

## Genesis of Pre-grant Oppositions & its current status

Thursday, December 10, 2009 08:00 IST

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The Patents Act, 1970, as amended in 2005, with active participation from the “law-makers” in the floor of the House, introduced the provision for Pre-grant Opposition, for the first time in India. It is worthwhile to look at as to what triggered this amendment to the original draft of 24th/26th December 2004 for amendment of the Patents Act, 1970 and the patent rules thereunder. It is also worthwhile to review how this provision works in India.

Prior to the series of post-TRIPs amendments, more particularly, prior to the third amendment, the Patents Act, 1970 had a provision for opposition. Under Sec. 25, an opposition could have been filed within four month from the date of advertisement of the acceptance of a complete specification by “any person interested”. This can also be technically qualified as a Pre-grant Opposition, though it may be more appropriate to term this as “Post-Acceptance Opposition”.

As per this provision, the opposition needed to be filed post publication of acceptance and prior to grant of the patent. The patent application was examined, amended if required during prosecution, accepted if found patentable by the examiner and then published for receiving oppositions, if any. If there are no oppositions filed with four months (or extension if any), the patent would be sealed and subsequently granted. Technically, this used to be a Pre-grant (Post-Acceptance) Opposition. The publication which used to appear was the examined/amended version, not the application as applied for (in contrast to the current provision).

In the then proposed third amendment bill of December 2004, the draft bill provided for opposition only after grant, i.e. Post-grant Opposition. This change was proposed in course of one more step of post-TRIPs harmonization. However, there was wide-spread criticism against the doing away with the post-acceptance, Pre-grant Opposition. Once a patent is granted, rightly or wrongly, a Patentee can rush to a court to obtain stay/injunction against a competitor, (again) rightly or wrongly, very often ex-parte (though this is normally not granted in patent cases on ex-parte) and even with Anton-Piller Order (raid, seizure of infringing goods etc.). Since product patent regime was new to India, there was a need to provide safeguards against abuse of monopoly rights through product patents. The public response heavily in favour of retaining the “Pre-grant Opposition” was met with equally covert pressure on Government to retain the Post-grant provision as proposed in the third Amendment. The debate in the Parliament on the last day of the session, when the bill was tabled, was vociferous. India had already tasted the DSB (Dispute Settlement Board) of WTO, once earlier, for failure to put the first amendment which was notified on January 1, 1995, to comply with TRIPs provision, but failed to get passed in the Parliament (This was passed thereafter in 1999 in response to the WTO decision against India), with retrospective effect from 1.1.1995.

In view of the urgency and the deadline, the ruling party was under pressure to get the bill passed. The opposition was adamant. Hence, a few amendments as proposed on the floor of the House was accepted (unanimously) and the (third Amendment) Bill was passed with Parliament-proposed amendments, such as the Sec.3(d) [Explanation] and Pre-grant Opposition, Sec.25(1). While retaining the provision for Pre-grant Opposition under Sec.25(1), the provision as originally proposed for Post-grant Opposition was also retained under Sec.25(2). The Sec. 25(1) provision in the amended Act, differs from the original Pre-grant/Post-acceptance provision, in some respects.

Any person is entitled to file a Pre-grant Opposition under the amended Act. This is a substantially people-friendly, public-interest provision. The need for an opposition to be filed only by "an interested person" in the erstwhile Sec.25, has now moved to the Post-grant Opposition under Sec.25(2) of the Amended Act.

In a welfare state and a developing country like India, it is justified that adequate safeguards are built-in to avoid or prevent abuse of monopoly rights through patents. The inherent balance of rights and obligations are better served through the current provisions.

The product patent regime emerged rather sluggishly post-2005. The pending patent applications in the mailbox were published in the Patent Office Journal from end-January 2005. Filing of the Pre-grant Oppositions commenced in or around 2006. One of the early rejections was that of imatinib mesylate (Gleevec). Imatinib, and salts thereof, were disclosed in a 1993 PCT based Patent Application with 1992 priority.

Amorphous and Crystalline imatinib mesylate were claimed in India post-1995, claiming a Swiss priority (Switzerland became recognized for PC & PCT only later). On various grounds including wrongly claimed priority status and Sec. 3(d), among others, the Crystalline imatinib mesylate got rejected, consequent to a set of five Pre-grant Oppositions. The rejection as well as Sec. 3(d) was challenged by the Applicant in Chennai High Court. The Appeal was rejected on 3(d) by the Chennai High Court. The appeal on rejection of patent application was reverted to the IPAB (Intellectual Property Appellate Board) which came into existence in the meantime. The IPAB rejected the appeal. The Gleevec case continues to be a landmark case in India's nascent patent litigation history.

A large number of Pre-grant Oppositions were filed from 2006 to 2009. Most of these were successful. A few patent applications were abandoned after rejection by the Patent Office. A few litigations/ appeals/writ petitions are pending based on rejections resulting from Pre-grant Oppositions. However, the number of Pre-grant Oppositions filed hitherto, are only a fraction of the total product and process (including method of treatment applications) patent applications filed and granted in India. The trend of pre-grant opposition, which peaked out in 2008/2009 are on the decline and are expected to dwindle further over the years.

Post-grant Oppositions in India have been relatively lower compared to Pre-grant Oppositions. Initial enthusiasm of the patent offices in fairly dealing with Pre-grant Oppositions, have now dwindled with condescending approach that "let them oppose after grant through post-grant which is anyway open to the opponent". However, when a product patent has been granted frivolously or liberally, the trend has been to rush for

infringement action with injunction and also with Anton-Piller order as has happened already in a few cases. The opponents have invariably been resorting to counter-claim for revocation, whereby the suits are automatically transferred to the high court from the initial district court. Forum shopping has lately been the practice in India in patent infringement suits. The high court and Supreme Court judgements in India relating to patent infringement suits have already been commendable and comparable to the best anywhere else including more advanced IP enforcing countries.

A relatively novel provision available during the transition phase of product patent era in India has remained untested or unused, as on date. The Sec. 11-A(7) of the Patents Act, 1970, as amended (third Amendment) effective 1.1.2005, provides that if an enterprise has already invested in a manufacturing facility, started manufacturing and marketing a (infringing) product in India prior to 1.1.2005, and if a product patent is granted to the product after 2005, the product patent holder cannot sue the enterprise for patent infringement. Such patentee can only claim reasonable royalty (as fixed by the patent office) from the enterprise, such royalty being eligible for calculation only from the date of grant of the patent. Such enterprises who were already manufacturing and marketing the product prior to 1.1.2005, will be free to continue to manufacture and market, subject to such royalty as fixed by the Patent Controller. However, no such case has yet been reported. In view of lapse of nearly five years, no such case is expected, hereafter.

The DCG(I), who is primarily functioning under the Drugs & Cosmetics Act, 1940, unwittingly got involved in patent-related matters, even when there is no legal provision or jurisdiction. There is no data exclusivity provision yet in India, which if available, would have given the DCG(I), a locus standi for protecting the dossier filed for Drug Regulatory Approval. In the current scenario, the over-enthusiasm of the DCG(I) to notify for patent status or even patent infringement status was premature and uncalled for. However, taking apparently the call from DCG(I), Bayer in case of Sorafenib and Roche in case of Erlotinib initiated infringement suits against Cipla. The landmark judgements from Justice Ravindra Bhat of Delhi High Court followed by confirmation of judgement by the Appellate Bench of Chief Justice A P Shah and Justice Murlidhar (even imposing hefty penalty on Roche), took into account, for the first time, the third party interests of the patients in accessing affordable essential life saving medicines.

The recent judgements from high courts and Supreme Court have also been commendable, considering the public interest angle in pharma patent cases especially in Anti-HIV, Anti-cancer and other essential public health related patent enforcement suits.

In the meantime, the IPAB (Intellectual Property Appellate Board) has also been receiving Appeals for Revocation, most of which are pending. A landmark judgement from IPAB has been on the Gleevec (imatinib mesylate) product patent rejection.

In a welfare state, such as India, the provisions for Pre-grant Opposition (open to any person) and Post-grant Opposition (open only to an "interested person") coupled with the option to file for revocation through appeal to IPAB or counter-claim for revocation through the high court in case of an infringement suit filed in a district court are essential and are working effectively.

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