



Wake up call for Indian pharma

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*Unless Indian pharma companies wake up to the new “patent challenge” regime, they could “miss the bus”, opines **Dr Gopakumar G Nair**, Chief Executive Officer, Gopakumar Nair Associates*

It is time for Indian pharma industries to wake up and take note of the emerging patent litigation scenario in India. Patent litigations in India in past five years or more have taken India closer to US in ex-parte injunctions and duration of individual patent cases pending in High Courts even though India can be proud (?) that we have longest pendencies of patent suits in India. Indian patent law provisions for challenging patents and patent applications have been applauded and appreciated by third world countries and NGOs while MNCs and developed countries have decried and denounced these provisions. After a patent has been granted in India, there have been various options for an “interested person”, to challenge the validity of the patent. Firstly, a post-grant opposition could be filed in the Patent Office within one year of grant. Secondly, a revocation petition could be filed in the Intellectual Property Appellate Board (IPAB) any time after grant, before expiry, of the patent. Thirdly, if anyone is sued for infringement, that person could file a counter claim for invalidation in the High Court. These provisions having been supported by specific sections of the Patents Act (1970), such as Sec. 25(2), Sec.64, Sec.104 and Sec.107, they were being considered parallelly and independently. From June 2014 onwards, this scenario is changing drastically. Unless the pharma industry wakes up to the new “patent challenge” regime, one could “miss the bus” !

Unfortunately, unlike rest of the world, the Indian judiciary appears to be not applying their mind to the “quality” of the patent or the strength and validity of the claims in evaluating “prima facie case” in patent infringement suits, prior to granting “ex parte” injunctions or even hasty grant of injunctions after preliminary hearing. Thereafter, most cases involving

infringement suits remain pending for five or more years, even without “framing of issues” leave alone commencement of arguments. Such cases are pending in courts substantially related to pharma patents. Invariably, the sued (defendant) party, files a suit of “counter claim for revocation/invalidation” invariably in all cases. However, after the latest judgement of the Supreme Court in Aloys Wobben vs. Yogesh Mehra (The Enercon Case) (Civil Appeal No. 6718 OF 2013), this opportunity to file counter claim for revocation will no more be available if the same party has already filed (failed or pending) for revocation either through post-grant opposition or through a revocation petition in IPAB.

Pre-grant opposition: The first and best option

The “first and best option” for pharma competitors is, therefore, timely filing of a pre-grant opposition. Only 1-2 per cent of Indian patent applications are subjected to pre-grant opposition. This is primarily because most pharma companies do not “watch” the details of the pending patent applications in the official website published by the Indian Patent Office, every Friday of the month (www.ipindia.nic.in). It is, henceforth, imperative for Indian pharma to keep watching and taking note of pending patent applications with a view to file pre-grant oppositions after publication in official patent office website and before grant of the patent.

The advantages of filing pre-grant opposition are many. Firstly, this is the cheapest option compared to revocation or challenging invalidity during enforcement proceedings or infringement suits. The cost benefit is almost 1:100. Secondly, not succeeding in a pre-grant opposition does not bar the same opponent from opting for one of the three options for revocation, thereafter. Thirdly, filing a pre-grant opposition reasonably ensures “quality checks” at the patent office, because a pre-grant opponent helps the Patent Controller/Examiner by providing inputs, which may escape the notice of the patent office. In most cases, pre-grant opposition also provides additional “breathing time” for the opponent to plan further strategies till grant of a patent, which is likely to be infringed.

Pre-grant opposition can be filed by “any person”, not necessarily by an interested person. Therefore, it is possible for a third party individual to file the pre-grant. The grounds have to be selected from (a) to (k) under Sec. 25(1). Supporting evidence such as prior art, product in the market or arguments/affidavit in support should accompany the pre-grant opposition. Since, of late, pre-grant oppositions have also assumed “civil proceedings” format in written

submissions, reply statements and rejoinders, it is advisable to involve a professional in-house or external patent attorney while filing pre-grant oppositions.

Success rates in pre-grant oppositions are high in India. This is primarily because only vulnerable and weak patent applications are subject matter of pre-grant filings. Subject to doing the “home work” of evaluating the vulnerability of the invention in the patent application, pre-grant oppositions are the “best-bet” in a patent defense strategy.

The details of the relevant Supreme Court Judgement are available on <http://supremecourtofindia.nic.in/outtoday/ac671813.pdf>. A summary of the case is available in the JIPR

(The Supreme Court Clarifies Indian Patent Invalidity Proceedings) by Neeti Wilson

(<http://nopr.niscair.res.in/bitstream/123456789/29510/1/JIPR%2019%285%29%20358-360.pdf>).