SECTION 8: AN INCONVENIENT TRUTH?

Non-compliance with Section 8's requirements can scuttle the hopes of a potential patentee, as Shukadev Khuraijam reports.

When George Mallory was asked "Why do you want to climb Mount Everest?" he is supposed to have replied: "Because it is there." To the question "Why should we comply with Section 8?" the answer is the same.

Section 8 is a provision in the Indian patent statute which places on the applicant a 'duty of disclosure' to provide information on details of applications pursued in other countries. The provision has been an important focal point in India's developing patent jurisprudence, primarily as non-compliance with Section 8's requirements is a ground for refusing an application or revoking a patent.

It first caught the imagination of the patent fraternity in the infamous *Chemtura Corporation* case back in 2009, when the Delhi High Court vacated the interim injunction granted in favour of Chemtura, clearly influenced by its failure to meet this statutory obligation. The decision prompted many patent practitioners, when filing oppositions/revocations, to make brazen use of this ground, even when on technical considerations the patent stood on higher ground. In at least one instance, a granted patent was revoked on this ground alone in a post-grant opposition.

Adding to this simmering cauldron was the interim order passed in the *Roche v Cipla* infringement suit in the same year, better known as the *Tarceva* case. The obligation on the patent applicant was further amplified, especially in pharmaceutical cases, when the Delhi High Court observed perfunctorily: "This made the full disclosure by the plaintiffs of all the facts pertaining not only to the 'umbrella' compound but the crystal or other forms of the product to the Controller of Patents imperative."

The court refused an interim injunction to Roche, relying mainly on this rationale. Any patent practitioner in the pharma field would understand that an application for a basic compound and a subsequent application for a crystal form of the compound would not be of equal priority and the latter application may be filed years after the filing of the first application, which makes the 'full disclosure' contemplated confusing, if not insurmountable. In a welcome reprieve, when the final judgment was rendered in September 2012 the court, while confirming that Cipla was successful in making a case for revocation under Section 8, denied it the relief of revocation stating that the court had the discretion to revoke the patent, notwithstanding the ground being proved.

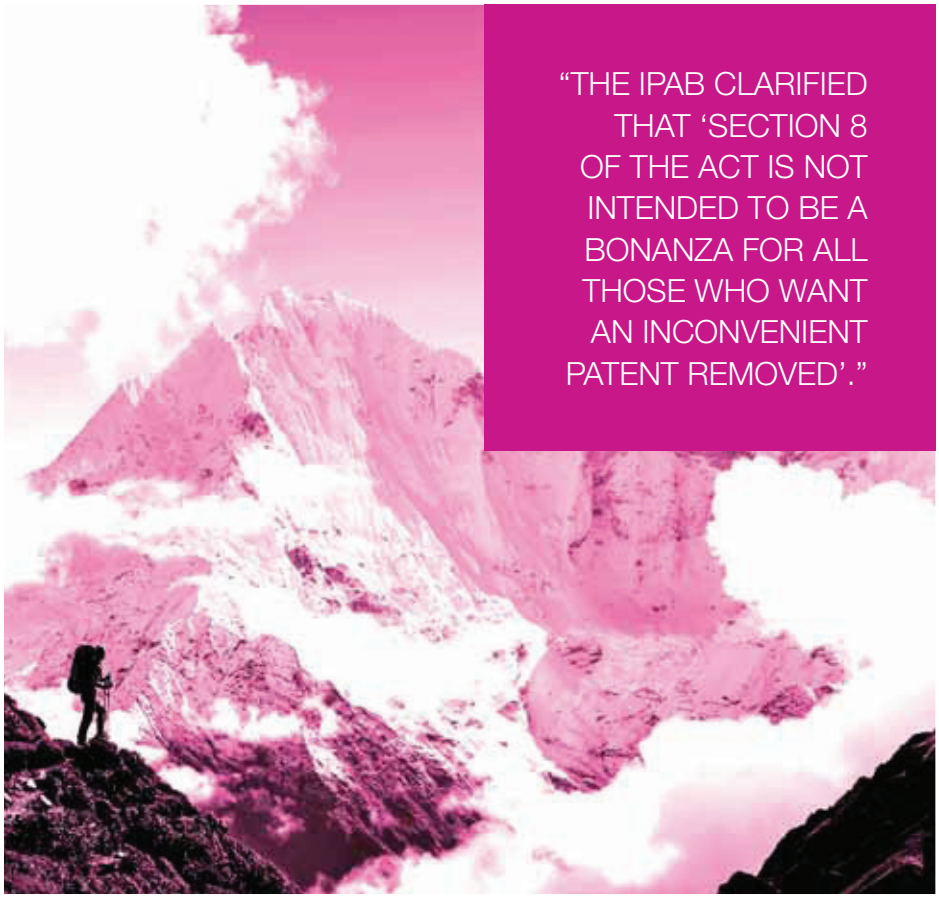
The Intellectual Property Appellate Board (IPAB) under the aegis of Justice Prabha Sridevan ruled prolifically on Section 8 in several matters, lending more clarity and authority. In the *GSK Tykerb* judgments, pertaining to an anti-cancer drug, the IPAB succinctly laid down the guidelines which should be followed by the petitioner when instituting revocation proceedings on the grounds of non-compliance with Section 8. The IPAB clarified that "Section 8 of the Act is not intended to be a bonanza for all those who want an inconvenient patent removed."

Importantly, the IPAB mandated that the petitioner alleging non-compliance is duty-bound to plead how Section 8 was violated by clearly specifying the documents which in the petitioner's opinion had been withheld and why such documents ought to have been filed.

The IPAB tellingly observed "This litigation is adversarial in nature, with an unmistakeable public-interest component, and hence unique. The adversary cannot take advantage of the public-interest component and abandon his duty as a litigant to plead and prove his case."

While the guidelines are laudable, the IPAB was formalistic in its stand that Section 8 is a duty cast on the patentee, which results in adverse consequences, if flouted. GSK in this case had argued that the incorporation of Section 8 might have been necessary when there was no infrastructure or technical support to ascertain the details of counterpart foreign applications. It pointed out that nowadays, however, the Section 8 requirement must be balanced and read in context in view of the existence of advanced search engines and the easy availability of information on the internet. The IPAB was not persuaded and observed the lines quoted at the beginning of this article.

The appellate body consistently maintained this position in all matters and was particularly scathing in its disapproval of a Patent Controller's opinion to the contrary in Sugen's *Sutent* case, involving another anti-cancer drug.



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It was no different in Allergan's Combigan patent pertaining to an ophthalmic composition, where it reiterated that the patentee has a statutory duty under Section 8 and cannot say that the particulars are available online, nor can the Examiner/Patent Controller condone the non-disclosure by saying the details are on the website. It stressed that Section 8 is not a penal provision and the object of the law is clear disclosure and cannot be diluted.

The interpretation of Section 8 appears to have taken a turn for the better in an order passed by the Delhi High Court in an infringement suit filed by Philips Electronics. The defendant had pleaded in its application that the documents on record established a clear and unequivocal admission by Philips that it had suppressed vital information. It therefore asserted that the patent in question should be revoked solely on the ground that Philips did not comply with the requirements of Section 8.

The *Roche* judgment *supra* was relied upon by Philips while the *Chemtura* case *supra* was the basis for the defendants' application. The court concurred with the opinion expressed in the *Roche* case and explicitly held that the *Chemtura* case is not relevant as it was decided in the context of vacation of an interim stay granted in favour of the plaintiff; the court was not deciding whether the patent itself should be revoked.

What is noteworthy is that the *Philips* case clarifies beyond doubt that non-disclosure of the Section 8 details at best raises a 'triable issue' and that a patent should not be revoked on this ground alone, without considering the case in its entirety.

The jurisprudence as it stands today appears at least to have lent some method to the madness sparked by the *Chemtura* judgment. Given the limited life of a patent which is already laden with deadlines having irrevocable consequences, to fail only on an apparently procedural ground which has arguably lost its relevance, is indeed harsh reality. The advice to right holders would be to remain diligent in their Section 8 obligations, while Indian patent jurisprudence simmers in its cauldron, hopefully to beget more pragmatic judgments in the near future. ■

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Shukadev Khuraijam has an all-round and in-depth experience of around ten years in various facets of patent practice: prosecution, opposition and litigation. He is well nuanced in the intricacies of the Indian Patents & Design law and has handled high-profile contentious matters before various forums including the IPO, IPAB and the Courts.