

Analysing the Pitfalls of Indian Patent Injunctions based on Fear of Infringement

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This article examines the emergence and implications of *quia timet* injunctions in patent cases in India. A *quia timet* action is an action based on a possible future injury and therefore stems from a threat of infringement. The common law remedy of *quia timet* injunctions and its application in recent cases in jurisdictions such as Canada, Europe and India are discussed. The analysis reveals that there are no set standards for granting such injunctions, making them subjective and speculative. It is argued that patent cases are not appropriate matters to grant and allow such actions. The recent emergence of such actions in Indian patent cases is worrisome. Given that patents are not presumed valid in India, that India does not follow the principle of ‘clearing the way’ and the questionable quality of patents being issued by the overburdened Indian Patent Office, *quia timet* actions may adversely impact innovation and public interest in India.

Keywords: Patent, injunction, threat of infringement

Courts in India are still grappling with understanding the correct standards for issuing interim and *quia timet* injunctions in patent cases. Scholars have argued for doing away with interim injunctions and proceeding directly to the stage of trial.¹ Such arguments are sustained for several reasons such as the complexity involved in assessing infringement in patent matters, the alternatives available for monetizing losses that may be suffered by the patentee during the period of trial and the public interest involved in speedy disposal of such cases.¹ Taking a cue from this ideological perspective, this paper seeks to examine the emergence and implications of *quia timet* injunctions in patent cases. Though such injunctions have been used in Indian trademark matters, their emergence in Indian patent jurisprudence is recent.

While interim injunctions and *quia timet* actions are based on similar ideas of preserving rights, the standards, timing and effects of these injunctions usually vary.

Standards Applied by Courts in Granting *Quia Timet* Injunctions

Interim injunctions are prohibitive orders that seek to restrain the defendant from carrying out the allegedly infringing activity. A request for interim injunction is made with the aim of persevering rights till final disposal of the case.² An application for

interim injunction may be made with the plaint and courts have often granted *ex-parte* interim injunctions even in matters related to process patents.³ In the case of process patents, interim *ex-parte* injunctions prove to be very controversial. This is because Section 104A of the Patent Act, 1970 shifts the burden on the defendant to prove that his process is not identical to the patented process. Thus, an *ex-parte* injunction (an injunction against the defendant, in his absence) acts to his disadvantage.⁴

The standard for issuing interim injunctions was laid down in the *American Cyanamide* decision and is that of a ‘triable case’.⁵ Indian courts have adopted differing standards while assessing what amounts to a ‘triable case’. Some courts have reasoned that the *American Cyanamide* standard is too low and wide and have resorted to assessing relative merits of the case.⁶ However, others have still stood by the *American Cyanamide* standard.⁷

Unlike interim injunctions, a *quia timet* injunction is based on a fear of possible future injury and therefore based on a mere threat of an infringing act.⁸ Therefore, in such cases the court must first assess whether a cause of action has arisen and then go on to decide injunctive relief. If the case is admitted and injunction granted, the injunction operates like a permanent injunction as it prevents the defendant from launching the product till the patent term expires.

Though *quia timet* injunctions are permanent, their assessment seems to be on the same standards

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as interim injunctions. Since no infringing activity has actually started and no injury has occurred, assessment of merits is oftentimes speculative. This results in injunctions being granted for merely 'triable issues'. The standards for allowing *quia timet* actions is still murky in India with no definite test laying down what actions could lead to the creation of a legitimate threat of infringement. Internationally too, courts have adopted various standards according to the facts and circumstances of each case.

Europe

A recent decision by the High Court of Justice (Chancery Division, Patent Court) in England considered a request for a *quia timet* injunction.⁹ In this case, the claimant was the patentee of efavirenz, a non-nucleoside reverse transcriptase inhibitor (used in the control of HIV infections). The patent was due to expire in August 2013. The patentee prayed for a *quia timet* injunction in 2012, as it feared that Teva, a generic manufacturer, intended to infringe its patent. This fear was based on four main facts; one, in October 2011 Teva had applied for marketing authorization for a generic version of efavirenz; second, when the patentee wrote to Teva to find out Teva's intentions of launch, they refused to disclose anything, explaining that their plans were confidential; third, in January 2012 this authorization was granted and lastly, Teva had in the past, surreptitiously launched an infringing generic atorvastatin (a drug still under patent). Moreover, Teva eschewed the opportunity to challenge the validity of the patent.

The court found these as valid grounds that created a legitimate threat to the patentee's rights. The fact that Teva applied for marketing authorization twenty-two months before the expiration of the patent coupled with its past conduct of introducing infringing generic medicines, led the court to admit the application and grant a *quia timet* injunction. As the court observed:

"To justify an order for interim relief one does not need to know precisely when Teva intend to launch, all one needs to know is that they intend to launch before expiry and before a full trial could be heard."¹⁰

Also since the approval was not a mere regulatory approval but a marketing approval, suggesting that the product was ready to be sold, may have led the court to believe that the threat was imminent.

However, mere marketing approvals have not swayed other European courts from granting and

admitting *quia timet* actions. For example, where a marketing authorization was obtained for a patented product that was due to expire in the near future, the court did not perceive a threat, as they inferred that launch could reasonably be expected only after expiry of the patent.¹¹ Also, where marketing authorization was obtained relatively early but the generic had also started proceedings to revoke the patent, the court could not infer a threat to launch while the patent was still in force and injunction was not granted.¹²

Canada

Canadian courts have been less inclined to admit claims requesting *quia timet* actions. The courts have adopted a strict two pronged test in assessing whether a *quia timet* action should be admitted and granted:

"I do not think, therefore, that I shall be very far wrong if I lay it down that there are at least two necessary ingredients for a *quia timet* action. There must, if no actual damage is proved, be proof of imminent danger, and there must also be proof that the apprehended damage will, if it comes, be very substantial. I should almost say it must be proved that it will be irreparable, because, if the danger is not proved to be so imminent that no one can doubt that, if the remedy is delayed, the damage will be suffered."¹³

This shows the application of a high standard of imminence and damage and not merely a 'triable case'. Mere insubstantial and speculative claims have been dismissed. In the recent decisions of *Eli Lilly Canada Inc v Nu-Pharm Inc*¹⁴ and *Astrazeneca Canada Inc v Novopharm Ltd*,¹⁵ the court held that the defendant's act of obtaining a Notice of Compliance and a Drug Identification Number under the Food and Drug Regulation for the claimant's patented drug, without evidence of actual manufacture, sale, import etc., would not meet the requirements of invoking the court's jurisdiction and were merely speculative assertions, characterized as an abuse of process:

"Aside from the alleged claim that Nu-Pharm's actions in obtaining its NOC and DIN for nu-olanzapine constitute infringement, the pleadings disclose nothing beyond an assertion that Nu-Pharm is positioning itself, through an unnamed third party, to enter the market for olanzapine."¹⁶

"The Federal Court Judge found that the claim of current infringement was an abuse of process as it was based on bald allegations made without any evidentiary foundation. With respect to the future

infringement, the Federal Court Judge found that the allegations were speculative in nature and lacked the degree of certainty required to support a *quia timet* action [...] This conclusion is based on a fair reading of the appellants' Statement of Claim and gives effect to the established proposition that a *quia timet* action must be based on more than mere possibilities."¹⁷

India

Most Indian cases have dealt with *quia timet* actions with regard to trademarks.¹⁸ However, there has been a recent surge in patent cases relating to *quia timet* actions. In *Bristol Myers Squibb Company v Bhutada and Ors*,¹⁹ the defendants requested the court to dismiss the plaintiff's *quia timet* action. The Court, however, did not dismiss the application nor was injunctive relief granted. In the present case, the plaintiff claimed that the defendant's actions of obtaining a manufacturing licence from the Drug Controller Licensing Authority, Karnataka for its patented drug (Dasatinib) and the listing on its website that Dasatinib was a product 'underdevelopment', all pointed to an imminent threat of infringement of patent.

The Court deferred the ascertainment of these claims to the stage of trial as they found that such a decision involved examination of facts and law which could not be adopted by examining merely the plaint. However, the plaint was admitted on the basis that the apprehension was 'prima facie credible'.

"At the stage prior to the trial, where a defendant is in a *quia timet* action seeking the return of the plaint for want of jurisdiction, the Court will have to take the allegation contained in the plaint to be correct. In other words, the Court is not expected to examine the written statements to test the veracity of the averments in the plaint. Also, considering that in a *quia timet* action the averments in the plaint would invariably express only an apprehension of an infringement, the Court can only examine whether such apprehension is prima facie credible enough for entertaining the suit, postponing the testing of the veracity of such averment to the stage of trial.

Thus, the real test would be when the court seized of such a matter is under doubt as to whether there is a possibility of threat becoming reality though the possibility of the same not becoming the reality is also not ruled out. In such cases, the question of jurisdiction on the basis of apprehension becomes a mixed question of fact and law and the same is thus deferred until the establishment of further facts in the trial."²⁰

The Madras High Court too has been careful in allowing and granting such kind of injunctions. In the case of *Matrix Laboratories*,²¹ the plaintiffs obtained a patent over erlotinib hydrochloride. The defendant had filed a revocation petition where they expressed their intention to commercially make, use, sell, distribute and market erlotinib hydrochloride. Additionally, the plaintiffs also found out that the defendant had been conducting clinical trials in certain laboratories. Based on these facts the plaintiffs apprehended an infringement by the defendant. The Madras High Court held that a mere statement made in a revocation proceeding or mere allegation of clinical trials with no evidence, did not give rise to cause of action and the *quia timet* action of the plaintiff was dismissed:

"The expression 'cause of action' has acquired a judicially settled meaning. Cause of action consists of bundle of facts, which the plaintiff must prove, in order to get a judgment in his favour. Whether any part of action has occurred within the jurisdiction of the Court would depend upon the facts and circumstances of the case. The statements made in the revocation petition without anything more cannot give rise to a cause of action to invoke jurisdiction of Madras High Court. [...] there is no iota of an evidence or material on the part of the respondents/plaintiffs to show that the appellant/defendant would conduct the lab test in future only at Lotus Labs Private Limited, Chennai. It is not the case that throughout India, Lotus Labs Private Limited, Chennai, alone is having the facility for conducting test for drugs. In such circumstances, we are of the view that merely because the appellant/defendant herein has once launched the drug Efavirenz 600 mg tablets, it will not lead to any conclusion that appellant/defendant would conduct the test only at the same laboratory in future and it will be launched at Chennai. In such circumstances, we are of the view that location of Lotus Labs Pvt. Ltd. at Chennai will not give a cause of action to file the suit in the Original Side of Madras High Court."²²

On the other hand, however, Novartis has been successful in obtaining interim *quia timet* injunctions. As recently as April 2014, the Delhi High Court granted a host of interim *quia timet* injunctions to Novartis against several generic manufacturers such as Bajaj Healthcare,²³ Alembic Pharmaceutical,²⁴ Glenmark Generics,²⁵ and Cadila Healthcare²⁶ over the anti-diabetic drug- Vildagliptin.²⁷ The dispute is over Novartis' patent which is valid till 2019.

In the first two cases, the court expressly ordered *ex-parte* interim injunctions against the generic manufacturers. On the basis of a reply to an RTI filed with the State Drug Controller, Novartis learnt that both Bajaj Healthcare as well as Alembic Pharmaceutical had obtained manufacturing licences as well as permission to sell generic Vildagliptin from the Drug Controller in early 2014. Furthermore, neither of them had opposed or challenged Novartis' patent. At the time of obtaining the injunction, the generics had not yet launched the drug. Novartis contended that on the basis of this information, the two generic manufacturers were in the process of launching the drug and irreparable damage would arise if the injunction were not issued. Merely on the basis on this submission, the court restrained the defendants from manufacturing, importing, selling, offering for sale, exporting and directly or indirectly, dealing in Vildagliptin and its combinations, except as provided under Section 107A of the Patent Act (exceptions to infringement) till the next hearing (on 28 July 2014).

In the Glenmark Generics and Cadila Healthcare cases, the generics themselves provided undertakings that assured the court that they will not manufacture for the purpose of marketing, any product that infringes the patented product of the plaintiff (Novartis), till the next date of hearing. These undertakings are equivalent to an injunction, with the difference that instead of the court, the party itself undertakes to restrain itself from the alleged acts.

Vildagliptin has become the eye of a patent injunction storm in India. Another set of *quia timet* injunctions were obtained by Novartis in March 2014 against Bicon and Wockhardt.²⁸ Wockhardt had initiated revocation proceedings before the IPAB in an attempt to annul the patent over Vildagliptin. Upon which, Novartis filed an RTI in order to obtain a list of manufacturers who had obtained regulatory approvals for Vildagliptin. Thereafter, two infringement suits were filed before the Delhi High Court against Bicon and Wockhardt. In both cases, injunctions were granted till the next hearing and the generics were prevented from manufacturing, selling, exporting etc., the impugned product.

Analysis of Case Law

As long back as 1884, in *Fletcher v Bealey*, equity courts laid down a rigid standard for the grant of *quia timet* injunctions, namely: 'proof of imminent danger;

proof that the threatened injury will be practically irreparable; and proof that whenever the injurious circumstances ensue, it will be impossible to protect plaintiff's interests, if relief is denied.'²⁹

However, what emerges from the above analyses of case law is that there is no definite way of ascertaining what could amount to 'proof of imminent danger' in a patent case. Mere marketing approvals, mere regulatory approvals, silence on marketing/launch plans by the generic or mere allegations of clinical trials, will not in themselves be sufficient to establish imminent threat. Also, there is always an inherent possibility of the defendant countering each of these factors thereby reducing the degree of imminence of danger. For example, though Teva obtained marketing approvals much before the expiry of the patent, evidence showed that it had several hundreds of unused marketing approvals.³⁰ Therefore, there was no guarantee that it would bring out this drug before the patent expired. Also, Teva argued that since efavirenz was a prescription drug they could not 'flood the market' and hence balance of convenience was not in favour of the patentee.¹⁰ However, the past conduct of Teva, failure to challenge validity of the patent and its refusal to correspond with the patentee weighed against it.

In contrast, the standards laid down in *Fletcher v Bealey* apply with ease to civil and trademark cases. In such matters, ascertaining imminent danger is possible. For example, in the case of *London Borough of Islington v Elliot and Morris*³¹ tree roots from the property owned by the defendant were encroaching on the plaintiff's property and the plaintiff feared severe damage to its buildings. The plaintiff brought a *quia timet* action to have the trees removed even though actual damage had not yet occurred. As is clear, in this case there was a clear and imminent danger as the roots would certainly grow and property would certainly be damaged if the trees were not removed.

Even in trademark matters, the degree of threat of future damage occurring can be more conclusively ascertained. Once a rival registers an identical mark, the probability of him actually using the mark is quite high.³² This is because unlike patents, trademarks do not expire, so the competitor clearly has no intention to wait for a particular period of time and it can be presumed that they intend to use the mark soon. Moreover, comparing trademarks and assessing a 'prima facie case' is easier than doing so in case of patents.

Injunctions are granted with the objective of preserving rights. In both civil and trademark cases, the right that has to be preserved is *prima facie* undisputed i.e. the plaintiff has a right over his property and a registered trademark is *prima facie* valid. Therefore, the owners have a legitimate interest in protecting and preserving their property.³³ However, there is no presumption of validity of patents in India. So, the defendant can always challenge the very existence of a patent thereby nullifying the patentee's right itself.³³

It is also pertinent to note that since the UK follows the doctrine of 'clearing the way' in case of generics, *quia timet* injunctions may be more justified. The 'clearing the way' principle has been developed over the last ten year by English courts and has enabled pharmaceutical companies to successfully obtain preliminary injunctions to prevent the launch of generic products. This principle was first evolved in *Smithkline Beecham Plc v Generics* in 2001:

"The defendants could, as soon as they settled upon the product they were intending to sell, have caused the litigation to start. They could have done a number of things: First, they could have launched a petition for the revocation of the patent and started a claim for a declaration of non-infringement. Or, since there are certain difficulties with the latter (for example onus of proof goes the other way round), they could simply have said to the patentees, "We intend (we are not saying when but it is a settled intention) to launch our product within the next five years. If you intend to sue us, sue us now". If they had taken such a course, having settled upon the product they intended to sell, the whole of this dispute would have been got out of the way before their date of intended launch... ..I see no question of principle involved here of any sort. It is purely commercial common sense. If there may be an obstacle in your way, clear it out."³⁴

If the generic company knows that there are patents that cover a product it intends to launch and if it fails to take preemptive steps, such as starting revocation proceedings or communicating its intention of launch so that the patentee may start infringement proceedings before the actual launch, it fails to 'clear its way'.³⁵ Therefore, if these steps are not taken, the generic has not 'cleared its way' and this usually convinces courts that the balance of convenience favours the granting of a preliminary injunction restraining a generic product launch. However, this principle has not been adopted in India and

English cases granting *quia timet* injunctions on such considerations may not be relied on by Indian courts.

Most importantly, the working of the Indian Patent Office has a direct bearing on the quality of patents that are being granted. Lack of human resources and inadequate planning of finances are factors plaguing the Indian Patent Office.³⁶ Applications remain inadequately examined and opposition mechanisms are poorly used.³⁶ This arguably results in poor quality of patents. Given this background, it is becomes even more necessary to avoid *quia timet* actions. Since patents that are litigated are the ones which society most values³⁷ and since the patent itself may not be valid, *quia timet* actions can negatively impact innovation and public interest in India.

Thus, it seems as if *quia timet* injunctions were never meant to be applied to patent related cases. Given the questionable quality of patents being granted in India, the subjectivity and high degree of speculation involved in admitting and granting such injunctions, such actions could be characterized as an 'abuse of process'.³⁸

The Patent Act, 1970 attempts to resolve such abuse through Section 106 read with Section 105. Through these provisions, relief is provided to non-patentees who have been subject to groundless threats of infringement by the patentee. In such cases, the person who is being unjustifiably threatened can institute a suit seeking injunction against the continuance of the threats as well as damages. This section puts the burden on the patentee to prove otherwise.

The ulterior purpose of restoring to *quia timet* actions which are merely speculative is to use injunctions as a weapon to curb otherwise legal activities and to assert dominance. It could also be aimed at cutting off legal and successful businesses of competitors.³⁹ It may also have a 'chilling effect' on other legitimate manufacturers. Moreover, a patent itself is a preventive legal tool as it allows the patentee to initiate action upon infringement. The scope of the process of this law is therefore curative. Seeking *quia timet* actions can be thus argued to be beyond the scope of relief contemplated by patent law.

Conclusion

Though for a patentee it would be utopian to able to obtain injunctions based on mere fears, the legal system should not cater to such demands. Even if the

threat of infringement materializes, the injury caused to the patentee may not be irreparable as he can be compensated for the same.³⁹ Given the uncertainty and high degree of speculation involved in granting such injunctions, just like scholars have urged in doing away with interim injunctions, there is a need to restrict the application of *quia timet* actions in patent cases, especially in India.

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- 37 Lemley M, Rational ignorance at the patent office, *Northwestern University Law Review*, 95 (4) (2001) 1497.
- 38 Abuse of process as explained in *C B Aggarwal v P Krishna Kapoor*, AIR 1995 Delhi 154: 'It is true that in a civilized society, legal process is the machinery for keeping order and doing justice. It can be used properly or it can be abused. It is used properly when it is invoked for the vindication of men's rights or the enforcement of just claims. It is abused when it is diverted from its true course to as to serve extortion or oppression; or to exert pressure so as to achieve an improper end. When it is so abused, it is a tort, a wrong known to the law. Thus initiation of proceedings must be abused and has to be for 'a collateral purpose for which the law does not intend to provide a relief for such institution. The tort of abuse of the process of the court would lie against a plaintiff where it could be shown that he had set proceedings on foot effect an object or purpose which was not within the scope of the process.'
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