Indian Courts Assess Vulnerability Versus Validity in Key Pharma Patent Infringement Rulings

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Before initiating a patent infringement lawsuit, the patent owner evaluates their chances of securing a preliminary injunction (PI). The chances of securing a PI often reduce in the event the defendant raises a credible challenge to the patent either through the filing of an invalidity action, which may be based on proceedings or statements made in another jurisdiction in relation to the same patent. Such statements, for example, relate to patent term extensions or admissions/statements made in other countries when the patent owner is defending their patent. Since 2015, these issues have time and again been extensively decided by the Delhi High Court.

The principles being followed for the purpose of the grant of injunction in patents was summarised in *Ten XC Wireless Inc v Mobi Antenna Technologies (Shenzhen) Co. Ltd* in 2011 as under:

- the registration of a patent, per se, does not entitle the plaintiffs to an injunction;
- there is no presumption of validity of a patent;
- the courts lean against monopolies. The purpose of the legal regime in the area is to ensure that the inventions should benefit the public at large; and
- the plaintiff is not entitled to an injunction if the defendant raises a credible challenge to the patent. Credible challenge means a serious question to be tried.

The issue relating to "credible challenge of a patent" for grant of preliminary injunction in a patent infringement lawsuit was addressed *vide order* dated 30 May 2024 by the Hon'ble Shimla High Court in the *Boehringer Ingelheim v Eris Life Sciences,* wherein issues relating to pricing and public interest and invalidity of the patent in China of the same family were being considered to deny a PI to the patent owner.

Public Interest

In 2009, in *Bayer Corporation and Ors v Cipla, Union of India and Ors*, the Delhi High Court held that if, after a patentee, rewarded for their toil – in the form of protection against infringement – were to be informed that someone, not holding a patent, would be reaping the fruits of their efforts and

investment, such a result would be destructive of the objectives underlying the Patents Act.

Six years later, in *Merck Sharp and Dohme Corporation and Anr v Glenmark Pharmaceuticals*, 2015 Hon'ble Division Bench of Delhi High Court held that the Court must be mindful, especially in a case where a strong case of infringement is established. As there is an interest in enforcing the Act in the absence of a PI, the market forces can cause irreparable damage if the defendant is allowed to operate in the interim during the trial. The price reduction by the defendant will cause a financial setback to the patentee, which the patentee may not be able to recover. The victory for the patentee, therefore, should not be pyrrhic but real.

Pricing and public interest issues once again came up again in *Bristol-Myers Squibb Company and Ors v Mr JD Joshi and Anr* on 29 June 2015, wherein the court, in relation to public interest, recognised that the Patent Act includes provisions that allows the examination of the plea of public interest towards allowance of the compulsory licence under the distinct chapter of the compulsory licensing and non-working of the patent, which is code in itself. The object of the injunction in patent matters is to protect the patentee against the injury by violation of right for which they could not be adequately compensated in damages recoverable in the action if ultimately a decree for damages is passed.

Similar to the position taken by the Division Bench of the Delhi High Court in *Merck v Glenmark* in 2015 and *Bayer* in 2009,the Shimla High Court in the *Boehringer Ingelheim* case rejected the contention of the defendant that the grant of an interim injunction would cause irreparable loss to the society due to the price difference between the product of the plaintiff and the defendant. The Court held that the defendant, being a commercial rival, cannot be allowed to raise the plea of public interest, because there are enough checks and balances in the Patents Act, 1970 to cater to the public interest, such as compulsory licence.

Presumption of Invalidity

Several decisions of the Delhi High Court in view of the High Court of Delhi Rules Governing Patent Suits, 2022 have taken a serious view of non-disclosure of proceedings initiated by or against the plaintiff in relation to the same patent. Absent any statutory presumption and given the scheme of the act, which enables challenge to the validity of a patent at several stages, there is neither any presumption as to the validity of a patent nor is the patent rendered immune for challenge to its validity.

The Division Bench of Delhi High Court in *F Hoffmann-LA Roche Ltd and Anr v Cipla Ltd* recognised that a multi-layered, multi-level examination of the opposition to the grant of patent cannot be accorded the highest weightage, as there is no presumption of invalidity in India in accordance with Section 13(4) of the Indian Patents Act.

In *Bristol-Myers Squibb Company v JD Joshi,*2015, the Court held that the presumption of validity exists only till such time the patent is challenged – a challenge that is credible and no further.

In the *Boehringer Ingelheim* case, the Shimla High Court distinguished between vulnerability and validity and held that while vulnerability is an issue to be assessed at the preliminary injunction stage, the issue of validity is an issue to be decided at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself. The court further held that at the stage of interim relief, the defendant must establish its assertion that its defence is not insubstantial and sets out a credible challenge to the validity of the patent.

The Court also recognised that the grant of the patents in other jurisdictions weighs in favour of the plaintiff and the rejection in China does not dilute the chances of securing an interim relief by the patent holder. The Shimla High Court in the BI case was of the view that non-disclosure of the fact invalidation of the corresponding patent in China has no bearing on the infringement lawsuit as the suit patent for Empagliflozin has been granted in at least 70 other jurisdictions. The Court also recognised that the laws relating to registration of patents are territorial in nature and therefore it is important to assess the credibility of the Indian Patent. It thus cannot be disputed that registration or invalidation of a patent by a particular country in general has no effect on the registration or invalidation of the same patent in some other country, because registration and invalidation of a patent is governed by the law of that particular country. This position is aligned with the earlier order of the Delhi High Court in *Communication Components Antenna Inc v Ace Technologies Corp and Ors, 2019.*The Court held that the language of the claims in different jurisdictions after it is granted in the various domestic jurisdictions would usually never be identical. This is due to the subjectivity that exists in the prosecution process of the application. Insofar as an Indian Court is concerned, while determining the question of validity of a patent, it would be concerned primarily with the claims that have been granted in India. The unique nature of the grant of patents in various jurisdictions or the wording of claims in various jurisdictions would only have a broad impact on the Indian patent.

With regard to filing of expert affidavits filed at the interim stage, the Shimla High Court held that an affidavit filed by the expert is at the behest of the defendant, which is neither a publication nor was it in existence prior to the filing of this civil suit and therefore will have to be examined at the trial stage, thus distinguishing between vulnerability and validity.

Conclusion

The aforesaid trends clearly demonstrate that the Courts in India are leaning towards the grant of PI in favour of the plaintiff in the case a plaintiff can make out a case for prima facie infringement. Also, what clearly emerges is that there is an obvious distinction between vulnerability of the suit patent at

the interim stage as opposed to validity of the same.

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