, (1996) 16 PTC 232 (India).
[30] DPS Parmar, *Consolidating Law of injunction in patent infringement - Indian Experience*, LEXORBIS (SEPT. 27, 2019), https://www.lexorbis.com/consolidating-law-of-injunction-in-patent-infringement-indian-experience.

III. JUDICIAL APPROACH

A. Bayer Corporation v. Union of India[31]

1. Facts and Judgment

A subject patent was granted by India's patent office on 3rd March 2008 to the petitioner Bayer Corporation, for their drug *"Sorafenib Tosylate"* that is sold under the name of "Nexavar" and used in the treatment of liver and kidney cancer. The petitioner Bayer Corporation was approached by the Indian drug making company Natco for the grant of voluntary license to produce and sell the drug in India under its brand name for Rs.10,000 per month as opposed to a whopping cost of Rs. 2,80,428 per month that was levied by the petitioner. The petitioner rejected Natco's application for grant of voluntary license of the drug Nexavar.

Only upon the patent holder's permission, can the patented drug be manufactured and sold by the third party. To get a compulsory license to manufacture and sell the Nexavar in India, Natco lodged an application under **Section 84(1)** of the Patents Act, 1970[32]to the Controller General of Patent. A *non-exclusive, non-assignable* compulsory license was eventually granted by the Controller, on 9th March 2012, to Natco to produce and sell the patented drug at a price of Rs. 8,800 and ordered them to pay the royalty 6% of its net sales to petitioner Bayer till the time of patent. Bayer appealed against the order of compulsory license in the Intellectual Property Appellate Board (IPAB) in 2013, contending that the order passed was in contravention with the Patents Act. The Board rejected the contention of Bayer and it upheld the order passed by the Controller General of Patents. On the issue of granting a compulsory license to the Natco in the Bombay High Court, Bayer challenged both the orders of 2012 and 2013 passed by the Controller General of Patent and by the IPAB. The apex court dismissed the petition as well. This helped clarify that irrespective of the subject matter, public interest garners the highest importance.

2. Analysis

The goals and objectives of the Patent Act are to encourage innovation, to protect the credit of the inventor and to avert them from any damage or infringement of their patent. But at the same time, this right cannot be exclusive at the cost of the general public. The mutual benefit for both

[31] Bayer Corporation v. Union of India, (2014) SCC Bom 963 (India).
[32] The Patents Act, 1970, No.39, Acts of Parliament, 1957, §84 cl.1 (India).

the public and the inventor is the main aim behind the entire legal framework related to IPR; hence patent holders can't illegitimately use it. The case at hand offered us a situation where personal interest was ruling over public interest just for earning profit on the patent that was invented by the patent holder, but the court elucidated that the misuse of the rights of patent and the greater good will always triumph over the profiteering interests. Hence the petition of Bayer Corporation was dismissed, and the court upheld the earlier decision of IPAB. The decision in the case at hand will overlay a long way to guarantee that the protection of public interest is not drowned by motives of self-benefit, personal interest of the patent holder in specific circumstances.

B. Hoffmann-La Roche Ltd v. Cipla Ltd.[33]

1. Facts and Judgment

A case for permanent injunction was instituted by F. Hoffmann-La Roche Ltd. and OSI Pharmaceuticals Inc., for restraining infringement of patent by Cipla Ltd. Mumbai. Indian Generic manufacturer Cipla had won the landmark Roche v. Cipla violation case within the Delhi High Court over Cipla's generic form of anti-cancer Drug Erlotinib.

The case was the first patent legal proceeding post-India's 2005 Product Patent Regime including public interest and costing issues additionally to India's Patent Act, Section 3(d) that stops evergreening.[34] Evergreening is a process where producers get the lifetime of their products extended that are on the verge of expiry, by several legal, business and technological tactics, in order to hold on to the royalties incurred from them, either by introducing fresh patents (for example over associated delivery systems, or new pharmaceutical mixtures), or by acquiring small scale companies or stagnating competitors, for extended periods of time than would usually be permissible under the law.[35]

In February 2007 Roche, along with Pfizer as joint applicants were granted a patent for the aforementioned drug. It was sold under the trademark name 'Tarceva'. The drug was not only

[33] F. Hoffmann-La Roche Ltd v. Cipla Ltd, (2009) 40 PTC 125 (India).
[34] UDAY S. RACHERLA, HISTORICAL EVOLUTION OF INDIA`S PATENT REGIME AND ITS IMPACT ON INNOVATION IN THE INDIAN PHARMACEUTICAL INDUSTRY 271-298, (1st ed. 2019).
[35] Frauce Thomas, *The Awful Truth About Evergreening*, THE AGE (JUNE 9, 2021), https://www.theage.com.au/national/the-awful-truth-about-evergreening-20040807-gdyero.html.

approved by several concerned agencies in the Europe and USA but also had a granted patent from the Controller General of Patents, New Delhi. The patented product after being introduced in the market in 2006 was brand named as TARCEVA for marketing purposes. Meanwhile, Cipla, the defendant announced their launch of a generic version of Tarceva (Erlotinib). The plaintiff alleged that their invention of Erlotinib was protected by law and developed after extensive years of research and huge expenditure. Hence it would be an outright violation of the plaintiff`s legal right if the defendant is granted the permission to manufacture or sell or market, the Tarveca drug in any form. However, after taking into consideration the bigger picture, it was concluded that if both the parties were allowed to sell the drug, then there would be a competition that would not only deter monopoly of the plaintiffs in the long run but also decrease the cost of the drug and increase production, which is crucial for such a lifesaving drug and in the larger public interest.

Hence, the court had to decide between guaranteeing lifesaving medicine at an inexpensive price and injunction order throughout the pendency of the trial. The court rightly prioritized the first over the second and rejected the plea of injunction on Cipla as several innocents who were not even parties to the suit would be needlessly impacted.

2. *Analysis*

In the current case, it's quite evident that the drug that was being sold in the market by Roche was costlier than the drug that was on the market by Cipla. While granting patent and pass ing injunction orders it is imperative to ascertain the general public benefit at large. In the present matter, the drug was a lifesaving drug that was being manufactured in India and at a relatively cheaper price and therefore the claim of infringement was rejected.

However, it should be noted that whereas the single judge decision relied on public interest as an element to refuse an injunction, the division bench rather decided on the component of irreparable injury being caused too many lives. A division bench later conjointly approved the order of the High court. The court during this case seemed concerned with the very fact that retreating offers of the drug could stop access and will have large implications for the public who weren’t parties to the suit.

Section 3(d) keeps an eye on ever greening above prescribed limits, as it tends to hinder the public health of the country, since the retailers charge exorbitant prices, which are unaffordable to the public at large. However, they still enjoy a considerable market share by creating a monopoly, which upsets the concept of patents in general. In the instant case as well, though the actual cost of the drug has been kept confidential, however, the court observed that Roche manufactured drug was costlier than Cipla. Hence, they concluded while granting patent and passing injunction orders what is more important is to see the public benefit at large. In the present case, the lifesaving drug was being manufactured in India and sold at a lesser price as compared to its competitor and was the only alternative for the public. Therefore, it led to the rejection of the claim of infringement.

C. Franz Xaver Huemer v. New Yash Engineers[36]

1. Facts and judgment

In this case, the appellant was a citizen of Austria who filed for a permanent injunction through his power of attorney, Mr. Lohia (proprietor of Lohia Starlinger), preventing the respondent from manufacturing, using, exercising, selling or marketing any items, which infringe the five patents granted to the plaintiff. The patented objects were some mechanical devices used in the textile industry. The respondent contended that there was no evidence of the plaintiff commercially exploiting his patents in India. Rather in a 1994 exhibition in Pragati Maidan, there was a substantial demand for the respondent's machine but none for the machines of Lohia Starlinger, hence the proprietor of the company decided to secure a power of attorney on 28 -2-1994 from the plaintiff and meanwhile filed suit on 26-2-1994. According to the respondent, the suit was filed because of malice and business rivalry as his machine was cheaper, had low maintenance, consumed lesser energy, and gave a higher output as compared to Lohia Machines.

The judgment of this case was, among the initial landmark decisions on the implications of non - working of patents, which notified that if a patent has not been researched and developed in India, a plea to restrain a third party from developing the same patent cannot be granted as it hampers the conditions of the market and the economy. The Delhi High Court held that a mechanical device that is a constructive invention must not be left untouched in the Indian industry, because not including the Indian public into such benefit would be detrimental to not only the notion of public welfare but also the economy.

[36] Franz Xaver Huemer v. New Yash Engineers, (1996) 16 PTC 232 (India).

2. Analysis

The crux of the ratio in this case was that the non-functionality of a patent can be a ground for a court to refuse an interim injunction on the ground that a patentee who is depriving the country of the patented invention cannot strip the Indian market and industry of the benefit of the invention by asking for an interim injunction against a third -party infringer. According to Sections 83 and 84 of the Patents Act, 1970, non-working of patents in India manifests a patent to compulsory licensing. However, in this regard the Indian courts have not given a concrete line of justification or reasoning. On similar lines, the same Court in another case[37] of a similar pattern ruled that an interim injunction will not be approved against the defendant who had allegedly infringed the plaintiff`s patent for a "4D Movie Experience". The balance of favour was tilted towards the defendants, as the plaintiff hadn't commercially exploited his patent and the defendant (even though had imitated the patented system) had put an enormous capital to manufacture the system. It is important to note here that when companies start off into new markets with fresh products it is crucial for them to float new technologies or products. However, it is imperative at this juncture to ensure that their products do not violate any existing patent in the concerned jurisdiction.

D. Comparative Analysis with the United States

The legal system of the United States also follows a similar mechanism to that of India when it comes to injunctions in patent infringement cases. The first three factors are also taken into account in US but when it comes to the public interest, it is only considered when the invention relates to areas like environment, healthcare, and public welfare.[38] The court in cases where the public interest is of importance undertakes a two-step investigation.[39] The court aims to initially determine whether the product in question, of which infringement is alleged, is vital in any way for the public at large.[40] Secondly, the court takes into account the availability of this vital product by substitutes that do not infringe the patent, should the preliminary injunction be granted.[41] Although this two-step method is not a matter of practice in India the same rationale

[37] Sandeep Jaidka v. Mukesh Mittal & Anr., (2014) 59 PTC 234 (India).
[38] Guangliang Zhang, *Remedies for Patent Infringement: A Comparative Study of U.S. and Chinese Law*, 1 J. MARSHALL REV. INTELL. PROP. L. 35 (2001).
[39] Samuel K. Lu, *The Fundamentals of Preliminary Injunctions, Permanent Injunctions, and Temporary Restraining Orders in Patent Cases*, 572 PLI/PAT 169, 175 (1999).
[40] *Id*.
[41] *Id*.

finds its way in the *obiter dicta* of any judgment in India. However, one major contrast in the US framework is that the applicant has a statutory duty[42] to provide a bond or security before the issuance of a preliminary injunction to ensure that the defendant is not at an added disadvantage if the trial turns out to be in their favour. This is one major loophole in Indian law where the discretion is granted to the court to issue an injunction but there is no duty cast upon the applicant to account for the change in court's opinion during the trial.

1. eBay Inc. v. MercExchange, L.L.C.[43]

i. Facts and Judgment

The petitioner, eBay, ran a popular Internet website that permitted private sellers to advertise goods they wanted to market, either through an auction or at a fixed price. A wholly-owned subsidiary of eBay, Half.com, which was the petitioner, ran a similar website. Respondent MercExchange, L.L.C., owned several patents, comprising of a business method patent for an electronic market intended to help the sale of goods between private parties by generating a central authority to boost the building of trust among participants.

MercExchange wanted to license its patent to eBay and Half.com, as was done in the past with other companies, but the parties were unsuccessful in reaching an agreement. Ultimately, MercExchange filed a patent infringement suit in the Virginia District Court against the two companies. The jury observed that MercExchange's patent was valid, that eBay and Half.com had violated that patent, and that an award of damages was proper. MercExchange's motion for permanent injunctive relief was denied by the District Court, following the jury verdict. The Court of Appeals for the Federal Circuit reversed the decision of the District Court, applying its universal rule that courts will issue permanent injunctions against patent infringement except in exceptional circumstances.

ii. Analysis

The US Patent Act expressly provides that injunctions must be issued in accordance with the principles of equity. Moreover, consistent with well-established principles of equity, a petitioner seeking a permanent injunction should satisfy a four-factor test before a court might grant such

[42] Fed. R. Civ. P. 65(c).
[43] eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 126 S. Ct. 1837 (2006).

relief. A litigator should demonstrate: (1) that it's suffered an irreparable injury; (2) that remedies accessible at law, like financial damages, are inadequate to compensate that injury; (3) that, a remedy in equity is warranted considering the balance of hardships between the litigator and the suspect; and (4) that an injunction will not hamper the general public interest.[44] Plaintiffs' interpretation that injunctions are mechanically granted is imperfect, as it fails to take into account that courts in rare instances do not issue injunctions. The decision to grant or deny permanent injunctive relief is an act of equitable discretion by the district court, reviewable on appeal for abuse of discretion.

Further, MercExchange was successful in standing up to the test of permanent injunction because their electronic market business between private players was beneficial for public interest as they were generating a central authority to boost the building of trust among participants, and making the purchase and selling of such electronic goods accessible and simple for the masses. Additionally, as every business runs on goodwill, hence eBay selling their goods without the license would affect their interest and cause an irreparable injury to their goodwill, in cases of customer complaints and low standard goods. Therefore, the remedy was granted keeping in consideration the hardships that the litigant could have foreseen in the future, including their immense effort in setting up a standard business and the goodwill created henceforth, as it would be difficult to compensate this loss with damages.

However, it is pertinent to note that public interest is not a complete exception to grant of patent or patent infringement. The courts will not always refuse injunctions on the ground of reasonable affordability of drugs to the public.[45] The courts have, in some instances, overlooked the public interest aspect in order to secure the rights of a patent holder and to prioritize the integrity of the patent system.[46]

2. Sanofi v. Apotex [47]

i. Facts and Judgment

The short path to drug approval in the United States is the Abbreviated New Drug Application ("ANDA"). It was introduced to permit a generic drug company to commence a "bioequivalent"

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[44] Jonathan Kim, *Injunction*, LEGAL INFORMATION INSTITUTE CORNELL LAW SCHOOL, https://www.law.cornell.edu//wex/injunction. (last visited June 19, 2021).
[45] Novartis AG v. Cipla Ltd., 2015 (61) PTC3 63 (India).
[46] Merck Sharp and Dohme v. Glenmark Pharmaceuticals, 2015 (63) PTC 257 (India).
[47] Sanofi v. Apotex, 488 F.Supp.2d 317 (S.D.N.Y. 2006).

edition of a currently permitted, brand-name drug.[48] Particularly, if a generic drug company challenged the legitimacy of patents representing a brand -name drug in its application, it could get a privilege after its request was accepted, where it could exclusively share the market of the brand-name drug with the established drug company for 180 days, in the ANDA mechanism. However, the concession is mainly conditioned on whether the leading drug company will bring a claim against the standard drug company for patent infringement and if the generic drug company could be successful in such litigation.

In order to prevent heart diseases, such as heart attacks and strokes, Plavix, also known as clopidogrel, was an approved and prescribed drug[49] that functioned by restricting platelets from sticking together.[50]A French drug business, Sanofi-Synthelabo started to develop Plavix, in 1972,[51]and in 1997, the U.S. Food and Drug Administration ("FDA") permitted the drug. Bristol-Myers Squibb sold the drug Plavix in the United States. The sale of Plavix garnered income of billions in 2008,[52] and was the second-best-grossing drug in the world in 2008.[53] However, Plavix was expensive.[54] The ANDA mechanism was used for a generic version of Plavix in November 2001 and was tendered to the FDA by a Canadian company Apotex, Inc. ("Apotex").[55] The patent holders of Plavix, Sanofi, filed a case against Apotex after Apotex put down its ANDA. The patentees in 2008 bagged the suit after six years of struggle and were successful in defending the legitimacy of the patent of Plavix.

ANDA is believed to promote drug companies' struggle in the market of a generic drug.[56] Specifically, ANDA is introduced to encourage a generic drug company to challenge a pioneer drug company and in this process increase competition in the market. But, the story of Sanofi-Synthelabo v. Apotex, Inc. discloses the unfulfilled objectives and goals of ANDA. As a result,

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[48] Wansheng Jerry Liu, *Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases*, 18 ALB. L.J. SCI. & TECH. 441, 447–48 (2008).

[49] Stephanie Saul, *Marketers of Plavix Outfoxed on a Deal*, N.Y. Times (Aug. 9, 2006), https://www.nytimes.com/2006/08/09/business/09drug.html.

[50] Reuters, *Risks with Heart Drug*, N.Y. Times, (Feb. 6, 2008), https://www.nytimes.com/2008/02/06/us/06brfs-RISKSWITHHEA_BRF.html

[51] Andrew Ross Sorkin, *Sanofi Makes Its Bid for Aventis; It Is Quickly Rejected as 'Inferior'*, N.Y. Times, (Jan. 27, 2004), https://www.nytimes.com/2004/01/27/business/sanofi-makes-its-bid-for-aventis-it-is-quickly-rejected-as-inferior.html.

[52] Natasha Singer, *Judge Orders Former Bristol-Myers Executive to Write Book*, N.Y. Times, (June 9, 2009), https://www.nytimes.com/2009/06/09/business/09bristol.html.

[53] Natasha Singer, F.D.A. Panel Approves Lilly Drug for Clotting, N.Y. Times, (Feb.4, 2009), https://www.nytimes.com/2009/02/04/business/04lilly.html.

[54] Gardiner Harris, Study Raises Questions on Plavix Safety, N.Y. Times, (Jan. 20, 2005), https://www.nytimes.com/2005/01/20/health/study-raises-questions-on-plavix-safety.html.

[55] Sanofi-Synthelabo v. Apotex, Inc. (Sanofi IV), 550 F.3d 1075, 1078.

[56] Stephanie Saul, *Drug Executive is Indicted on Secret Deal*, N.Y. Times, (Apr. 24, 2008), https://www.nytimes.com/2008/04/24/business/24bristol.html.

the generic drug company was unsuccessful in its patent challenge, and the leading drug company committed an antitrust crime during the ANDA fight between these two companies.

ii. Analysis

The issue to be evaluated here is whether the recognition of a preliminary injunction would go against public interest. The liability on the patentee when it comes to this component is mostly in the negative, that is to establish that public interest would not be affected by the grant of an injunction. Though there is public interest involved in enabling access to generic versions of medicines at lesser prices, but there is also a public interest ingredient in enforcing patents and encouraging innovation. If harmonizing these two competing interests in a specific case indicates that simultaneous interests are at equipoise or faintly in favour of the patentee, the "public interest" point of the analysis tilts towards the patentee. If, however, the interest in favour of making accessible generic drug version at a lower price outweighs the competing interest, this prong of the analysis favours the accused infringer. In the framework of harmonizing the above interests, the US courts give the idea that the position of price differential alone is not a tipping point i.e. the sheer fact of the accused infringer selling at a lesser price than the patentee is alone is not sufficient to overshadow the interest in enforcing a valid patent.

In *Sanofi-Synthelabo v. Apotex, Inc*., the Federal Circuit held that the district court had applied a conjecture of irreparable harm in deciding whether to award a preliminary injunction.[57] Characteristically, in a patent infringement case, though there exists a public interest in defending rights guaranteed by valid patents, the point of contention of the district court's study should be whether there existed a few decisive public interests that would be offended by the grant of preliminary relief. There were noteworthy public interests on either side in the impugned litigation, but the Court found that the balance in the context of this action lied in favour of Sanofi.

Public interest indisputably lies in plummeting the obstacles to generic competition in the pharmaceutical industry, since then the valuable drugs at reduced prices will be accessible to the public. This is most definitely a rational position for a producer of generic drugs to take and, indeed, the Court decided that there is a significant public interest in making lower-priced generic drugs available and accessible to the public. In addition, the repudiation of the state attorneys to endorse the anticipated settlement between Sanofi and Apotex shows that the

[57] Sanofi-Synthelabo v. Apotex, Inc, 470 F.3d 1368, 1381 (Fed. Cir. 2006).

regulators determined that the public interest was served by preventing the agreement's barrier to probable competition. The public interest in lower-priced drugs is definitely significant. Nevertheless, the public interest in lower-priced drugs is weighed by a noteworthy public interest in motivating the enormous investment in research and development that is necessary before a new drug can be developed and brought to market. The Federal Circuit lately measured these competing interests in *Pfizer Inc. v. Teva Pharms*.[58] In that case, just as here, a company desiring to bring about a generic edition of a patented drug argued that the public interest must be favoured and contested a preliminary injunction on the theory that the Hatch-Waxman Act framework 'makes low-cost generic drugs available to the public through increased competition.' The district court discarded this argument, opining that a preliminary injunction that implements a valid patent against an infringer 'does no more than further public policy inherent in the patent laws designed to encourage useful inventions by rewarding the inventor with a limited period of market exclusivity.'

As set forth above, both the public interest involved in lesser costing drugs on one hand and the public interest in motivating investment in drug development and safeguarding the exclusionary rights devolved in legitimate pharmaceutical patents on the other, are present here. The judiciary found the public interest lied slightly in favour of Sanofi, where Apotex concedes that its product violates Sanofi's patent as Congress had fashioned the patent laws in such a way as to balance the public's interest in market competition with the public's interest in working on innovation.

IV. RECOMMENDATIONS AND CONCLUSIONS

The authors are in agreement with the decisions of the honourable courts in weighing the balance of scales of public interest against an injunction in infringement of a patent. However, there are a few points that are necessary to be considered.

- While determining the existence of a prima facie case, a two-fold modification is required. First, the patent law regime needs to be amended and there needs to be a presumption in favour of the validity of a patent. Secondly, while deciding on a preliminary injunction application in a patent infringement case, the court need not delve into the validity of the patent, irrespective of the number of years it has been since the patent was granted.

[58] Pfizer Inc. v. Teva Pharms, 429 F.3d at 1364 (Fed. Cir. 2005).

- It is commendable that the courts have proactively considered the factor of public interest, which takes consumer welfare within its ambit. However, the consideration of antitrust is still amiss in the legislative and judicial approach. It has hardly found its way even impliedly in the decisions of the courts. Although there exists a separate Commission to adjudicate upon competition law issues, in patent cases, the courts must consider whether the grant or rejection of an injunction will have an effect on the competition in the market.
- Another factor that could be taken into consideration is the interest of the patentee as against the public interest because the patentee would have spent years of research and invested a fortune to get where they are. As is evident from the analysis of the judicial trend in the US courts, they often take into consideration the rights of the patentee and the public interest in enforcing those rights. In the U.K. as well, the courts have recognized the fact that enforcing valid patents is itself a matter of public interest.[59]However, this is something that is still lacking in the Indian jurisprudence and must find its way in.

Injunction is an equitable remedy which, jurisprudentially speaking, refers to the power of courts to do justice to both the parties, by exercising its discretion.[60] However, as we observed, the balance of hardships required in patent cases is quite different. Thus, the judicial standard applied in these cases must be independent of those of civil litigation cases, owing to the public interest of both the parties involved.

[59] Chiron v. Organon, [1995] F.S.R. 325.
[60] Kevin C. Kennedy, *Equitable Remedies and Principled Discretion: The Michigan Experience*, 74 U. DET. MERCY L. REV. 609 (1996-1997).