



F. Hoffmann-La Roche Ltd., et al. v. Cipla Limited

I.A 642/2008 IN CS (OS) 89/2008; 148 (2008) DLT 598, MIPR 2008 (2) 35

Country: India

Region: Asia

Year: 2008

Court: High Court of Delhi

Health Topics: Chronic and noncommunicable diseases, Medicines

Human Rights: Right to life

Facts

The Plaintiffs were the owners of the patented cancer-drug Erlotinib. Erlotinib is a Quinazolin derivative and destroys some types of cancer cells with little secondary effects. The Defendant announced that it was going to sell a generic version of Erlotinib in India and in foreign markets. The Plaintiffs sought a permanent injunction to stop the Defendant, claiming that selling a generic version of Erlotinib would infringe on their patent.

Decision and Reasoning

The Court refused to impose an injunction. However, the Court required the Defendant to ensure reliable accounts of sales of its drug in case it later has to pay damages to the Plaintiff.

The Court noted that the relevant law, Section 3(d), had been changed in 2005, with an addition imposing a "non-obvious" requirement on new drugs. This addition must be included in the determination of the patent's validity.

The Court noted that injunctions are not automatically provided even when infringement is discerned. It developed guidelines for when to issue an interlocutory injunctions, which included assessing the factors in the traditional test, following a rule of caution that does not presume all patents are valid, and that the standard for a defendant to challenge the patent is whether it is a genuine challenge (i.e. has raised an arguable case), as opposed to a vexatious defense.

The Court found that the defendant's argument that the patent is invalid due to obviousness was credible or "not implausible." The Court reviewed what US and UK courts have said about obviousness but noted that it is not evaluating the merits of the argument at this stage. The Defendant argued that the relevant methyl substitution from the original quinazoline compound was obvious to someone skilled in the art. The Plaintiff did not directly respond to the argument and instead pointed out that the substitution is not shown in documents presented by the Defendant. The Court also noted that in applying for the patent, the Plaintiff did not show comparative data between Erlotinib and existing drugs, which would demonstrate difference. The Court dismissed as irrelevant the Plaintiff's argument that the Defendant's drug is inferior. After reviewing all these factors, the Court found the Defendant's argument was credible.

The Court then reviewed the balance of conveniences, finding them in favor of the Defendant. The Court noted that an injunction would dismantle the distribution network that the Defendant had developed, making future distribution more difficult; would limit access to life saving drugs; and would cause an irreparable hardship to those people needing Defendant's drugs. In contrast the Plaintiff would only suffer monetary damages, which could be remedied at trial. The Court found that when the public interests of granting an injunction to affirm a patent and access to life saving medicine, the latter must win out.

Decision Excerpts

"In this background the Court cannot be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted. The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if injunction were granted. Such injuries to third parties are un-compensatable. Another way of viewing it is that if the injunction in the case of a life saving drug were to be granted, the Court would in effect be stifling Article 21 so far as those would have or could

have access to Erloticip are concerned.â€• (Para. 85)

â€œTherefore, this Court is of the opinion that as between the two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a life saving drug, the balance has to be tilted in favour of the latter. The damage or injury that would occur to the plaintiff in such case is capable of assessment in monetary terms. However, the injury to the public which would be deprived of the defendantâ€™s product, which may lead to shortening of lives of several unknown persons, who are not parties to the suit, and which damage cannot be restituted in monetary terms, is not only uncompensatable, it is irreparable. Thus, irreparable injury would be caused if the injunction sought for is granted.â€• (Para. 86)

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