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Research

Patent Litigation in India

Strategy and Law

July 2021

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We are an India Centric Global law firm **(www.nishithdesai.com)** with four offices in India and the only law firm with license to practice Indian law from our Munich, Singapore, Palo Alto and New York offices. We are a firm of specialists and the go-to firm for companies that want to conduct business in India, navigate its complex business regulations and grow. Over 70% of our clients are foreign multinationals and over 84.5% are repeat clients.

Our reputation is well regarded for handling complex high value transactions and cross border litigation; that prestige extends to engaging and mentoring the start-up community that we passionately support and encourage. We also enjoy global recognition for our research with an ability to anticipate and address challenges from a strategic, legal and tax perspective in an integrated way. In fact, the framework and standards for the Asset Management industry within India was pioneered by us in the early 1990s, and we continue remain respected industry experts.

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Contents

1. Introduction

Patent rights are precious commodities and are fiercely protected. Since the early **2000**s, India has seen a rapid increase in patent litigations. With patent protection being extended to all types of technologies including foods, pharmaceuticals, etc. in 2005, Indian courts saw a growth in patent infringement actions post 2005 specifically in relation to pharmaceutical patents. Today, courts are regularly dealing with patent infringement disputes involving sophisticated innovations in the field of pharmaceuticals, telecommunications, agriculture, etc.

Patent law in India is codified under the Patents Act, 1970 (**"Patents Act"**) which is similar, in many ways, to the UK Patents Act, 1949. For this reason, a majority of principles of patent law in India have developed in a manner similar to those in the UK. However, India being a developing country, principles aiming to ensure a balance between rights of a patent holder and public interest (such as access to medicine) have played a significant role in development of patent law jurisprudence in India.

Owing to the various steps involved such as determination of scope of claims, validity of a patent and infringement analysis, patent litigations are still considered complex litigations in India. Over the years, courts have dealt with high-tech patent disputes and developed principles surrounding claim construction, establishing infringement of patents involving different types of inventions, role of scientific experts, etc. These principles are important to understand how courts in India approach patent litigations, and are also essential for the formulation of an effective litigation strategy to ensure timely and positive results.

Recent Developments

From a procedural perspective, the legislature has taken steps to streamline patent (and other intellectual property) litigation. In 2015, the Commercial Courts Act, 2015 (**"CCA"**) was enacted for the formation of "Commercial Courts" for speedy disposal of commercial disputes, including disputes involving intellectual property rights. The CCA has introduced strict timelines for adjudication for commercial disputes. Interestingly, the CCA has also introduced the concept of mandatory pre-litigation mediation of commercial disputes when no urgent relief is sought.

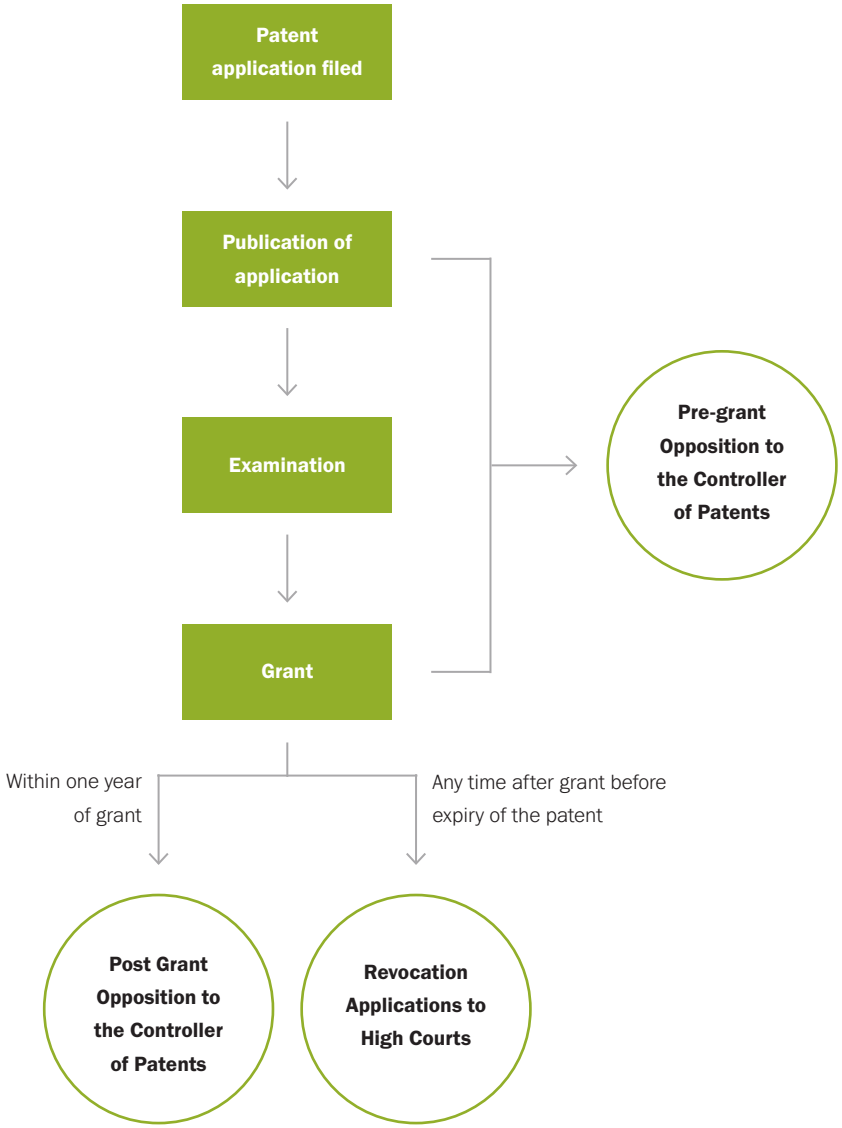
Recently, the Tribunals Reform (Rationalisation and Conditions of Service) Ordinance, 2021[1] (**"2021 Ordinance"**) has been promulgated to abolish the Intellectual Property Appellate Board (**"IPAB"**) which is the appellate tribunal dealing with all appeals from the Indian Patent Office, and Commercial Courts and High Courts have been granted the jurisdiction to decide on all such appeals. This move has been welcomed by many in the industry as a step to expedite the appeals process.

1. Available at https://copyright.gov.in/Documents/Pdf/Tribunals_Reforms__Rationalisation_And_Conditions_Of_Service__Ordinance__2021.pdf (Last accessed on June 19, 2021).

2. Types of litigations/proceedings

Apart from the patent infringement proceedings discussed in detail in this paper, several other forms of adversarial proceedings with respect to granted patents/pending patent applications may be filed from time to time. The outcome and / or timing of these proceedings can have an impact on the strategy for patent infringement actions and therefore, are important to be understood.

The chart below demonstrates the different proceedings that can be initiated with respect to a patent application/ granted patent at various stages of prosecution of the patent application and after grant of the patent:



I. Pre-Grant Opposition

A pre-grant opposition may be filed opposing grant of a patent application at any time between publication of the application and grant of the patent. The grounds for filing a pre-grant opposition against the grant of a patent before the Controller of Patents (**"Controller"**) are contained in Section 25(1) of the Patents Act (see **Annexure A**).

Such an opposition may be filed by "any person", without there being any further qualifications under the

provision. In a pre-grant opposition, under Rule 55 of the Patents Rules, 2003 (**"Patent Rules"**) the Controller considers the notice of opposition only once a request for examination has been filed by the patent applicant. After considering the notice of opposition, where the Controller is of the opinion that the patent application shall be refused, or that the complete specification requires amendment, a notice to that effect is given to the applicant. Upon the filing of requisite statement and evidence by the applicant, the Controller may hold a hearing if so requested by either party, nd thereafter may either refuse to grant the patent or require the complete specification to be amended to his satisfaction. Further, the rejection of a pre-grant opposition by the Controller at any stage does not give the opponent a right to appeal against such a decision. Such rejections also cannot be challenged in writ petitions before High Courts, since such rejections do not take away the opponents' alternate statutory remedies of post-grant opposition and revocation[2] discussed below).

II. Post-Grant Opposition

A post-grant opposition can be filed challenging the grant of patent only within one year from the date of grant of the patent. In case of post-grant oppositions filed before the Controller under Section 25(2) of the Patents Act, the grounds available are identical to those available in case of pre-grant oppositions.

Post-grant oppositions differ from pre-grant oppositions in that they can be filed only by **"persons interested",** which is a more limited range of applicants than the latter. Section 2(1)(t) of the Patents Act defines a person interested to include **"a person engaged in, or in promoting, research in the same field as that to which the invention relates."**[3] It has been held by the Supreme Court that "a person interested" is **"a person who has a direct, present and tangible interest with a patent, and the grant of the patent adversely affects his rights"**[4] A "person interested" would include any individual who desires to make independent use of either the invention itself (which has been patented), or desires to exploit the process (which has been patented) in his individual production activity.[5]

Procedurally, a post-grant opposition is governed by Section 25(3), whereby the Controller constitutes an Opposition Board and refers the notice of opposition for its examination and recommendations. After receiving the recommendations of the Opposition Board, the Controller gives the patentee and the opponent an opportunity of being heard. The Controller may take a decision under Section 25(4) to maintain, amend or revoke the patent. Until recently, appeals against such decisions of the Controller were to be filed before the IPAB. By virtue of the recent amendment to Section 117A of the Patents Act under the 2021 Ordinance, such appeals will now be heard by High Courts of relevant jurisdiction.

III. Revocation

Once the period of one year has expired after the grant of a patent, the patent can be challenged by way of a revocation petition. Under Section 64 of the Patents Act[6], any "persons interested", or the Central Government may file petitions before High Courts seeking rectification of a granted patent at any time after grant. Patents may also be revoked under this provision when a defendant in a suit for infringement files a counterclaim challenging the validity of a patent. As per the amendment made by the 2021 Ordinance, revocation applications under this section can be filed by any person interested, the Central Government, or on the filing of a counter claim by a defendant in an infringement suit before the relevant High Courts. The locus for filing a revocation petition under Section 64 as a

2. UCB Farchim v. Cipla, W.P.(C) 332 of 2010, Delhi High Court judgment dated February 8, 2010
3. Section 2(1)(t), Patents Act.
4. Aloys Wobben v. Yogesh Mehra, (2014) 15 SCC 360.
5. ibid.
6. As amended by the Tribunals Reforms (Rationalisation and Conditions of Service) Ordinance, 2021.

"person interested" is the same as that contemplated for post-grant oppositions under Section 25(2). A comparison of the grounds available for filing pre/post-grant oppositions and revocations have been listed at Annexure A below.

IV. Compulsory licensing

Under Section 84 of the Patents Act, a person interested can file an application before the Controller for a compulsory license in respect of a patent granted at least three years prior to the date of such application. Under this section, the Controller may grant a license to such an applicant if it is shown that: (i) the reasonable requirements of the public with respect to the patented invention have not been satisfied; or (ii) the patented invention is not available to the public at a reasonably affordable price, or (iii) the patented invention is not worked in the territory of India. While granting the license, the Controller also considers whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions.[7] A decision made under this section by the Controller allowing or rejecting an application for compulsory license has been made appealable under Section 117-A. Read with the 2021 Ordinance, such appeals will lie before relevant High Courts.

Till date, a compulsory license has been granted in India only once in favour of Natco Pharma Limited for Bayer's patent for the drug Sorafenib Tosyalte. For a more detailed discussion on this issue, please see our hotline at **Annexure B.**

V. Procedural conflicts

A. Simultaneous counter claim and revocation proceedings against a patent

Although the Patents Act provides various provisions for the opposition/revocation of patents after grant, it does not provide for the outcome in cases where such provisions are invoked simultaneously. In the case of **Aloys Wobben v. Yogesh Mehra**[8] **("Aloys Wobben case")**, the Supreme Court held that the initiation of a revocation proceedings by a "person interested", would eclipse such person's right to simultaneously file a counterclaim under Section 64. Therefore, if a defendant in their capacity as "any person interested", had filed a "revocation petition" before the institution of an "infringement suit", they cannot be permitted to file a "counter-claim" on the same cause of action. Similarly, if a counterclaim was filed before filing of revocation, the defendant cannot initiate revocation proceedings as well. In practice, in view of this judgment, courts have allowed a defendant to choose if they wish to continue with the revocation petition or file a counterclaim. Defendants have therefore been able to withdraw their revocation in order to file a counterclaim instead.

B. Filing of a pre-grant opposition during pendency of appeal against rejection of a patent application

In cases where a patent application has been rejected by the Controller, a patent applicant can file an appeal against the rejection under Section 117-A of the Patents Act before the relevant High Court. However, where such an appeal is pending, no pre-grant opposition can be filed before the Controller challenging the grant of such a patent.[9]

7. BDR Pharmaceuticals International Pvt. Ltd v. Bristol Myers Squibb Company, CLA No.1 of 2013, Order of the Controller of Patents, dated October 29, 2013.
8. Supra note.
9. Dhaval Diyora v. Union of India and ors. decided on November 5th, 2020 by Bombay High Court Writ Petition (L)) no. 3718 of 2020.

3. Infringement Under the Patents Act

Unlike the Trademarks Act, 1999,[10] the Patents Act does not define the term "infringement" of a granted patent. Hence, under the Patents Act, infringement is determined on the basis of the exclusive rights granted to a patentee. Section 48 of the Patents Act,[11] confers exclusive rights upon the patentee to exclude third parties from making, importing, using, offering for sale or selling the patented product or patented process.

A suit for patent infringement can therefore be filed against any person carrying out activities specified in Section 48 without authorisation from the patentee. These include, in relation to a product patent:

1. manufacturers[12]/importers[13] of patented product; and
2. distributors and sellers[14] offering patented products for sale.

Similarly, for a process patent, any person using the process and/ or using, offering for sale, selling or importing the product obtained directly by that process without authorisation from the patentee can be sued. This would include manufacturers using the patented process and distributors and sellers offering for sale the product obtained from the patented process. When two or more persons have jointly infringed the patent, both can be made parties to the same infringement action.

As stated above, Section 48 grants to the patentee the exclusive right to exclude third parties from using a patented product or the product obtained from the patented process. It remains to be seen if a user of an infringing product can also be sued.

I. Test for patent infringement

Courts in India have followed the below mentioned test to determine infringement of a patent[15]:

A. Determine the meaning and scope of the patent claims asserted to be infringed

Claim construction is the first step of an infringement analysis. Indian courts from time to time have discussed the tools for construction of claims. In **Raj Parkash v. Mangat Ram Chowdhry And Ors.**[16] the Delhi High Court noted that **"the main function of the court is to construe the claims (stated at the end of specifications in the patent) which are alleged to have been infringed without reference to the body of the specifications and to refer to the specification only if there is any ambiguity or difficulty in the construction of the claims in question."**

10. See Section 29 of the Trademarks Act 1999.
11. See Section 48 of the Patents Act.
12. Koninklije Philips N.V. & Anr. v. Rajesh Bansal, CS (COMM) 24 of 2016 and Koninklije Philips N.V. & Anr. v. Bhagirathi Electronics, CS (COMM) 436 of 2017, Delhi High Court, judgement dated 12 July 2018.
13. Communication Components Antenna Inc. v. Ace Technologies Corp. & Ors. [CS (COMM) 1222 of 2018], Delhi High Court judgment dated 12 July 2019.
14. Ibid.
15. F. Hoffmann-La Roche Ltd. & Ors. v. Cipla Ltd., 225 (2015) DLT 391, citing Herbert Markman v. Westview, 52 F.3d 967.
16. AIR 1978 Delhi 1.

The principles of claim construction have also been discussed in detail by the Delhi High Court in **F. Hoffmann-La Roche Ltd. and Ors. v. Cipla Ltd.**[17] In addition to the claim language and the complete specification, courts in India may also rely on extrinsic evidence such as inventor testimony, dictionaries and treaties to determine the scope of the claims, however, such evidence is likely to be given lesser value.[18]

B. Compare the properly construed claim with the device accused of infringing

The comparison in a patent infringement action is not between the plaintiff's product/process and the defendant's product/process, but between the claims and the defendant's product/process. The plaintiff must therefore establish that the defendant's product/process contains all features of the plaintiff's patent's claims.[19]

i. Infringement by Equivalence and the Doctrine of Pith and Marrow

In the case of **Winans v. Denmead**[20], a "Triple Identity Test" was introduced to determine infringement, to see if a patent is infringed without even a literal infringement if some other elements of the accused device or process:

i. Performs substantially the same function,

ii. In substantially the same way,

iii. To achieve substantially the same result.

Such an approach is taken to determine if there is infringement by equivalence.

The test was adopted in the recent case of **Ravi Kamal Bali v. Kala Tech**[21] where the court considered whether the defendants' products do the same work, in substantially the same way and accomplish substantially the same result and therefore constitute an infringement of the plaintiff's patents. While the court in this case appeared to agree with the plaintiff's contention, no injunction was granted to the plaintiff due to suppression of material facts.

While applying the test for infringement, courts in India and the UK have taken another approach similar to the doctrine of equivalence, called the doctrine of pith and marrow. Application of the doctrine of pith and marrow is similar to the doctrine of equivalence since under the former, the courts look into not just the literal sense of the claim but also the substance of the claim. The Delhi High Court observed in **Raj Parkash v. Mangat Ram Chowdhry & Ors.**[22] that the specification and claims must be read from the point of view of a person skilled in the art to understand the pith and marrow of the invention. Similarly, the Madras High Court in **TVS Motor Company Ltd. v. Bajaj Auto Limited**[23] held that it needs to be seen whether the alleged infringement has taken the substance of the invention ignoring the fact as to omission of certain parts or addition of certain parts.

17. F. Hoffmann-La Roche Ltd. & Ors. v. Cipla Ltd, supra note 5.
18. Ibid.
19. See Chapter 4, Section (iii) below for a further discussion on ways to establish infringement by mapping the patent claims.
20. 56 U.S. 330 1853.
21. 2008 (110) Bom. L.R. 2167.
22. Raj Prakash v. Mangat Ram Choudhary, AIR [1978] (Del) Delhi 1.
23. 2018 (1) CTC 849 2008 (36) PTC 417 Mad.

II. Types of patent infringement

Patent infringement can broadly fall in the following categories:

a. **Literal Infringement** occurs when each and every component claimed in patent specification has been used in alleged infringing product/device or process. Accused product or process falls directly within the scope of patent claims.

b. **Induced Infringement:** It is a form of infringement wherein a person does not directly infringe a patent but induces or influences someone to make unauthorized use of someone's patent, actively inducing someone to make prohibited use of someone else's patented property.[24]

c. **Contributory Infringement:** In this form of infringement a person contributes to the unauthorized use of patented property. It is determined by the degree of knowledge a party has regarding the possibility of infringement, even if no direct infringement per se has been carried out by the party.[25]

The concepts of induced infringement and contributory infringement are not covered in the Patents Act, although they are recognised in relation to trademarks.[26] However, since these are principles of common law, a party may still be able to make a case relying on common law principles.

III. Burden of proof in patent infringement actions

The burden of establishing the case of infringement rests on the plaintiff. However, in infringement actions related to process patents, the burden of proof may shift to the defendant as provided under Section 104A of the Patents Act.[27] As per the provision, in an infringement action pertaining to a process patent, the court may direct the defendant to provide that the process used by the defendant to obtain a product is different from the patented process of the plaintiff if there is a substantial likelihood that the identical product is made by the defendant's process and the plaintiff has been unable to determine the process used by the defendant. Section 104A also provides that for the court to shift the burden of proof in this manner, the plaintiff must first establish that the defendant's product is identical to the product obtained directly by the patented process.[28]

24. Global-Tech Appliances, Inc. v. SEB S.A., 131 S. Ct. 2060 (2011).
25. Grimme v Scott [2010] EWCA Civ 1110.
26. Christian Louboutin Sas v. Nakul Bajaj & Ors., CS (COMM) 344/2018, I.As. 19124/2014, 20912/2014, 23749/2014 & 9106/2015, Delhi High Court, judgment dated 02 November 2018.
27. See section 104-A of the Patents Act
28. Also see Glenmark Pharmaceuticals Ltd. and Anr. v. Symed Laboratories, Order of the Delhi High Court in FAO (OS) 60/2015 dated 05.02.2015.

4. Reliefs Available to the Patentee

Section 108(1) of the Patents Act, 1970 provides for reliefs in suits for infringement. The reliefs that are available to a patentee under this Section are –

I. Temporary/Interlocutory Injunction

A temporary injunction or an interim injunction is an injunction granted during the pendency of the infringement action. The object of the temporary injunction is to protect the plaintiff against injury by violation of his right for which he could not be adequately compensated in damages recoverable in an action if the uncertainty were resolved in his favour at the trial.[29] To seek a temporary injunction, the plaintiff must move an application under Order 39 Rules 1 and 2 of the Code of Civil Procedure, 1908 (**"CPC"**) along with the suit itself.

A temporary injunction can be sought ex parte, i.e., without the presence of the defendant, at the initial hearing of a suit at which point the defendant has not been served with a notice of the suit.[30]

A. Threshold for grant of injunction

An injunction, temporary or permanent, is granted if:

1. There is a prima facie case that the patent is valid and is infringed;
2. The patent holder will suffer an irreparable loss if the injunction is not granted; and
3. The balance of convenience is in favour of the injunction being granted.[31]

In patent infringement actions, in addition to the above three thresholds, courts at times also consider whether grant of the interim injunction would be detrimental to the public interest.

B. Prima Facie Case

There is no presumption of validity attached to a granted patent under the Patents Act. Therefore, to grant a temporary injunction, first a prima facie case about the existence of the monopoly, right and its infringement must be established.[32]

The court is unlikely to grant a temporary injunction if there exists a question about the validity of the patent.[33] On the other hand, if the patent in question has been tested in a pre-grant/post-grant/revocation, courts are likely to weigh in favour of the plaintiff. In the case of **3M Innovative Properties Ltd v. Venus Safety & Health Pvt Ltd**[34]**,** the Delhi High Court held that where a patent has been granted in US and India after examining existing prior art, there is a higher burden of proof to establish invalidity.

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29. Sandeep Jaidka v. Mukesh Mittal & Anr. 2014 (59) PTC 234 (DEL) citing American Cynamid Co. v Ethicon Ltd. [1975] RPC 513.
30. Due to the ongoing pandemic, the rules regarding service to defendants have been modified by several courts in India. For instance, the Delhi High Court has made service before filing of a suit upon the defendant mandatory. It is possible for a plaintiff to move an application and seek exemption from such service.
31. National Research Corporation of India v. the Delhi Cloth & General Mills Co. Ltd., AIR 1980 Del 13.
32. Surendra Lal Mahendra Jain v. Glazers, 1981 PTC 112 (117).
33. V. Manika Thevar v. Star Plough Works, AIR 1965 Madras 327.
34. FAO(OS) 292/2014 & CM No. 10651/2014.

For this purpose, courts consider if a defendant's challenge to the validity of the plaintiff's patent is credible. "Credible challenge" means that there is a serious question to be tried in the suit with respect to the validity of the patent.[35] The defendant is required to show that the patent is "vulnerable" and that the challenge raises a "serious substantial question" and a triable issue.[36] At the preliminary stage, the Court does not examine the challenge in any detail and arrive at a definite finding on the question of validity, but only determines if the patent is vulnerable to challenge.[37]

Courts over the years have observed how and when courts may consider a patent to be valid. For instance, in **National Research and Development Corporation of India v. Delhi Cloth & General Mills,**[38] the Delhi High Court noted that if "there has been a previous trial in which the patent has been held to be valid, or that the patentee has worked and enjoyed the patent for many years without dispute, or it may be that as between the parties the plaintiff is relieved from the onus of establishing validity, as where the defendant has admitted it or is so placed in his relationship to the plaintiff as to be estopped from denying it," the court may assume that the patent is valid.

Another principle that has been developed over the years is the "six year validity" rule. There have been some rulings wherein courts have observed that if a patent is valid for six years, a court may presume validity.[39] However, in several decisions, the six year validity rule has been questioned by courts.[40]

C. Irreparable Harm/Loss

An irreparable loss is a loss which cannot be compensated in terms of money. Before granting an injunction, courts will consider if damages are an adequate remedy. Factors that may be relevant for this determination may include delay in approaching court, loss to the defendant, etc. Since the test of irreparable harm is that loss to the plaintiff cannot be quantified in terms of money, quantifying of damages in a legal notice sent to the infringer prior to filing of suit may be disadvantageous to a claim of irreparable harm during the suit.

D. Balance of convenience

One of the most important factors for balance of convenience is the disadvantage suffered by either or both parties and the extent of disadvantage which cannot be compensated by damages. Factors like expiry of patent within short period of time, equal size of parties may go in the favour of the patent holder whereas factors like stultification of defendant's investment, loss of employment, and public interest may go in favour of the defendant.[41]

E. Public interest: The fourth factor in infringement analysis

Often in patent infringement cases (especially those involving pharmaceutical products), courts in India have also considered a fourth factor of public interest while determining whether an injunction ought to be granted. In **F. Hoffmann La-Roche v. Cipla Ltd.,**[42] the Delhi High Court noted:

35. F. Hoffmann-LA Roche Ltd. and Ors. v. Cipla Ltd. 2009 (40) PTC 125 (Del).
36. Ibid.
37. Ibid.
38. AIR 1980 Del 132.
39. See National Research and Development Corporation of India v. Delhi Cloth &General Mills Co. Ltd., AIR 1980 Del. 132.
40. See 3M Innovative Properties Company v Venus Safety & Health (IA No. 20605/2013 & IA No. 1276/2014 in CS[OS] No. 2558/2013); Mariappan v. AR Safiullah (2008) 38 PTC 341 (Madras).
41. Supra note 5, at 235.
42. See supra note 25.

> *'81. This Court is inclined to concur with the learned single Judge that in a country like India where question of general public access to life saving drugs assumes great significance, the adverse impact on such access which the grant of injunction in a case like the instant one is likely to have, would have to be accounted for. Erlocip is the Indian equivalent produced by the defendant in India as a generic drug manufacturer. It is priced at Rs.1600 per tablet. Even if this does not make it inexpensive, the question of greater availability of such drug in the market assumes significance.'*

In **Merck Sharp and Dohme Corporation and Anr. v. Glenmark Pharmaceuticals**[43], the Delhi High Court observed that public interest is now well established in Indian jurisprudence and the Court must look at the public interest in granting an injunction, as access to drugs is an important facet of the patent regime. Recently, however, the Delhi High Court has also clarified that merely on supposed public interest, a court cannot grant interlocutory injunction, unmindful of the existence of a prima facie case, or the considerations of balance of convenience and irreparable loss.[44]

II. Permanent Injunction

On proving infringement in trial, permanent injunction may be granted to the patent holder. By way of a permanent injunction, the defendant can be restrained from engaging in infringement activities perpetually.

III. Damages or account of profits

A plaintiff can choose between claiming damages and accounts of profits in a patent infringement action.[45] Damages refers to the loss sustained by plaintiff because of infringer's activities. On the other hand, "accounts of profits: refers to the profits made by the infringer by infringement activities.

The calculation of damages or account of profits for infringement may be made from the date of publication of the patent application (and not the date of its grant), as Section 11A of the Patents Act provides that **"the applicant shall have the like privileges and rights as if a patent for the invention had been granted on the date of publication of the application."**

Damages awarded may be of the following types, amongst others:

1. General and special damages
2. Exemplary damages
3. Punitive damages[46]

From a practical perspective, till date a handful of patent infringement actions have reached the stage of award of damages. Typically, patent infringement actions are filed with the goal of obtaining an injunction to restrain the defendant from continuing infringement.

43. Merck Sharp and Dohme Corporation and Anr. v. Glenmark Pharmaceuticals, 2015 (63) PTC 257 (Del).
44. Indoco Remedies Ltd v. Bristol Myers Squibb Holdings, 2020 (83) PTC 551 (Del).
45. Section 108 of the Patents Act.
46. For a general discussion on the law of damages in India, please refer to http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/Law_of_Damages_in_India.pdf.

As per Section 111 of the Patents Act,[47] a court may refuse to award damages or accounts of profits for the following reasons:

1. The defendant proves that at the date of the infringement she was not aware and had no reasonable grounds for believing that the patent existed;

2. Infringement has been committed after failure to pay renewal fee for the patent;

3. In a case where a specification has been amended after publication, the court can refuse to grant damages or accounts of profits if the use of the invention has been before the date of the decision allowing the amendment, unless the court is satisfied that the specification as originally published was framed in good faith and with reasonable skill and knowledge.

To avoid a refusal of grant of damages under point (1) above, it is important to state the patent number on the product/product packaging of a patented product. Once a product is marked in this manner, a defendant may not be able to avail (1) as a ground to avoid damages. In recent times, companies have also started "virtually" marking their products by publishing a list of all their patents along with the product being marketed under that patent.

IV. Seizure, forfeiture or destruction of infringing products/goods/ and /or materials and implements predominantly used in the creation of the infringing products/goods

Under order 26, Rule 9 of the CPC,[48] courts may appoint a local commissioner to visit the defendant's premises to seize infringing products and collect/preserve other evidence. If a plaintiff apprehends that the defendants may destroy evidence once they receive notice of the suit, the plaintiffs can seek appointment of a local commissioner. Such appointment is typically sought in the initial hearing of the suit, prior to serving the defendant to prevent a defendant from destroying any evidence. The patentee during the inspection with the local commissioner can inspect devices, processes that allegedly infringe the patent. The inspection can include visually perceived, measured, weighed, felt, technical aids for inspection such as a microscope. The various forms of evidence that can be collected via inspection include, screenshots, downloads, working demos/videos, photographs, video recordings. This information can then be used during patent infringement proceedings.

47. Section 111 of the Patents Act.

48. See Order 26 Rule 9 of the CPC.

5. Considerations for Devising Pre-Litigation Strategy

Factors such as delay in filing of a suit, questions of validity of the suit patent, etc. can seriously affect the outcome of a patent infringement action. For this reason, prior to filing the suit it is essential for the patentee to conduct certain internal checks on the activities of the infringer to formulate an appropriate strategy for the suit. Doing so is also essential to find solutions for any loopholes in the case. Some essential checks that a patentee should conduct prior to filing of a suit are provided below:

I. Evidence collection

The first step before initiating a patent infringement suit is to determine if there is actual infringement of the patent. In this process the first and foremost step is to collect information about the infringing product or the process. This information about the product can be collated from online sources such as product brochures, manuals or by examining the infringing product or by conducting market investigations.

In particular, for inventions such as pharmaceutical compounds/compositions, formulations of insecticides or other such products, it is common to rely on the disclosures on the product packaging/brochures of the infringing product. As per the Drugs and Cosmetics Rules, 1945 framed under the Drugs and Cosmetics Act, 1940, the seller of a drug is required to state the ingredients of the drug on the packaging.[49] Similarly, under the Insecticide Rules, 1971 framed under the Insecticides Act, 1968, the label of an insecticide must contain the kind and name of active and other ingredients and percentage of each ingredient.[50] In the absence of the defendant's product that can be analysed, the patentee may rely on the label to establish a prima facie case.

Further, in case of a process patent, it is difficult to determine whether there is an infringement based on the information that is publicly available, as in most cases the process of manufacturing is usually undertaken behind closed doors.

Patentees can use several other ways to determine if a certain third party is carrying out infringement activities. It is possible for the patentee to engage a private investigator to determine the extent of the defendant's infringement activities, the nature of the defendant's business, the duration of infringement, the territorial extent of infringement, etc.

In some situations, it may be difficult for a plaintiff to obtain the product of the defendant or the infringement action may be based on an apprehension that the defendant is about to infringe the plaintiff's patent.[51]

II. Evaluate the strength of your patent

As stated above, there is no presumption of validity of a patent in a suit for infringement and the plaintiffs are required to establish prima facie validity of patent.[52] A defendant can raise any grounds of invalidity of a patent provided

49. See Rule 96 of the Drugs and Cosmetics Rules, 1945.
50. See Rule 19 of the Insecticide Rules, 1971.
51. See Section 5(vii) of this Chapter for a discussion on quia timet actions.
52. Ten XC Wireless Inc & Anr v. Mobi Antenna Technologies, 187 (2012) DLT 632.

under Section 64 of the Patents Act as a defence in a patent infringement action.[53] Further, even at the interim stage, a defendant can challenge the validity of the suit patent which can result in a denial of an interim injunction to the patentee. For this reason, a patentee must evaluate the strength of their patent prior to filing of the suit.

III. Map the claims with the infringing product

The scope of the patent is determined by the claims.[54] An infringement analysis involves comparison of each and every limitation of the claim with the alleged infringing product. The analysis cannot be performed by comparing the product manufactured by the patentee with the allegedly infringing product.[55] Therefore, an analysis of the claims of the patent vis-à-vis the infringing products must be conducted prior to filing of a suit.

As discussed above, an injunction in a patent infringement action may be difficult to obtain if the court is of the view that the invention is of a technical nature.[56] For this reason, the patentee must go prepared, with a clear analysis of the claims vs. the infringing product.[57] Expert affidavits are an easy and frequently used method to provide a comparison of the patent vs. the infringing product.

Filing of an expert evidence at the preliminary stage is not a requirement under the Patents Act. However, doing so helps the court in appreciating the complex technologies relevant for a particular dispute. In **Vringo Infrastructure Inc. and Anr. v. Indiamart Intermesh Ltd. and Ors.**[58] the Delhi High Court considered the expert affidavit filed by the plaintiffs to determine if the plaintiffs had established a prima facie case in their favour for grant of an interim injunction. Therefore, it is not uncommon for courts to consider expert affidavits even at the interim stage.

IV. Who can be an expert?

The Division Bench of the Delhi High Court, in **Vringo Infrastructure Inc. and Anr. v. Indiamart Intermesh Ltd. and Ors.**[59] held that it is accepted and recognised that a person could be an expert in an area of specialised knowledge by experience and she need not hold a degree in the field of specialised knowledge. The Court clarified that a person can also become an expert by virtue of one's vocation or occupation.

A. "Hot-Tubbing"- The Joint Examination of Experts

An interesting practise that has developed recently in the context of consideration of expert testimony by courts in patent disputes is that of "hot-tubbing". Hot-tubbing is a method of taking evidence, and involves: **"Experts giving their evidence concurrently, i.e., both together in the witness box. Although courts and tribunals may have varying practices, in general, the experts (two or more) are called together, sworn or affirmed, and given the opportunity to answer the same questions, to comment on each other's replies, to enter into a dialogue with each other and to put questions to each other."**[60]

53. Section 107 of the Patents Act.
54. Section 10(4)(c) of the Patents Act.
55. Hind Mosaic and Cement Works & Anr. v. Shree Shahjanand Trading Corporation & Anr., 2008 (37) PTC 128 (Guj).
56. Adarsh Ramanujan, Patent Law Cases And Materials : A Synthesis For India, Wolters Kluwer India Pvt. Ltd., 2020.
57. See F. Hoffmann-La Roche Ltd. & Ors. v. Cipla Ltd, supra note 5, wherein the court has discussed how x-ray diffraction analysis is not the correct test for establishment of infringement.
58. 2014 (60) PTC 437 (Del).
59. Ibid.
60. Micromax Informatics Ltd. v. Telefonaktiebolget L.M. Ericsson, FAO (OS) (COMM) 169/2017 & C.M. APPL.4963/2018, High Court of Delhi, Judgment dated 23.04.2019.

Hot-tubbing is a departure from the traditional sequential examinations of expert witnesses of parties to a suit at the trial stage. It seeks to streamline the procedure for expert testimony by allowing the expert witnesses of both sides to be examined jointly. This enables the identification of issues on which the parties are in agreement, and issues which are disputed that require further consideration by the court. The system was initially developed in Australia in 1985,[61] and has gained prevalence in patent disputes across the globe through the years.

The practice of hot-tubbing has been recognised in India through an amendment made to the Delhi High Court (Original Side) Rules, 2018 (**"2018 Delhi High Court Rules"**).[62] Chapter XI, Rule 6 of the amended 2018 Delhi High Court Rules provides that the Court may adopt hot-tubbing techniques while recording expert testimony. The amendment has also inserted Annexure G to the 2018 Delhi High Court Rules, which provides for a procedure to be followed in cases where hot-tubbing is adopted, that includes, inter alia: (i) the preparation of a joint statement by the expert witnesses of both parties which identifies an agreed statement of facts and disputed issues; (ii) the questioning of expert witnesses by the counsels of both parties; and (iii) recording of statements of both expert witnesses by the court on disputed issues. Notably, in its 2019 decision in the case of **Micromax Informatics Ltd. v. Telefonaktiebolget L.M. Ericsson,**[63] the High Court of Delhi discussed the importance of hot-tubbing in patent suits. It observed that such practices help the court in arriving at the truth by enabling the expert witnesses to give their evidence in a "less adversarial environment". The court in this case also opined that hot-tubbing, though not mandatory, should be adopted in patent disputes since it enables a swifter resolution of such matters.

i. External expert vs. Internal analysis

Since obtaining an independent, third party expert's analysis may take some time, in a time sensitive action, a patentee can also rely on an analysis conducted in-house. However, relying on an internal analysis is always risky as the defendants in the suit may argue that the analysis is biased.

ii. Court appointed scientific advisor

Under Section 115 of the Patents Act, the court can appoint a scientific advisor to seek their expert assistance. However, this provision is not used very often for appointment of scientific advisers by the court. As per Rule 103 of the Patents Rules, the Controller is required to maintain a roll of scientific advisers for the purpose of Section 115 of the Patents Act.[64] Such scientific advisers must:

i. hold a degree in science, engineering or technology or equivalent;

ii. have at least fifteen years of technical, practical or research experience; and

iii. hold or should have held a responsible post in a scientific or technical department of the Central or State Government or in any organisation.[65]

The above factors may also be used by parties as guiding principles for determining who should be appointed as an expert witness.

61. Spika Trading Pty Ltd v. Royal Insurance Australia Ltd., (1985) 3 ANZ.

62. See Notification No. 722/Rules/DHC dated 16.10.2018 issued by the High Court of Delhi amending the Delhi High Court (Original Side) Rules, 2018.

63. 2019 SCC OnLine Del 8295.

64. See Section 115 of the Patents Act and Rule 103 of the Patents Rules.

65. Rule 103, Patents Rules.

V. Evaluating strategy

Based on the evidence collected against the defendant, a patentee must evaluate its strategy before filing of the suit. An obvious choice in IP disputes is to obtain an interim injunction against the defendant to restrain the defendant from selling the infringing goods. However, obtaining an interim injunction may be difficult in some cases. It is possible that a court may deny an interim injunction where the patent relates to complex technologies and the court believes that a trial is required to determine the question of infringement. Denial of an interim injunction is also possible if there is a delay in approaching the court due to which the balance of convenience has shifted in favour of the defendant or if the defendant raises a credible challenge to the patent.

In an infringement action involving technologies such as standard essential patents or in disputes between a licensor and licensee, the goal may be to enter into a royalty arrangement with the infringer. In such a case, the patentee can consider mediation as provided for under the CCA.

A. Pre-institution mediation under the CCA

Section 12A of the CCA[66] provides parties with an alternative means to resolve disputes through discussions and negotiations with the help of a mediator. The provision states that a plaintiff must initiate mediation before filing a suit, with a limited carve out for suits filed with applications for urgent interim relief.

In India, most IP infringement suits are filed with an application seeking a preliminary injunction. This would qualify as "urgent interim relief" under Section 12A and initiation of mediation prior to filing of the suit would not be mandatory. However, in disputes where a patentee is not seeking a preliminary injunction and wants to use litigation as a tool to negotiate terms for granting limited rights to their IP, pre-initiation mediation is a viable option.

B. Arbitration of patent infringement disputes

Arbitration is an alternative dispute resolution mean wherein the matters are decided following the procedures of law (however, outside the Courts). Arbitration in particular works extremely efficiently in areas of commercial and international disputes as the arbitral tribunal acts as a quasi-judicial system to counter lengthy litigation process and overburdened judiciary. Contracts generally contain an arbitration clause so as to settle matters in a speedy manner. Infringement of patents under a contract by another party, such as a licensee, acting out of the scope of the licensee agreement or clearly infringing a patent can be sued and such matters can be solved through arbitration. However, parties opting for arbitration as a means to resolve patent disputes must ensure that the scope of their claims affects only the specific individuals to the proceedings (rights in personam) without extending to the world at large (rights in rem). **Annexure E** to this paper contains a more detailed discussion of the arbitrability of IP disputes.

VI. When to file the suit

The timing of a suit is an important consideration. The Delhi High Court in **Dr. Reddy's Laboratories Ltd. v. Reddy Pharmaceuticals Limited**[67] noted:

66. See Section 12A of the Commercial Courts Act.

67. 2004 (29) PTC 435(Del).

> *"Owners of trade marks or copy rights are not expected to run after every infringer and thereby remain involved in litigation at the cost of their business time. If the impugned infringement is too trivial or insignificant and is not capable of harming their business interests, they may overlook and ignore petty violations till they assume alarming proportions....*
>
> *...They can wait till the time the user of their name starts harming their business interests and starts misleading and confusing their customers."*

While the observations above have been made in relation to trademark and copyright infringement, a similar argument can be made in patent infringement actions as well. However, the patentee must also ensure that delay in filing of the suit should not be considered as acquiescence of the acts of the defendant. Courts have held that delay by itself may not result in denial of relief. The Madras High Court in the case of **Salzer Electronics Ltd. v. SG Controls and Ors.**[68], referred to Delhi High Court judgement, **M/s Hindustan Pencils Pvt. Ltd. v. M/s India Stationery Products Co.**[69] for contending that a mere delay cannot disentitle the patentee from getting the relief from the court.

A. Quia timet actions

It is possible for a patentee to file a suit before the defendant launches the infringing product in the market. Such an action is referred to as a **quia timet** action and is filed based on a threat or apprehension that the actions of the defendant are likely to cause prejudice to the plaintiff. The burden of proof on the plaintiff in a **quia timet** action is heavier than other cases where the threat of infringement has already materialized.[70]

Quia timet actions have been filed in the past on the basis of information that the defendant has obtained marketing approval for the drug in question[71] and even on the basis of news reports that the defendant is about to launch a product covered by the plaintiff's patent.[72]

VII. Concerns of confidentiality

Patent infringement suits may entail the examination of various confidential documents which parties may be unwilling to disclose to each other or to the public. In this regard, there have been recent developments in Indian law to address any such concerns that parties may have while filing patent infringement suits, with the conceptualisation of "confidentiality clubs."

The 2018 Delhi High Court Rules have recognised that confidentiality clubs may be set up by the court in cases which involve documents which are commercially or otherwise confidential in nature.[73] The illustrative example given in the 2018 Delhi High Court Rules provides that the parties may nominate no more than three lawyers (who are not, and never have been, in-house counsel for either of the parties) and no more than two external experts, to constitute a confidentiality club which would be permitted to examine confidential documents filed by the relevant parties in a sealed cover. However, disclosure of the contents of such documents by members of the confidentiality club is prohibited even to other representatives of the parties concerned. Such a system is designed

68. 2013 (54) PTC 140 (Mad).
69. AIR 1990 Del 19.
70. Bristol Myers Squibb v V C Bhutada, 2013 (56) PTC 268.
71. Ibid.
72. Teva Pharmaceutical Industries v. Natco Pharma Ltd., 2014 (210) DLT 591; 2014 (59) PTC 124.
73. See Rule 17, Chapter VII and Annexure F of the amended Delhi High Court Rules.

to preserve the confidential nature of commercial documents of parties, while ensuring that complete evidence is presented before the court in the suit.

In the recent case of **Interdigital Corporation v. Xiaomi,**[74] the High Court of Delhi considered the concept of confidentiality clubs in detail, and recognised their relevance in patent disputes where both parties consent to their formation. However, based upon the facts before it, the court held that a confidentiality club could not be set up in the manner sought by the plaintiff in that matter against the consent of the defendant. It held that, **"Whether either of the parties, to a litigation, needs, or does not need, to see a particular document, would be a decision which essentially rests with the party itself".** Thus, it must be noted that although confidentiality clubs are an effective means to conduct patent litigation while protecting the secrecy of relevant documents, their adoption is done on a document-to-document basis by courts, and not as a matter of general principle.

74. 277 (2021) DLT 396.

6. Procedural Considerations

I. Pecuniary Jurisdiction

As per Section 104 of the Patents Act, a suit for infringement of a patent can be filed in a district court with jurisdiction or in a high court, depending on the pecuniary value of the suit. Section 104 further provides that where a counter-claim for revocation of the patent is made by the defendant, the suit, along with the counter-claim, must be transferred to the relevant High Court.

In 2015, Commercial Courts were established at High Courts and District Courts where District Courts have original jurisdiction for adjudication of all "Commercial Disputes" valued at more than INR 3,00,000 (about USD 4,338). The definition of "Commercial Disputes" under the CCA is broad and generally covers commercial transactions which also includes disputes arising out of intellectual property rights.

Different states have formulated different rules to set pecuniary limits for commercial disputes that can be filed at the district court level. For example, in Delhi, a "Commercial Dispute" of a value lower than INR 2,00,00,000 (about USD 276,442) can be filed at the district court, while suits which are valued higher than this amount must be filed before the Delhi High Court.[75]

Pecuniary jurisdiction is determined on the basis of the damages claimed in a patent infringement suit. Alternatively, the patentee can value their suit patent at a certain value for the purpose of pecuniary jurisdiction.

Considering that patent infringement actions can involve complex technologies, patentees prefer to file suits directly in high courts, in states where high courts have original jurisdiction. For instance, patent infringement actions in Delhi are mostly filed directly before the Delhi High Court.

II. Territorial jurisdiction

Every court has its own local or territorial limits beyond which it cannot exercise its jurisdiction. As per the CPC, Indian courts generally have territorial jurisdiction over a specific suit in the following circumstances:

- Where the whole or part of the cause of action (the facts on account of which a person gets a right to file a suit for a relief) arose in the territorial jurisdiction of the court.
- Where the defendant resides or carries on business for gain within the territorial jurisdiction of the court.[76]

Therefore, in a patent infringement suit, a patentee must establish that the defendant either resides within the territorial jurisdiction of the court where the suit is filed or that the defendant is carrying on business in such area. Such jurisdiction can be established on the basis of the defendant's registered office or, in some cases, through a branch office. Jurisdiction may also be established on the basis of presence of infringing products in the area.

75. Section 5(2) of the Delhi High Court Act, 1966 as amended by the Delhi High Court (Amendment) Act, 2015.

76. See Section 20 of the CPC.

III. Who can file?

A patentee whose patent is infringed can file a patent infringement suit. Apart from the patentee, the Patents Act permits the exclusive licensee of a patent to file a patent infringement action with respect to any acts of infringement that have occurred after the grant of the license.[77]

Further, any person to whom a compulsory license has been granted under the provisions of the Patents Act may call upon the patentee by notice to initiate proceedings to prevent further infringement. If, however, the patentee does not initiate proceedings within two months of such notice, such licensee can initiate proceedings as if she is the patent holder.[78]

A. "Exclusive Licensee" status

Section 2(1) of the Patents Act defines an "exclusive license" as "a licence from a patentee which confers on the licensee, on the licensee and persons authorised by him, to the exclusion of all other persons (including the patentee), any right in respect of the patented invention."

As per Section 69 of the Patents Act, an assignee or licensee of a patent must make an application to the Controller for registration of their title in the register of patents.[79] Along with such application, the assignee/licensee must file the agreement by way of which the rights have been granted to them.[80] Section 69(5) provides that any agreement providing such title/interest to a person will not be admitted by the Controller or by any court as evidence of the title/interest unless the Controller or the court directs otherwise in writing.[81] In the case of **SERGI Transformer Explosion Prevention Technologies Private Limited vs. CTR Manufacturing Industries Limited.,**[82] the Delhi High Court held that the assignment of a patent would be valid the moment the assignment agreement is executed. Validity of the assignment is not dependent on its registration. In relation to Section 69(5), the court stated that if an assignment agreement that has not been registered with the patent office is produced as evidence of title before the controller/court, the court is empowered to accept it as evidence by providing reasons in writing for acceptance.

Therefore, if an exclusive licensee or even an assignee of a patent intends to file a suit, it must be ensured that their title/interest in the suit has been recorded in the register of patents.

77. Section 109(1) of the Patents Act provides that: "The holder of an exclusive licence shall have the like right as the patentee to institute a suit in respect of any infringement of the patent committed after the date of the licence, and in awarding damages or an account of profits or granting any other relief in any such suit the court shall take into consideration any loss suffered or likely to be suffered by the exclusive licensee as such or, as the case may be, the profits earned by means of the infringement so far as it constitutes an infringement of the rights of the exclusive licensee as such."

78. Section 110 of the Patents Act provides that: "Any person to whom a licence has been granted under section 84 shall be entitled to call upon the patentee to take proceedings to prevent any infringement of the patent, and, if the patentee refuses or neglects to do so within two months after being so called upon, the licensee may institute proceedings for the infringement in his own name as though he were the patentee, making the patentee a defendant; but a patentee so added as defendant shall not be liable for any costs unless he enters an appearance and takes part in the proceedings."

79. Section 69(1) of the Patents Act states that: "Where any person becomes entitled by assignment, transmission or operation of law to a patent or to a share in a patent or becomes entitled as a mortgagee, licensee or otherwise to any other interest in a patent, he shall apply in writing in the prescribed manner to the Controller for the registration of his title or, as the case may be, of notice of his interest in the register."

80. Rule 91 of the Patents Rules.

81. Section 69(5) of the Patents Act states that: "Except for the purposes of an application under sub-section (1) or of an application to rectify the register, a document in respect of which no entry has been made in the register under sub-section (3) shall not be admitted by the Controller or by any court as evidence of the title of any person to a patent or to a share or interest therein unless the Controller or the court, for reasons to be recorded in writing, otherwise directs."

82. 2015 (64) PTC 357 (Del).

IV. Limitation

As discussed above, an action for infringement can be initiated once patent rights are granted by the Indian Patent Office, even with respect to acts of infringement which occurred prior to the actual grant of such patent but after its publication.[83] It must, however, be ensured that a suit for infringement is filed within a period of three years from the date of infringement or from the date of knowledge of the infringement.[84] Additionally, courts have held that in cases of infringement of intellectual property, each act of infringement constitutes a fresh cause of action, and that the said period of three years would be available to a party to initiate proceedings from each such act of infringement.[85]

V. Proposed changes in conducting patent suits

The conduct of patent infringement suits before the Delhi High Court is likely to see major changes in the near future, since the court has recently sought comments from members of the Bar in respect of the proposed draft of the High Court of Delhi Rules Governing Patent Suits, 2020 (**"Draft Rules for Patent Suits"**)[86], in exercise of the Court's power under Section 158 of the Patents Act. The Draft Rules for Patent Suits provide for the mandatory contents of pleadings, as well as the various requisite documents to be filed. They also contemplate the various stages in patent suits and proceedings to be undertaken at each stage. The rules divide patent infringement proceedings into stages including: (i) a first hearing for grant of interim reliefs; (ii) filing of affidavits of admission/ denial along with claim construction briefs, invalidity briefs and infringement briefs, along with a technical primer on the basic undisputed technology covering the patent where directed by the court; (iii) three case management hearings where evidence is led by the parties and reviewed by the court; and (iv) a final hearing. Adopting such a specialised system for patent infringement suits would enable the court to deliver an informed decision on matters of great technicality in an expedited manner.

83. See the first proviso to Section 11A(7) of the Patents Act

84. See Article 88, Limitation Act, 1963.

85. M/s Bengal Waterproof Limited v. M/s.Bombay Waterproof Manufacturing Company and Another, AIR 1997 SC 1398.

86. See the draft High Court of Delhi Rules Governing Patent Suits, 2020, issued on 09.11.2020.

7. Defences to Infringement

Under Section 107 of the Patents Act,[87] every ground which is available for the revocation of a patent under Section 64 may be used as a ground of defence in a suit for infringement. There are 17 grounds under Section 64, some of which are:

1. The applicant for the patent was not entitled to do so under the Patents Act;
2. The subject of any claim of the complete specification is not an invention under the Patents Act;
3. The invention is obvious or not new in light of existing public knowledge or use, or prior publication;
4. The invention is not useful; and
5. The patent was obtained on a false suggestion or representation.

Further, the use of the patented invention or process for experimental or research purposes (including for teaching) or for the Government's own use are also grounds for defence.[88]

Further, Section 107A exempts certain actions from the purview of infringements:

I. Parallel imports

Parallel importation refers to the legal production and sale of goods, and subsequent exportation. This exemption is contained under Section 107A(b)[89] which states that the importation of a patented product by a person, from another person who is legally authorised to produce and sell or distribute the product, will not be considered an infringement of patent rights. This exception follows from a reading of Article 6[90] with Article 28[91] of the Trade-Related Aspects of Intellectual Property Rights Agreement (**"TRIPS"**) (and Article 5(d)[92] of the Doha Declaration on the TRIPS and public health) which provide flexibility to member states of the TRIPS to limit the patentee's exclusive right to import to the extent that this limitation is in relation to the exhaustion of the patent.

The principle of exhaustion imposes certain limits on the patentee's exclusive rights by terminating all patent rights to an item such as use and re-sell after the initial authorised sale. The exemption to parallel imports is aimed at helping Indian consumers avail of lower prices when the patentee had already placed a product in the global market and made profits on the first sale thereon.[93]

87. Section 107 of the Patents Act
88. Section 47 of the Patents Act.
89. Section 107A of the Patents Act provides that: "Certain acts not to be considered as infringement.—For the purposes of this Act,— (a)... (b) importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as a infringement of patent rights".
90. Article 6 of the TRIPS provides that: "Exhaustion - For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."
91. Article 28(1)of the TRIPS: "Rights Conferred: A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing(6) for these purposes that product;..." Footnote 6 to Article 28 states "This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6."
92. Article 5(d) – "The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge..."
93. See Shamnad Basheer, Mrinali Kochupillai, 'Exhausting Patent Rights in India: Parallel Imports and TRIPS Compliance, Vol 13, Journal of Intellectual Property Rights (September 2008).

The interpretation of Section 107A(b) is ambiguous on certain aspects, with a major concern being whether the phrase "duly authorised under the law" refers to the laws of India, or to the laws of the exporting country. If it refers to the laws of India, it would mean that while applying this provision, the relevant court would have to decide whether the person in **the exporting country** was duly authorised as per Indian law, which is an absurd conclusion, since the legislature in India would not draft a provision to decide what is legal in another country. Therefore, it can be argued that "duly authorised under the law" should be read to mean duly authorised under the law of the exporting country. This was implicitly recognised in the case of **Strix Limited v. Maharaja Appliances Limited,**[94] where the court seemed to imply that the production of details of the Chinese patent held by the supplier of the defendant could be relied on to invoke the parallel importation defense. However, since the details were not produced in the said case, the court went on to grant an injunction against the defendant. Another question to be considered is if contractual authorisation could be covered under "duly authorised under the law". For instance, if A, a patent holder in China enters into an agreement with B, granting B the right to manufacture and sell the product covered by the patent in China - It is yet to be considered by courts if import by B into India could be covered under Section 107A(b).

II. Bolar provision

Section 107A(a) of the Patents Act, commonly referred to as the "Bolar" provision permits any manufacturer to make, construct, use, sell, import or export[95] any patented invention with a view to generating data that could then be submitted to a regulatory authority. The aim of this section is to ensure the prompt availability of products, especially generic drugs, in the market, as soon as the patent expires or is invalidated, so that consumers may benefit from this early entry of affordably priced products.[96]

In order to avail of this exemption, the use must be "reasonably related" to the purpose of development of information to be used to obtain regulatory approvals. In 2019, the Delhi High Court laid down certain guidelines for determining whether the use is "reasonably related", including factors such as the party which is using the patented goods, the nature and quantity of such goods, etc.[97] The exception under Section 107A (a) applies even in case of exports outside India for obtaining approvals under the laws of other countries.[98] A more detailed discussion on this aspect can be found at our hotline at **Annexure C.**

In addition to these grounds, there are certain defences under the Patents Act, or those recognised by courts in India, as detailed below.

94. 2008) I.A. No.7441 of 2008 in C.S. (OS) No.1206 of 2008
95. Bayer Corporation v. Union of India, 2019 SCC OnLine Del 8209.
96. Id.
97. Id.
98. Bayer Corporation and Ors. v. Union of India and Ors., 2019 (78) PTC 521 (Del).

8. Defences against patent infringement

I. Prosecution history estoppel

As discussed above, the infringement of a patent may be literal or by the application of the doctrine of equivalence. The doctrine of equivalence states that the patentee can be allowed to **"claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes".**[99] Therefore, a person cannot escape a claim for patent infringement by making inessential changes to the patented goods.

A counter to the doctrine of equivalence is the defence of prosecution history estoppel. Under this defence, if a patentee has made any amendments to its claim to avoid prior art, or has made a narrowing amendment to satisfy any statutory requirement or the demands of an examination report, the patentee cannot then claim infringement of claims which have been excluded.[100] However, in order to avail of this defence, the defendant must show that the patentee constricted his claim by excluding something essential; and when the defendant added that essential integer, he was not guilty of infringement. The US case of **Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,**[101] is an important precedent for this defence, and has been cited by the Bombay High Court in **CTR Manufacturing Industries Limited v. Sergi Transformer Explosion Prevention Technologies Pvt. Ltd.**[102]

Prosecution history estoppel has been taken a step further in the recent decision of the Delhi High Court in **Astrazeneca AB & Anr. v. Intas Pharmaceuticals Ltd.**[103] In this case, the Delhi High Court considered not only the prosecution history of the patent family of Astrazeneca's patent IN 205147 and IN 235625 but also considered submissions made by Astrazeneca in infringement actions in the United States while deciding Astrazeneca's application for grant of an interim injunction.[104]

II. Innocent Infringement

Section 111 of the Patents Act states that if a defendant proves that at the date of infringement it was not aware and had no reasonable grounds to believe that the patent existed, the court shall not grant damages or an account of profits. However, the courts can grant an injunction against any such defendant. The person will not be deemed to be aware of, or have reasonable grounds to believe in, the existence of the patent if mere words such as "patent" or "patented" are applied along with the article, unless the patent number also accompanies such words.

III. Suit for declaration of non-infringement

Under Section 105 of the Patents Act, at any time after the grant of a patent, a person may institute a suit for a declaration that the use of a particular process, or the making, use or sale of any article by him does not or would not constitute an infringement of a claim of a patent. This is regardless of whether an assertion in this regard has been made by the patentee or by an exclusive licensee. However, prior to such declaration, the plaintiff must show that:

99. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 US 722 (2002).
100. CTR Manufacturing Industries Limited v. Sergi Transformer Explosion Prevention Technologies Pvt. Ltd., 2015 SCC OnLine Bom. 5538.
101. Supra note 100.
102. 2015 SCC OnLine Bom. 5538.
103. 2020 (84) PTC 326 (Del).
104. At the time of publication of this paper, this judgment is in appeal.

a. **"he has applied in writing to the patentee or exclusive licensee for a written acknowledgement to the effect of the declaration claimed and has furnished him with full particulars in writing of the process or article in question; and**

b. **that the patentee or licensee has refused or neglected to give such an acknowledgement".**

In **Bajaj Auto Ltd. v. TVS Motor Company Ltd,**[105] the Madras High Court has held that the above requirements must be fulfilled by the plaintiff and a declaration cannot be filed on the basis of lack of proof on the defendant's part alone. Importantly, in such a suit for declaration, the validity of a claim of the specification of the patent is not called in question. Moreover, the making or refusal to make a declaration by the court is not deemed to imply the patent's validity or invalidity.

105. 2010 SCC OnLine Mad 5031.

9. Conclusion

Considering that patent infringement actions impose very high burdens of proof on a patentee and tend to be litigated over long periods of time, drafting of patent claims with care and precision assumes a high degree of significance. Further, even when there appear to be infringements of patented inventions, patentees must evaluate the strength of their own patent and their likelihood of establishing infringement before bringing claims of infringement before courts of law. Patentees must bear in mind that an adverse decision may result in the loss of the patent itself, and hence must exercise due care and caution while pursuing such remedies. Additionally, the public interest considerations which would weigh with courts must also be taken into account while seeking enforcement of a patent. As seen above, courts have sometimes shown an inclination to favour the rights of the public to access certain inventions over the rights covered by patents. In cases where the parties intend to ultimately enter into licensing agreements, it may be advisable to pursue pre-institution mediation under the CCA where commercially feasible.

Annexure A

Grounds for Opposition and Revocation

No.	Pre-Grant and Post-Grant Opposition (11 grounds)	Revocation (18 grounds)
1	Wrongful obtainment of the invention - Sections 25(1)(a), 25(2)(a)	Patent was **wrongfully obtained** in violation of rights of another party/ petitioner/person through which patent has been claimed - Sec. 64 (1) (c)
2	Anticipation by prior publication, anywhere in the world - Sections 25(1)(b), 25(2)(b)	Invention claimed is not new; is publicly known, publicly used in India before the priority date or **was published in India or elsewhere** in the documents referred in Section 13 of the Patents Act, 1970 - Sec. 64 (1) (e)
3	Anticipation by prior claiming in India - Sections 25(1)(c), 25(2)(c)	An invention with same complete specifications has **already been claimed,** and has been granted patent in India. - Sec. 64 (1) (a)
4	Public knowledge or public use in India before the priority date - Sections 25(1)(d), 25(2)(d)	Invention claimed is not new; is **publicly known, publicly used in India before the priority date** or was published in India or elsewhere in the documents referred in Section 13 of the Patents Act, 1970 - Sec. 64 (1) (e)
5	Obviousness and clear lack of inventive step in the invention - Sections 25(1)(e), 25(2)(e)	Invention is **obvious or lacks any inventive step** - Sec. 64 (1) (f)
6	Being an excluded subject matter (such as those inter alia provided in Section 3) - Sections 25(1)(f), 25(2)(f)	Subject of the claim is **not patentable** under the Patents Act, 1970 - Sec. 64 (1) (k)
7	Insufficiency of disclosure of the complete specification - Sections 25(1)(g), 25(2)(g)	The **specifications do not sufficiently and fairly** describe the invention or method of working of the patent and **does not disclose** the 'best method' of performing the patent which was known to the patentee - Sec. 64 (1) (h)
8	Non-compliance of the requirement of Section 8 or furnishing materially false information - Sections 25(1)(h), 25(2)(h)	Applicant has **not been able to disclose information required under Section 8 or has furnished information which was known by him to be false** - Sec. 64 (1) (m)
9	Non-filing of the application within 12 months of filing the first application in a convention country - Sections 25(1)(i), 25(2)(i)	
10	Non-disclosure or wrongful mention of the source or geographical origin of biological material - Sections 25(1)(j), 25(2)(j)	Complete specification doesn't disclose, or mentions erroneously the **source or geographical origin of biological material used** in the invention - Sec. 64 (1) (p)
11	Anticipation with regard to traditional knowledge of any community anywhere in the world - Sections 25(1)(k), 25(2)(k)	Invention claimed was **foreseen** in light of the **knowledge available within any local or native community** in India or elsewhere - Sec. 64 (1) (q)
12		The patent was granted to a person who was not entitled to apply for the same - Sec. 64 (1) (b)
13		Subject of the claim does not amount to invention - Sec. 64 (1) (d)
14		Invention is not of any use - Sec. 64 (1) (g)

Annexure A

15		Scope of claim or complete specification is not clearly defined or not based on the matter disclosed in the specification - Sec. 64 (1) (i)
16		Patent obtained through false suggestion or representation - Sec. 64 (1) (j)
17		Invention claimed was secretly used in India before the date of claim - Sec. 64 (1) (l)
18		Applicant has contravened direction for secrecy under Section 35 or made a foreign application in contravention of Section 39 - Sec. 64 (1) (n)
19		Leave to amend specification under Section 57 or Section 58 was obtained through fraud - Sec. 64 (1) (o)

Annexure B

Bombay HC Upholds India's First Compulsory License

- The Bombay HC in this case has upheld the order of the IPAB, which affirmed the order of the Controller of Patents to grant Compulsory License to NATCO for Bayer's Indian patent on Sorafenib Tosyalte (Nexavar).
- NATCO's application for Compulsory License of Patent was the first in India.
- This case is significant as it gives certain new interpretation to the conditions that needs to be met under the Indian Patents Act, 1970 for grant of Compulsory License.
- The Bombay HC held that in respect of medicine the adequate extent for meeting the demand of the drug has to be 100%.
- The Bombay HC held that dual pricing can be applied to meet the requirement of the public and not for making available the drug under reasonably affordable price.
- The Bombay HC held that the sale by the patent infringer can be taken into account to meet the reasonable requirement of the public only when the patentee has granted a defacto license i.e. has not filed a patent infringement suit against the infringer.

I. Background

Bayer Corporation, USA (**"Bayer"**) had developed Sorafenib Tosyalte (**"the Drug"**), marketed as Nexavar, and obtained a patent from US authorities (United States Patent Office) in 1999. The drug is a life extending drug which is used for treating patients suffering from advanced stages of kidney cancer (Renal Cell Carcinoma) and liver cancer (Hepatocellular Carcinoma).

Bayer was granted a patent for the Drug in India in March 2008. In December 6, 2010, Natco Pharma Ltd (**"Natco"**) approached Bayer for grant of a voluntary licence. Bayer in a response dated December 27, 2010 rejected Natco's request for grant of voluntary license and requested Natco to approach within 14 days in case Natco had anything further to add. After the expiration of three years from the date of grant of the Indian patent to the Drug, Natco applied to the Controller General of Patents (**"Controller"**) for a compulsory license under Section 84 (1) of the Patents Act 1970 (**"the Act"**) proposing to manufacture and sell the drug at a price of Rs.8800/- per month of therapy. Bayer opposed this application on various grounds, however in March 2012, the Controller granted the first Compulsory License to Nacto to manufacture and sell the drug. A detailed analysis of Compulsory license provision under the Act and the analysis of Controller's order is available in our IP Lab **here.**

Thereafter, Bayer filed an appeal challenging the order of the Controller before the Intellectual Property Appellate Board (**"IPAB"**). The IPAB, in March 2013, dismissed the appeal and upheld the decision of the Controller. In the order IPAB raised the rate of royalty to be paid by Natco to Bayer from 6% to 7 %. A detailed analysis of the IPAB's order is given in our hotline **here.**

Bayer challenged IPAB's order before the High Court of Bombay (**"HC"**) by way of a writ petition. The HC examined the relevant provisions of the Act and upheld IPAB's Order.

Annexure B

II. Issues Before The High Court

A. Voluntary License

As per the Act, two conditions are required to be satisfied before an application for Compulsory Licence (**"CL"**) is considered by the Controller.

- An application for CL can be made only after the expiry of three years from the date of grant of Patent.
- The applicant should make efforts to obtain a license ("Voluntary License") from the patentee on reasonable terms and conditions.

The first condition was satisfied. With regard to the condition of voluntary licence, Bayer argued that Natco did not make bonafide efforts to obtain a voluntary license as Natco failed to approach again after the communication dated December 27, 2010.

The HC was of the view that Bayer had clearly declined the request for license and no purpose would have been served by Bayer's vague statement in response that requested Natco to approach within 14 days in case Natco had anything further to add. The request made by Bayer only stated that Natco may revert in case they had anything to add to the application of voluntary license already made. The HC held that Natco has satisfied the second condition precedent to application for compulsory license.

B. Reasonable Requirements of Public

Bayer contended that the onus is on Natco to establish that the reasonable requirement of the public has not been satisfied by Bayer. The HC accepted this position. Bayer contended that-

- Natco had failed to establish that the reasonable requirements of the public have not been satisfied;
- it was not possible to determine this without determining the number of patients requiring the Drug;
- the Drug is for treatment of persons in the final stages of the diseases and it is not required that every patient suffering from kidney cancer and liver cancer is required to consume the drug. The doctor has the option of adopting other measures rather than prescribing the drug.

The HC noted that reasonable requirement of the public cannot be met on a mathematical basis and it can only be determined based on the evidences produced. The HC noted the Controller's observation of the figures provided in GLOBOCAN 2008 and the affidavit of Dr Manish Garg who was the Country Medical Director of Bayer at the relevant time. According to the affidavit an aggregate of 8842 patients suffering from kidney cancer and liver cancer would require the drug. However, Bayer had sold only 593 boxes of the drug which was sufficient only for 200 patients.

Bayer contented that the sales made by Cipla Limited (**"Cipla"**), who were producing the patented drug, infringing the rights of the patent holder should also be taken into account while considering the total quantum of the patented drug made available in India.

However, the HC was of the view that the quantity manufactured by Cipla could not be taken into account. This view was taken due to the pending patent infringement suit between Cipla and Bayer at the Delhi High Court and the possibility that the production by Cipla could be stopped any day if an Injunction order is passed. The HC held that Cipla's goods can be taken into account only when Bayer accepts the participation of Cipla and in essence grants a defacto license to Cipla.

The HC also noted the Controller's observation that even if the drug supplied by Cipla was added to Bayer's supply the aggregate will still not be sufficient to meet the reasonable requirement of the patients as, Cipla had supplied only 4686 packets of drug.

Further, the HC also held that Bayer did not consider Cipla' sale while filing Form 27.[106]

The HC also provided an interpretation to the words "adequate extent" given in Section 84(7). The HC was of the view that the aspect of adequate extent will vary depending on the type of patented product. The HC held that **in respect of medicine the adequate extent has to be 100% and the medicine should be made available to every patient. The rights given to a patentee cannot deprive any patient from satisfying their need for the medicine.**

C. Reasonably Affordable Price

Bayer argued that prior to determining whether the drug was available to the public at reasonably affordable price, it was important to first determine what can be construed as reasonable affordable price in relation to the drug. The HC was of the view that the Act does not bestow any investigative powers on the Controller. **The Controller can only ensure that patented article is available at reasonably affordable price based on the relative price offered by the patentee and the applicant.** The HC held that Bayer was not selling the drug at reasonably affordable price since Natco was offering the drug at Rs 8,800 per month of therapy as compared to Bayer's price of Rs 2,84,000 per month of therapy. This shows that the reasonably affordable price is that of Natco and not Bayer.

Bayer further argued that "reasonably affordable price" should not be seen from the perspective of the users alone but from the perspective of the inventor also. The inventor spends considerable expenditure in developing a drug, conducting its trials and launching it in the market. Many molecules developed incurring huge expenditure cannot be marketed at all. Cost incurred for research regarding such failed molecules also has to be recovered from those molecules which are finally launched for public use. Such cost factors have not been taken into account by the Controller while determining the reasonably affordable price. Bayer also submitted affidavits of Mr. Dintar, Head of Global Drugs Discovery Operations at Bayer before the Controller which stated that Bayer had invested about Rs 114 billion in the year 2010 towards research and development activities. In response Natco had filed an affidavit of Mr James Love stating that the amount spent on research by Bayer from 1994 to 2004 was recovered by Bayer one year.

The HC further noted that Bayer did not submit its own books of accounts to show the expenses incurred in development of the specific patented drug and the money already realized by sale of the patented drug worldwide. Bayer also refused to produce its Balance Sheet asked for by the Controller. The HC was of the view that, if the book of accounts and Balance Sheet were produced it could have aided in determining the reasonable price at which Bayer could have made the drug available to the public. Further, the HC also observed that that 50% of the cost had already been reimbursed by the US government since the drug had been classified as an orphan drug[107].

The next contention put forward by Bayer was that patients are from different economic strata with varying capacity for paying the cost of the drug. Bayer had already put in place a Patient Assistant Program ("PAP") under which needy patients as recommended by doctors were given free tablets for one full month if they bought medicines for three days' use.

The HC held that under the PAP programme patented drugs were being made available only to patients who are recommended by the doctor. Further, the patients who fall under PAP can avail the special price solely at Bayer's discretion. The special price is not available in ordinary course to every patient. Thus, this cannot be taken into consideration while determining "reasonably affordable price".

106. Form 27 is required to be filed by the Patentee providing information related the extent of use of the patented invention and reasons if any for non-use. For more details on Form 27 filings please refer to our Hotline at this link.

107. An orphan drug refers to a drug which is intended to treat or prevent a rare disease.

The HC further held that the concept of dual pricing would be sufficient to comply with reasonable requirement of the public and not under reasonably affordable price. The HC took this view after placing reliance on Section 84(7) of the Act which provides for factors for satisfying the reasonable requirement of the public. Section 84(7)(a)(ii) necessitates that the patented article be available to an adequate extent or on reasonable terms. The HC held that the term "reasonable terms" refers to cases where the medicine is made available to economically backward patient through adoption of special prices.

D. Not Worked in the Territory of India

This has been the most important point in dispute. While the Controller was of the view that the patented product will be considered to be worked in India only if the patentee manufactures the patented product in India within reasonable time, the IPAB held that this issue should be considered on a case to case basis and the same approach cannot be adopted for all patented products and import of a patented product can also be considered as working the patent in the territory of India.

Bayer drew attention to Article 27 of the TRIPS which provides that there would be no discrimination in respect of patented product whether legally manufactured or imported. The same view is also apparent from Form 27 prescribed under the Act and the Patent Rules. Patentee has to file a statement in Form 27 with the Controller regarding the working of the patent in India. In the aforesaid form the patentee while giving details of working of patented drug in India, has to make declaration of working in India of the patented product under two classifications namely manufacture in India and imported from other countries.

The HC observed that working a patented invention in the territory of India has to be considered by reading Section 83 of the Act which provides for legislative guidelines to predict the meaning of the words "worked in the territory of India". The HC focussed on the following provision of Section 83:

(b) the patent is not granted to enable the Patentee to enjoy a monopoly for the importation of the patented article;

(c) the technological knowledge must be transferred and disseminated to the mutual advantage of producers and users of technological knowledge;

(f) the patent right should not be abused by the patentee by indulging in activities that unreasonably restrain trade or adversely affect the international transfer of technology.

Reading the above guidelines, the HC was of the view that the patentee is required to make some efforts to manufacture the patented product within the territory of India and user of the technological knowledge included patients who consumed the patented drug. Having said that the HC agreed with the view of IPAB that the matter should be considered on case to case basis and manufacture in India is not the sole method of working a patent in India. A patent can be worked in India by importing the patented article in adequate quantity and supplying it. However, working by import can be accepted only after the patentee provides satisfying reasons for not manufacturing the patented product in India.

III. Conclusion

The observations of the HC are summarised below:

Reasonable requirement of the public:

- This cannot be calculated on a mathematical basis and it can only be determined based on the evidences produced by both parties.

- The aspect of "adequate extent" for meeting the demand of the patented article will vary depending on the type of patented product. In respect of medicine the adequate extent has to be 100% of the requirement. The patented drug should be made available to every patient.
- The concept of dual pricing will help in satisfying reasonable requirement of the public and not for making available the drug under reasonably affordable price.

Reasonably affordable price:

- The Act does not bestow any investigative powers on the Controller. The Controller can only ensure that patented article is available at reasonably affordable price based on the relative price offered by the patentee and the applicant.
- The investment made by the patentee in developing the patented drug can be taken into account while determining whether the patented drug is available at reasonably affordable price, based on the evidence adduced by the patentee.

Use by the infringer: The sale by the patent infringer can be taken into account to meet the reasonable requirement of the public only when the patentee has granted a defacto license i.e. has not filed a patent infringement suit against the infringer.

Use by importation: A patent can be worked in India by importing the patented article in adequate quantity and supplying it. However, working by import can be accepted only after the patentee provides satisfactory reasons for not manufacturing the patented product in India.

The above observations will have a bearing on subsequent applications for CL.

IV. Analysis

Importantly this case demonstrates that out rightly rejecting an application for a voluntary license of a patent by the patentee might not be the most prudent way of addressing a potential compulsory licensing application by the same voluntary licensing applicant. It should be kept in mind that the Act does envisage under Section 84 (6) of the Act that the Controller needs to look into the below factors

- **the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;**
- **the ability of the applicant to work the invention to the public advantage;**
- **the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;**
- **as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit: PROVIDED that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee,**

A patentee while responding to a request for a voluntary license to put forward queries to the applicant in relation to the applicant's ability to manufacture the patented drug to the advantage of the public, the capital capacity of the applicant to undertake the process of manufacturing of the patented drug etc. In case the voluntary licensing

applicant responds to the queries it would be clear that the voluntary license applicant is a serious applicant and based on the response a call could be taken by the patentee, whether further negotiations can be carried put on terms and conditions to grant a voluntary license from the patentee. In case the voluntary license applicant fails to respond it proves that the applicant has not made any credible attempt to obtain the voluntary license.

Another important outcome of this order is while reaffirming the position of the IPAB, the HC held that in case a patented product is not manufactured in India but is wholly imported, it cannot be said that the patented product is 'not worked in India'. Though the court observed manufacturing in India is not necessary, but the burden is on the patentee to show the reasons behind the inability to manufacture the product in India. The reason may also include delay in obtaining regulatory permission for manufacturing the patented product in India. However, "not worked in India" will be determined on a case to case basis and the court has not provided any specific guidelines. It would be advisable to consider manufacturing on loan license basis in India, in case the Patentee does not have manufacturing facilities in India.

Another important takeaway from the order can be the application of dual pricing to meet the reasonable requirement of the public. Thus different prices for the same product can be offered to meet the requirement of patients who are from different economic strata with varying capacity for paying the cost of the drug. However, practically this may be difficult to achieve.

The HC has not dealt in detail regarding what can be construed as reasonably affordable price. The HC just observed that if the book of accounts and Balance Sheet were produced to determine the expenses and reimbursement it could have aided in determining the reasonable price at which Bayer could have made the drug available to the public. However, this could create a problem since the price considered reasonable to the patentee might not considered as reasonable to the authorities even after looking at the book of accounts. This is still a question entirely based on facts that needs to be resolved.

The decision has also opened a plethora of questions. First question is in relation to the grant of de facto license to the infringer by the patent. According to the decision the de facto license will be considered to be given when the patentee has not filed a patent infringement suit against the infringer. This leads to the question, whether the patentee should sue or not sue the infringers? If the patentee sues, the product manufactured by the infringers will not be taken into consideration for the purpose of meeting the reasonable requirement of the public. If the patentee does not sue, it will be considered that the patentee has given a de facto license to the infringer to manufacture the patented product. Even if the patentee sues, there is no certainty that an interim injunction will be granted. This leads to a precarious situation, where there is no injunction and the infringing sales affect the business plan of the patentee.

Further, the HC has held that in relation to the interpretation of **"adequate extent"** for medicines the adequate extent has to be 100% and the medicine should be made available to every patient.. What is an "adequate extent" should ideally be decided on a case to case basis. The number of patients in need of the drug will vary from case to case. Various factors such as :

- The alternative drugs or therapies available for the treatment of the disease,
- The possibility that the doctor would not prescribe the patented drug,
- The graveness of the disease intended to be treated using the patented drugs.

will have to be considered before arriving on the number of patients that need the patented drug. Both the applicant for the compulsory license and the patentee will have to lead evidence i.e. data on this point and based on the evidence produced by the parties the Controller will have to analyse the data to determine the number of

patients that need the patented drug. This process will get complicated as there will be substantial contention between the parties on the methodology and the factors to be considered in determining the number of patients needing the patented drug.

Further, Section 84 (7) (iii) does not give such a strict interpretation, that is the reason **why** it states an **"adequate extent"** and not **"full extent".**

This order may raise serious concerns to patent holders, especially of drugs. Striking a balance between the rights of the patent holder and the users of the patented product is always difficult and it is all the more difficult in the case of drugs wherein a humanitarian approach takes precedence over commercial approach. However it may be too early to come to such conclusion since this is the first ever compulsory license and also considering various facts specific to the case.

Annexure C

Export of Patented Product by A Non-Patentee for Obtaining Regulatory Approval Allowed: Delhi High Court

The Delhi High Court has held that:

- Sale under Section 107A(a) of the Patents Act, 1970 includes export of a patented product by a non-patentee
- A non-patentee can sell (including export), use, etc. a patented product under Section 107A(a) so long as the end use and purpose of such sale, export, use, etc. is reasonably related to research and development of information in compliance with the relevant regulations in India or the importing country.

The Division Bench of the Delhi High Court has held that export of a patented product by a non-patentee for the purpose of obtaining regulatory approval is allowed under Section 107A(a) of the Patents Act, 1970 (**"the Act"**) and therefore does not amount to infringement. The Court laid down guidelines to be followed by courts in an infringement action to determine whether a Defendant's exports are in fact for research purposes under Section 107A(a).

Section 107A reads:

> **107A Certain acts not to be considered as infringement. -For the purposes of this Act,-**
>
> a. **any act of making, constructing,using, selling or importing] a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product;**
>
> b. **importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product,**
>
> **shall not be considered as a infringement of patent rights.**

I. Background

The judgment was a result of appeals against the combined judgment of the Single Judge passed in two separate actions by Bayer:

a. A writ petition[108] filed by Bayer seeking directions from the Court to direct Customs Authorities to seize all exports of Sorafenat made by Natco which formed subject matter of Bayer's Patent No.215758 and

108. W.P.(C) No.1971/2014

b. a suit[109] filed against Alembic to injunct Alembic Pharmaceuticals Ltd. from making, selling, distributing, advertising, exporting, offering for sale and in any manner directly or indirectly dealing in "RIVAROXABAN' and any product that infringes Bayer's patent IN 211300.

The Defendant/Respondent in both actions alleged that export of the patented product was for the purpose of obtaining regulatory approvals in other countries and therefore did not amount to infringement under Section 107A(a) of the Act. It was argued that Section 107A(a) allowed sale of a patented product for research purposes and "sale" within the meaning of the provision includes export.

The Single Judge held that the **"language of Section 107A of Patents Act permits exports from India of a patented invention solely for uses reasonably related to the development and submission of information required under any law in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product."**

II. Key Findings of The Division Bench

A. "Sale" under Section 107A(a) includes "export"

i. Bayer's arguments

i. **Section 107A(a) does not specifically mention "export"** - Section 84[110] and 92A[111] specifically mention exports whereas the legislature has excluded the term from Section 107A(a). Therefore, the intent of the legislature was to exclude exports of patented products from the purview of Section 107A(a).

ii. **Export can only be of information for obtaining regulatory approval and not of the patented product** - Section 107A(a) permits carrying out activities mentioned therein (sale, use, manufacture) in India for the purpose of generating data which may then be submitted before the regulatory authority in India or a country other than India. Therefore, according to Bayer's interpretation, the transfer from India to another country is only of information and not the patented product itself.

iii. **Section 107A(a) is an exception to Section 48[112] of the Act and therefore cannot be interpreted in a manner wider than Section 48** –Section 48 gives a patentee the right to sell in India only. Therefore, Section 107A(a) cannot be interpreted in a manner to grant an additional right to a non-patentee, i.e. export of the patented product.

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109. CS(COMM) No. 1592/2016

110. Section 84 deals with compulsory licenses ("CL") – the grounds for grant of a CL; procedure to be followed and factors to be considered by the Controller for grant of a CL. Section 84(7)(a) mentions exports in the following manner:
(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied-
(a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,-
(i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or
(ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or
(iii) a market for export of the patented article manufactured in India is not being supplied or developed; or
(iv) the establishment or development of commercial activities in India is prejudiced;

111. Section 92A deals with compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances.

112. Section 48. Rights of patentees—
Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee—
(a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India;
(b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India

ii. Arguments by Natco/Alembic

i. As per the plain meaning of the provision, export of the patented product itself is allowed solely for the purposes mentioned in Section 107A(a). Natco/Alembic relied on judgments to argue that "sale" would include "export". It was also highlighted that the laws of many countries require studies to be conducted within the country for obtaining regulatory approval. In such cases, non-patentees cannot rely on information from studies conducted in India for obtaining regulatory approval.

ii. Section 107A is not a proviso to or an exception to Section 48 but is an independent provision giving rights to a non-patentee.

iii. Court's holding

i. The Court held that "sale" under Section 107A(a) includes export. The Court rejected Bayer's interpretation of the provision and held that the provision cannot be interpreted in a restrictive manner to mean transfer of only information and not of the patented product itself from India to other countries. The Court held that the key is to determine the purpose of the sale, i.e. the objective of carrying on experiment, research and developing information. As long as the purpose of sale is research to prepare for obtaining regulatory approval, the provision cannot be interpreted in a restricted manner.

ii. Regarding express mention of the term "export" in certain other provisions of the Act, the Court noted that the objectives behind Sections 84 and 92A[113] are different – these provisions deal with compulsory licensing whereas Section 107A(a) deals with an exception when use of a patented product is for research purposes and therefore considering the different objects behind the provisions, the terms used therein cannot be interpreted in a similar manner.

iii. The Court also considered the history and the object behind enactment of Section 107A and held that Section 107A is an independent provision and cannot be read as a proviso to Section 48 and therefore, its scope cannot be limited.

B. Test to regulate the use of Section 107A(a) exemption

The Court noted that different countries have different requirements of quantities to be used in studies, where the studies are to be conducted and therefore there can be no rigid rule to determine whether section 107A(a) applies and each case will have to be decided on an analysis of the evidence including proof of the relevant regulatory requirements. The key is to determine the intent of use, i.e. it must be determined whether the use of the patented product is for commercial purposes.

The Court also laid down certain guidelines to be considered by courts to determine whether use, sale, etc. is "reasonably related" to the purpose of development of information to be used to obtain regulatory approvals. It was held that in a case where a plaintiff alleges infringement on account of exports or an exporter seeking a declaration of non-infringement on account of exports under Section 107A(a), courts should consider the following, and any other matter that may be relevant:

1. The patent granted;

2. The nature of the product or elements sought to be exported;

3. The details of the party importing the product;

113. Sections 84 and 92A fall under Chapter XVI dealing with "Working of Patents, Compulsory Licenses and Revocation."

4. The quantity sought to be exported;

5. Other particulars with respect to the end use of the product, to establish that it is solely for research and development of information to regulatory authorities in the other country;

6. All particulars regarding the relevant regulations, covering the kind and scope of inquiry, including the quantities of the product (i.e the patented product or compound, API or fine chemical needed). These details have to be provided by the exporter/seller of the product. The Court clarified that in case the defendant is not the seller, it should disclose who had purchased the product in the relevant quantities, to assist the court in impleading the relevant party in the proceedings;

7. If the regulations are in another language, the defendant must provide an authentic English translation to facilitate a speedy resolution;

8. If necessary, court can order verification through the Indian mission (and its trade division) abroad regarding the authentication of the third party and/ or its facilities abroad.

It was further held that during adjudication of such matters, courts should issue appropriate interim orders requiring the Defendant to give an undertaking by way of affidavit to compensate the plaintiff, specifying the extent of such monetary compensation, in the event the court eventually held that the Defendant's acts amounted to infringement and the suit were to be decreed in favour of the plaintiff and the extent of such monetary compensation.
This affidavit should be:

a. of an authorized personnel;

b. kept alive during the pendency of litigation;

c. duly authenticated by the board of director or other controlling body of the defendant, and;

d. whenever the company or entity undergoes amalgamation or transfer, suitable undertaking from the successor organization should be obtained;

Lastly, to protect exporters of generic drugs against frivolous litigation by patentees, the Court held that if it is held by the court that the exporter is not involved in sale or export of any patented product, but a generic article, unprotected by patent law, when denying relief, suitable restitutionary relief should be awarded to the defendants in monetary terms, to preclude litigation that prevents trade or competition.

C. Disputes related to sale of patented products under Section 107A(a) are subject matter of civil suits

The Court held that since an adjudication under Section 107A(a) involves investigation into facts and could result in reliefs to private parties for enforcement of private rights, i.e. patent rights, such disputes cannot form subject-matter of writ proceedings but should be filed as civil suits.

The Court also noted that it cannot issue blanket directions of any kind to Customs authorities related to mandatory seizure, prohibition or labelling requirements since such aspects are within the domain of the executive and cannot be decided by courts.

Annexure C

III. Key Takeaways From The Decision

The judgment is a landmark decision in relation to use of patented products by non-patentees. While the Court has allowed exports for obtaining regulatory approval, the extensive guidelines laid down, including the requirement to provide an undertaking to compensate the plaintiff, will ensure protection of the rights of a patentee in the event patented products are being exported for commercial exploitation under the garb of Section 107A(a).

Patentees should conduct proper due diligence before filing an infringement suit against a non-patentee exporting a product covered by their patent. In the event in the infringement proceedings the defendant is able to prove that their product is not the patentee's patented product but is a generic drug, the patentees could be asked to compensate the defendant, as laid down by the court. To establish that the Plaintiff conducted proper due diligence before filing a suit, patentee can place on record reports of tests conducted on the defendant's product, if it is possible to obtain the product. Patentees could to the extent possible gather information about packaging material, export details including details of country of export, quantities exported to determine if the laws of such country require tests to be conducted in that country.

To protect their interests, entities exporting a patented product outside of India for purposes mentioned under Section 107A to an entity in another country should obtain appropriate representations backed by indemnities from the importing party to the effect that they will use the exported product solely for the purpose of obtaining regulatory approval and not for commercial exploitation.

Annexure D

Novartis Indian Supreme Court Judgment: What is Efficacy for Pharmaceutical Invention ?

The Indian Supreme Court (SC) on April 1, 2013 delivered a landmark judgment rejecting Novartis's 1998 Indian patent application for beta-crystalline form of Imatinib Mesylate, a drug used to treat chronic myeloid leukemia (CML), a type of blood cancer marketed under the names "Glivec"or "Gleevec". This also ended Novartis eight year battle with various Indian legal forums to get its drug patented.

The SC for the first time has interpreted Section 3 (d) of the Indian Patent Act, 1970 (Act), which attempts to curtail ever-greening of patent.[114] The SC in its 112 page judgment traced the history of Indian patent law starting from the Justice Tek Chand committee report, 1949 to the 2005 amendment of Act, the SC laid particular emphasis on (i) Justice Ayyangar report on Patent Law Revision, 1959 (the 1970 Act was enacted based on the recommendations in this report) (ii) effect on the Indian Pharmaceutical industry due to the changes in the Patent Law (the SC looked at statistics relating to Market share of Indian Pharmaceutical companies vs. MNC pharmaceutical companies pre 1970 and post 1970) (iii) why pharmaceutical, chemical and food product patents were not permitted till 2005, (iv) how India had to retrospectively introduce product patent regime after having lost at the WTO (World Trade Organization), wherein the WTO panel and the appellate body had ruled that India had failed to meet its TRIPS (Trade Related Aspects of Intellectual Property Rights) obligations (v) relevant provisions of the TRIPS agreement and flexibilities under the Doha declaration (vi) the facts and the background leading to introduction of Section 3 (d) including parliamentary debates and the letters received from various organizations like WHO (World Health Organization) and UNAIDS . After extensive deliberation on these points the SC proceeded to apply the law to the facts of Novartis patent application.

In this update, we have discussed the specific facts discussed by the SC and its findings and have also commented upon other observations that will have bearing on the patent prosecution in India.

I. Background

The facts of the case have been summarized in the table below.

	Fact and Comments
July 17, 1998	Novartis filed Indian patent application for the beta-crystalline form of Imatinib Mesylate (**"Product"**). At that time the Act allowed acceptance of product patent applications as per "mail box" process and the same was contemplated to be examined post January 1, 2005 once India introduced product patent regime. This was in line with TRIPS requirement.
1998 – Jan 1,2005	The application was kept in mailbox as required under TRIPS and the Act.
2002 – 2003	In the meantime, Novartis applied for and was granted exclusive marketing rights (EMR) in relation to Product under the then existing Section 24A of the Act, which also was in line with TRIPS.

114. http://www.nishithdesai.com/IP-hotline/NDA-Hotline-IP-Sept-8-2004w.htm; http://www.nishithdesai.com/Pharma-update/Pharma-update-Nov15-2003.htm

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Jan 1, 2005	India introduced product patent regime and simultaneously amended Section 3(d) of the Act.[115] Section 3(d) disallows the patenting of a new variant of an already known substance unless such new form has significant efficacy over the older version. This was introduced with a view to prevent ever-greening and granting of frivolous patents.
2005	Novartis patent application before it was taken up for examination attracted five pre-grant opposition filed by Cancer Patients Aid Association, NATCO Pharma, Cipla, Ranbaxy Laboratories and Hetro Drugs (Opponents).
Jan 25, 2006	Asst. Controller of Patents upheld the pre-grant oppositions and rejected Novartis' patent application (**"Controller Order"**) on the grounds that the application lacked novelty, was obvious and was not an invention in view of Section 3(d) of the Act. Controller held that the Product was a new version of an older molecule that Novartis first patented in 1993 and the increment in efficacy is not substantial enough to receive the grant of a patent
May 2006	Since the appellate authority Intellectual Property Appellate Board (IPAB) under the Act was not established, Novartis filed writ petitions before the Madras High Court against the Union of India, the Controller General of Patents & Designs (**"Controller"**), Opponents. Novartis contended that (i) the Controller erred in interpreting the enhanced efficacy standard imbibed in Section 3(d) with regard to Product, (ii) Section 3(d) was vague, ambiguous and contrary to the requirements of TRIPs and that it violated Article 14 (right to equality) of the Constitution of India, (iii) the Controller disregarded the in-house laboratory test performed by Novartis' scientists on rats to show that a 30% increase in bioavailability between imatinib and imatinib mesylate was adequate to meet up the "enhanced efficacy" benchmark of section 3(d).
April 2007	The Central Government issued a notification under Section 117G of the Act whereby all appeals from the order of Controller, pending before the High Court, were transferred to the IPAB set up in Madras. Therefore, the Madras High Court transferred the appeal from the Controller's order rejecting patent to the IPAB. However, the Madras High Court, reserved the right to pronounce its judgment on the issue of the constitutional validity of Section 3(d) of the Act.
August 6, 2007	The Madras High Court held that Section 3(d) does not violate Article 14 (right to equality) of the Constitution of India.[116] This order was not appealed further by Novartis.
June 26, 2009	The IPAB reversed the decision of the Assistant Controller on the issues of anticipation and obviousness. However, the IPAB held that the subject matter of the patent application was barred from patentability under Section 3 (d) of the Act and therefore rejected the patent. However, it allowed the process patent for the Product.
August 11, 2009	Against the order of the IPAB Novartis filed a special leave petition (SLP) under Article 136 of the Indian Constitution in the Indian Supreme Court.
April 1, 2013	Order of the Supreme Court

The SC had made an exception and admitted the SLP side-stepping the jurisdiction of the Madras High Court, in view of the importance of the case and the number of seminal issues that were involved in the case. The SC noted that this was an exception and any attempt directly challenging an IPAB order before the SC side-stepping the High Court was strongly discouraged.

We have examined below each concept discussed by the Supreme Court:

A. Invention vs. Patentability

A subject matter in order to get a patent under the Act has to pass the test of Invention and Patentability, both being distinct concepts.

In order for a subject matter to pass the test of Invention it must satisfy the following conditions as laid down under Section 2(1) (j) and Section 2(1) (ja) of the Act

115. http://www.nishithdesai.com/Pharma-update/2007/Pharma-update-Aug1007.htm

116. http://www.nishithdesai.com/Pharma-update/2007/Pharma-update-Aug1007.htm

i. It must be "new";

ii. It must be "capable of being made or used in an industry"

iii. It must have inventive step

a. entails technical advance over existing knowledge;

Or

b. has an economic significance

And

c. makes the invention not obvious to a person skilled in the art.

Once a product or a process has passed the test of Invention it also has to pass the test of Patentability. A subject matter passes the test of Patentability if it has not been specifically excluded from Patentability under the Act. Section 3 and Section 4 of the Act list down subject matter which is not patentable.

B. The Invention

The invention as claimed in the patent application was the beta-crystalline form of Imatinib Mesylate. This was a derivative of the free base form called Imatinib disclosed vide example 21 of a patent application filed by Novartis in US on April 2, 1993 (Zimmermann patent).

According to Novartis the invention as claimed in the patent application involved two inventions. The first invention involved selecting example 21 out of the 37 examples given in the Zimmermann patent and then choosing methane sulfonic acid to produce the methane sulfonic acid addition salt of the free base Imatinib, called Imatinib Mesylate. The second invention involved making Imatinib Mesylate suitable for oral administration, which resulted in creation of the present invention in question i.e. beta-crystalline form of Imatinib Mesylate.

According to the opponents the Zimmermann Patent in addition to the Imatinib also disclosed Imatinib Mesylate. Thus, there was only one invention, which is making Imatinib Mesylate suitable for oral administration.

C. Imatinib vs. Imatinib Mesylate

In order to verify the claim of Novartis that its application involved two inventions, it was essential for the SC to determine whether the Zimmermann patent in addition to Imatinib disclosed Imatinib Mesylate. If the answer was in the affirmative then Novartis claim of two inventions was incorrect because if the Zimmermann patent did disclose Imatinib Mesylate then the first invention i.e. Imatinib Mesylate would not qualify as an invention under Section 2 (1) (j) and 2(1) (ja) of the Act, as it will not be a technical advance over the existing knowledge.

The SC referred to the following disclosures in the Zimmermann patent and developments surrounding the Zimmermann patent:

- "may form acid addition salts, for example with inorganic acids, such as hydrochloric acid, sulfuric acid or a phosphoric acid, or with suitable organic carboxylic or sulfonic acids..."
- "any reference to the free compounds should be understood as including the corresponding salts, where appropriate and expedient."

- "The invention relates also to a method of treating warm-blooded animals suffering from a tumoral disease, which comprises administering to warm blooded animals requiring such treatment an effective, tumour-inhibiting amount of a compound of formula I or of a pharmaceutically acceptable salt thereof.."
- On April 9, 1998 Novartis had filed for a New Drug Application to obtain a Food and Drug Administration (FDA) marketing approval in the US for Gleevec with which it had furnished information that the active ingredient of the drug was Imatinib Mesylate and the same was covered by the Zimmerman patent.
- The FDA approval for the Drug Gleevac (Imatinib Mesylate) was granted on May 10, 2001 and was commercially launched in the market much before the grant of the patent for beta crystalline form of Imatinib Mesylate
- Novartis had sent a legal notice to Natco Pharma in the UK to stop selling their drug called VEENAT consisting of Imatinib Mesylate because it was infringing there European equivalent of the Zimmermann Patent.
- Novartis patent application in the US for beta crystalline form of Imatinib Mesylate was rejected by the US examiner. Novartis appealed the examiners decision to the Board of Patent Appeals and Interference (Board). In its decision the Board had observed that the "specification of the Zimmermann patent teaches any person skilled in the art how to use imatinib, or a pharmaceutically acceptable salt thereof"
- Novartis had not filed for a separate patent for Imatinib Mesylate
- Two articles published in Cancer Research and Nature Medicine in 1996 authored by Jurg Zimmermann (Inventor in the Zimmermann patent) had a detailed discussion about the anti-tumoral properties of Imatinib and its methanesulfonate salt i.e. Imatinib Mesylate.

Based on the above facts the SC held that the Zimmerman patent did disclose Imatinib Mesylate as well as its pharmacological properties. Thus, Novartis claim of its invention involving two inventions failed and it consisted of only one invention, which is making Imatinib Mesylate suitable for oral administration which had resulted in the beta crystalline form of Imatinib Mesylate. This finding of the SC was also essential as a precursor to determine, the known substance that beta crystalline form of Imatinib Mesylate should be compared with for establishing enhanced efficacy under Section 3 (d).

D. Patentability Analysis – Section 3 (d)

The main argument of the opponents was that the Product was not patentable under Section 3 (d)..

Section 3 (d) reads as:

- **[(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.**
- **Explanation : For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;]**

In order to pass the bar of Section 3(d) it was required to be proved that the Product has enhanced efficacy over the known form of the subject matter.

Annexure D

E. What was the known substance?

After examining the pleadings and expert affidavits, the SC observed that Novartis' argument was that the known substance was Imatinib as disclosed in Zimmerman patent from which beta-crystalline form of Imatinib Mesylate was derived and that the substance immediately preceding beta crystalline form of Imatinib Mesylate was Imatinib and not Imatinib Mesylate as the Zimmerman patent did not disclose Imatinib Mesylate. The SC rejected this argument because it had made a finding that the Zimmerman patent did disclose Imatinib Mesylate. Further, the SC also rejected this argument in view of the fact that this was in contrast to the oral and written submissions of Novartis before the SC, wherein Novartis had argued that its invention involved two stages removed from Imatinib in free base, and the substance immediately preceding the subject product is Imatinib Mesylate.

Hence, the SC concluded that the known substance was Imatinib Mesylate from which beta-crystalline form of Imatinib Mesylate was derived.

F. Efficacy under Section 3(d)

Since the term "efficacy" is not defined in the Act, the SC referred to the Oxford Dictionary and observed that Efficacy means "the ability to produce a desired or intended result". Accordingly the SC observed that the test of efficacy depends "upon the function, utility or the purpose of the product under consideration". Therefore, the SC held that in case of medicines, whose function is to cure disease, the test of efficacy can only be "therapeutic efficacy".

In relation to "enhanced efficacy", the SC held that the parameters for proving enhanced therapeutic efficacy especially in case of medicines should receive a narrow and a strict interpretation. To support this interpretation SC relied on (i) the explanation to Section 3 (d) which requires derivatives to "differ significantly in properties with regard to efficacy", so not all advantageous and beneficial parameters would amount to enhancement of efficacy; and (ii) the main text of Section 3 (d) which states "enhancement of known efficacy". The SC held that the new form of a known substance has to have significant advantageous and beneficial properties over known substance in order to pass the bar of enhanced therapeutic efficacy under Section 3 (d).

However, the SC pointed out that just because the word efficacy has to be given a strict interpretation under Section 3 (d) that does not in any way mean that it bars all incremental inventions of chemical and pharmaceutical substances. Essentially Section 3 (d) provides a bar that incremental inventions of chemical and pharmaceutical substances need to pass in order to be patentable.

G. Efficacy of beta-crystalline form of Imatinib Mesylate

As discussed above the SC had concluded that the known substance was Imatinib Mesylate and not free base Imatinib. However, all the evidence submitted by Novartis compared the efficacy of Product with that of Imatinib, there was no evidence provided by Novartis which compared the efficacy of the Product with that of Imatinib Mesylate.

However, SC went on to examine the expert affidavits submitted by Novartis according to which the following properties exhibited by the Product demonstrated its enhanced efficacy over Imatinib:

1. More beneficial flow properties
2. Better thermodynamic stability
3. Lower hygroscopicity
4. 30 % increase in bio-availability

The SC held that the first three properties of the Product related to improving processability and storage, thus they did not in any way demonstrate enhancement of therapeutic efficacy over Imatinib Mesylate as required to pass the test of Section 3(d). The SC came to this conclusion even though the affidavits submitted by Novartis compared the Product over Imatinib.

The SC after this was left with 30 % increase in bio-availability, with regard to this the SC held that increase in bioavailability could lead to enhancement of efficacy but it has to be specifically claimed and established by research data. In this case the SC did not find any research data to this effect other than the submission of the counsel and material "to indicate that the beta-crystalline form of Imatinib Mesylate will produce an enhanced or superior efficacy (therapeutic) on molecular basis than that could be achieved with Imatinib free base in vivo animal".

In view of the above findings the SC held and concluded that Novartis claim for the Product failed both the test of invention and patentability under Section 2(1) (j), Section 2(1) (ja) and Section 3 (d) of the Act.

II. Analysis

The SC did not have any guidance from the Act in interpreting Section 3 (d). Hence it referred to the parliamentary debates and the circumstances surrounding enactment of Section 3 (d) to a great extent to give a purposive interpretation. Further, considering that Section 3 (d) is very unique to India, it was very important both for the pharma industry and the patent office to have guidance on its interpretation . Though SC has attempted to clarify certain aspects, some issues are still open.

One debate that was laid to rest was whether efficacy under Section 3 (d) for pharmaceuticals is therapeutic efficacy. The SC has made it clear that efficacy for a pharmaceuticals refers to only therapeutic efficacy. The SC ruled that enhanced therapeutic efficacy should be interpreted strictly and properties such as improving storage, processability and inherent pharmacological properties do not amount to enhancement of therapeutic efficacy.

Thus, there is some guidance on parameters that do not amount to enhanced therapeutic efficacy but there is no guidance as to what parameters amount to therapeutic efficacy. The SC does state that increase in bioavailability can amount to enhancement of therapeutic efficacy if established by research data. One can take a cue from this that appropriate research data needs to be provided to show enhancement of therapeutic efficacy but the question what kind of research data would suffice to meet this requirement has been kept open. Guidance on these aspects would have been of immense help to the various stakeholders even though the court did not have to rule on these aspects to decide the present case.

Another important aspect highlighted in the judgment is the need to identify exact prior substance against which the invention should be compared. The practical difficulty in obtaining comparative data will need to be resolved once it is clear as to the nature of data that will be accepted to prove therapeutic efficacy. This clarity is likely to come in through the orders of the controllers and IPAB in similar matters.

One vexing issue prior to this judgment faced by patent applicants was whether the evidence required to establish enhancement of therapeutic efficacy should be included in the specification or external evidence would suffice. This issue seems to have been laid to rest, since the SC has relied on external evidence i.e. expert affidavits to decide enhancement of efficacy in this case.

The SC has clarified that the judgment in this case should not be understood to mean that Section 3(d) bars all incremental inventions of chemical and pharmaceutical substances. However, the bar that has been set by the SC to surpass the hurdle of Section 3 (d) is very high.

Annexure D

As a matter of principle if prevention of ever-greening of patent is the real mischief that is sought to be remedied by Section 3(d), then it is important to take into consideration whether prior substance was indeed commercialized. The reason being often the prior substance is in free base form and not the salt form. A free base form generally cannot be administered to humans whereas a salt form can be administered thus the free base form cannot be commercialized. In a drug discovery cycle it is the free base form which is discovered first, thus generally phrama companies file for a patent for the free base form encompassing all salt forms in order not to lose the priority, at this stage the pharma companies are not generally aware as to what salt form of the free base would have most therapeutic efficacy. This discovery is generally made after conducting extensive human or animal clinical trials.

This point becomes very important because if a salt form cannot be claimed separately due to Section 3 (d). Then in order to stop a patent infringer from using the salt form of its drug, the pharmaceutical company has to rely on its patent covering its free base form. However, the first argument raised by the defendant in its counter claim is that the salt form is not covered under the free base patent and a broad claim which claims all salt forms is not enabling. Thus, the defendant is not infringing the patent. This issue is sub judice in the Merck v/s. Glenmark suit before the Delhi High Court.

Hence, this is a big dilemma for pharmaceutical companies and needs to be addressed. The purpose of Section 3(d) is to prevent pharmaceutical companies from extending their period of monopoly i.e. evergreening of patents but it should not stifle inventions. Hence, the parliament and judiciary should revisit the provision so that it is only the new form of the known "commercialized" substance may not be granted patent unless enhanced therapeutic efficacy is shown.

Annexure E

Arbitrability of Intellectual Property Disputes: A Perspective From India

This article was originally published on 3rd July 2019 in the Oxford Journal of Intellectual Property Law & Practice.

Summary

With growing cross-border investments and intellectual property transactions, there is a global surge in IP disputes. Consequently, arbitration of IP disputes is gaining traction world-wide. In India, stakeholders in IP transactions are fast turning to arbitration than to traditional courts. However, the conclusion whether certain IP disputes should be adjudicated through arbitration or through courts is not always easy to arrive at. It is critical to understand legal and judicial trends in India that can guide parties to tailor arbitration agreements, and assist courts and arbitrators in effective decision-making. This article examines the aforesaid trends, and discusses aspects that should be evaluated during negotiation of contracts involving intellectual property.

For complete article, please visit
https://academic.oup.com/jiplp/article/14/8/632/5528003?guestAccessKey=a2f7da7c-7979-4a53-8966-d07cc0a63b52

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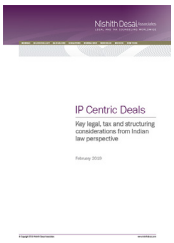

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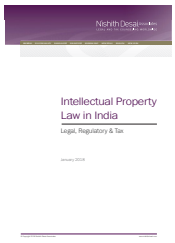

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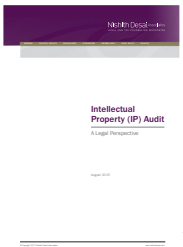

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Research @ NDA

Research is the DNA of NDA. In early 1980s, our firm emerged from an extensive, and then pioneering, research by Nishith M. Desai on the taxation of cross-border transactions. The research book written by him provided the foundation for our international tax practice. Since then, we have relied upon research to be the cornerstone of our practice development. Today, research is fully ingrained in the firm's culture.

Our dedication to research has been instrumental in creating thought leadership in various areas of law and public policy. Through research, we develop intellectual capital and leverage it actively for both our clients and the development of our associates. We use research to discover new thinking, approaches, skills and reflections on jurisprudence, and ultimately deliver superior value to our clients. Over time, we have embedded a culture and built processes of learning through research that give us a robust edge in providing best quality advices and services to our clients, to our fraternity and to the community at large.

Every member of the firm is required to participate in research activities. The seeds of research are typically sown in hour-long continuing education sessions conducted every day as the first thing in the morning. Free interactions in these sessions help associates identify new legal, regulatory, technological and business trends that require intellectual investigation from the legal and tax perspectives. Then, one or few associates take up an emerging trend or issue under the guidance of seniors and put it through our "Anticipate-Prepare-Deliver" research model.

As the first step, they would conduct a capsule research, which involves a quick analysis of readily available secondary data. Often such basic research provides valuable insights and creates broader understanding of the issue for the involved associates, who in turn would disseminate it to other associates through tacit and explicit knowledge exchange processes. For us, knowledge sharing is as important an attribute as knowledge acquisition.

When the issue requires further investigation, we develop an extensive research paper. Often we collect our own primary data when we feel the issue demands going deep to the root or when we find gaps in secondary data. In some cases, we have even taken up multi-year research projects to investigate every aspect of the topic and build unparallel mastery. Our TMT practice, IP practice, Pharma & Healthcare/Med-Tech and Medical Device, practice and energy sector practice have emerged from such projects. Research in essence graduates to Knowledge, and finally to **Intellectual Property.**

Over the years, we have produced some outstanding research papers, articles, webinars and talks. Almost on daily basis, we analyze and offer our perspective on latest legal developments through our regular "Hotlines", which go out to our clients and fraternity. These Hotlines provide immediate awareness and quick reference, and have been eagerly received. We also provide expanded commentary on issues through detailed articles for publication in newspapers and periodicals for dissemination to wider audience. Our Lab Reports dissect and analyze a published, distinctive legal transaction using multiple lenses and offer various perspectives, including some even overlooked by the executors of the transaction. We regularly write extensive research articles and disseminate them through our website. Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with much needed comparative research for rule making. Our discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged. Although we invest heavily in terms of time and expenses in our research activities, we are happy to provide unlimited access to our research to our clients and the community for greater good.

As we continue to grow through our research-based approach, we now have established an exclusive four-acre, state-of-the-art research center, just a 45-minute ferry ride from Mumbai but in the middle of verdant hills of reclusive Alibaug-Raigadh district. **Imaginarium AliGunjan** is a platform for creative thinking; an apolitical eco-system that connects multi-disciplinary threads of ideas, innovation and imagination. Designed to inspire 'blue sky' thinking, research, exploration and synthesis, reflections and communication, it aims to bring in wholeness – that leads to answers to the biggest challenges of our time and beyond. It seeks to be a bridge that connects the futuristic advancements of diverse disciplines. It offers a space, both virtually and literally, for integration and synthesis of knowhow and innovation from various streams and serves as a dais to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear your suggestions on our research reports. Please feel free to contact us at **research@nishithdesai.com**

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