



October 19 2022

JYOTI RAMANI



Court rules against generics companies in infringement suit concerning diabetes drug Linagliptin

K&S Partners | Healthcare & Life Sciences - India

› Facts

› Decision

The Himachal Pradesh High Court recently issued ad-interim injunctions to a patentee, Boehringer Ingelheim (BI), against five Indian generic companies (the defendants).⁽¹⁾ The patented drug in question was Linagliptin, a diabetes drug covered by Indian patent No. 243301 (IN 301).

Facts

BI filed separate infringement suits against the companies and sought interim injunctions to restrain them from violating its patent rights during the course of the suits. BI argued that a preliminary injunction should be granted in its favour because:

- the subject patent was old, well established, highly commercially successful and extensively useful;
- the patent had been granted in favour of BI following the substantive provisions of the Patents Act 1970; and
- the defendants had raised no pre-grant opposition, post-grant opposition or objection to the quality and strength of the subject patent. They had only filed revocation proceedings a day before launching their infringing products on the market.

In defence, the Indian generic companies argued that:

- BI had obtained two patents – namely:

- patent No. 227719 (IN 719), for the "Markush" formula, being the "genus" patent, which expired on 21 February 2022; and
- the subject suit patent, patent IN 301, which was a "species" patent.

Both patents covered the same invention; however, the patentee had not disclosed the distinguishing inventive step of patent IN 301 from patent IN 719 to the Court.

- They had in fact challenged the "species" suit patent by filing a revocation petition against it. This was a credible challenge to the patent in issue; therefore, no interim relief should be granted.

Decision

The Court issued interim injunctions in favour of BI and restrained the defendants in the respective civil suits (either themselves or through, for example, their directors) jointly, and severally, from infringing the subject patent – that is, patent IN 301.

The Court relied on the following key principles, established by earlier judgments in patent infringement suits:

(i) The registration of a patent per se does not entitle the plaintiffs to an injunction. The certificate does not establish a conclusive right.

(ii) There is no presumption of validity of a patent, which is evident from the reading of Section 13(4), 64, and 107 of the Patents Act;

(iii) The claimed invention must be tested and tried in the laboratory of Courts.

(iv) 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.

(v) The plaintiff is not entitled to an injunction if the defendant raises a credible challenge to the patent. A credible challenge means a serious question to be tried. The defendant need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage whereas validity is the issue 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.

(vi) At this stage, the Court is not expected to examine the challenge in detail and arrive at a definite finding on the question of the validity of the patent. That will have to wait at the time of trial. However, the Court must be satisfied that a substantial, tenable, and credible challenge has been made; and that

(vii) The plaintiff is not entitled to an injunction if the patent is recent, its validity has not been established and there is serious controversy about the validity of the patent.

Having heard the parties, the Court decided as follows on the various issues.

Credible challenge

The Court noted that the fact that the patent had been granted showed that the Indian Patent Office had been satisfied. Therefore, it could not be said that by highlighting the facts or pleadings of the plaint before the Court, the defendants had laid a credible challenge to the subject patent to deny interim relief to BI at this stage. The Court added that the vulnerability of a patent cannot be concluded simply on the yet-to-be-proved assertions or defence of the defendants.

The Court additionally observed that while a patent had been granted to BI, the defendants lacked a patent to cover the infringing goods. Additionally, they had filed neither a pre- or post-grant challenge to BI's patent. According to the Supreme Court in *M/s Bishwanath Prasad Radhey Shyam*, the grant of a patent does not ensure its validity. However, if infringement of the patent is not prevented, the patent holder will suffer irreparable damage. Further, the infringer cannot stand on the same pedestal as the patent holder, who is vulnerable.

Evergreening

The defendants had alleged that the suit patent IN 301 constituted "evergreening" of the expired patent, IN 719. The Court, however, held that it could make no observations in this regard because this was an issue to be decided based on the defence coupled with the evidence that may be brought by the parties in support of their respective contentions. The Court, at this stage, had to see whether BI had made out a case for the grant of interim relief.

Balance of convenience

The Court held that the defendants, not owning a patent for the chemical Linagliptin, had taken a calculated risk, fully understanding that the medication they had wanted to commercialise was duly covered by BI's patent. The Court further stated that although patent IN 719 had recently expired and had entered the public domain, the defendants had not requested revocation of the suit patent during the validity of patent IN 719 before producing and marketing their respective products. This, in the Court's opinion, tipped the scales of convenience in BI's favour.

Improperly filed suit

In *Boehringer Ingelheim v Macleods*, the defendant, Macleods Pharma, filed an application contending that the suit had been improperly filed in that the person signing as constituted attorney of the plaintiffs was barred by law from representing the patentee. Dismissing the contentions, the Court held as follows:

- Order VII, rule 11 of the Indian Civil Procedure Code (CPC) envisages that a plaint will be rejected where it does not disclose a cause of action or where the suit appears from the statement in the plaint to be barred by any law.
- In the present case, the defendants had not argued that the plaint was liable to be rejected as it did not disclose a cause of action. Therefore, the Court would not dwell on this aspect.
- The defendant's contention that the suit in hand was liable to be rejected under section 53 (4) of the Patents Act 1970 was totally misconceived. This provision only provides that the protection available to a patent holder during the term of patent ceases after the expiry of the term. In the present case, the term of the subject patent had not expired.
- The words "barred by any law" must be construed strictly by the Court. A plaintiff may not be entitled to the relief requested on account of certain statutory provisions.
- As regards the suit not having been filed by a duly authorised person, whether the suit was maintainable was not an issue that could be decided by the Court under the provisions of order VII, rule 11(d) of the CPC.

For further information on this topic please contact Jyoti Choithani Ramani at K&S Partners by telephone (+91 80 4042 7900) or email (jramani@knspartners.com). The K&S Partners website can be accessed at www.knspartners.com.

Endnotes

(1) *Boehringer Ingelheim Pharma GmbH & Co KG and Boehringer Ingelheim (India) Pvt Ltd v Macleods Pharmaceutical Limited* (order dated 21 April 2022) and *MSN Laboratories Pvt Ltd, Eris Lifesciences Ltd, Emcure Pharma Limited and Optimus Pharma Pvt Ltd* (order dated 1 June 2022).