The elephant in the Patent Office

Over the last few years the **Indian Patent Office (IPO)** has been focussing on granting patents expeditiously and reducing the backlog of pending applications. Newly recruited examiners have been sending in examination reports rapidly in a race to reduce the examination timeline and increase the grant rate. There needs to be some caution here as the IPO has set an example of having one of the toughest standards in the world to distinguish real innovation from trivial tweaks — a change brought about by the introduction of the anti-evergreening provisions in the Patents Act.

India hit the headlines when it incorporated certain anti-evergreening provisions such as Sections 3(d), 3(e) and 3(i) into the Patents Act to restrict patentability of a host of secondary patents — essentially alternative forms of already existing patented drugs aimed at further extending their term of protection. These provisions together with the decision of the Supreme Court in the **Novartis case have shown** us a way forward to have access to affordable medicines. Through these provisions, India is leading by example for other developing countries such as Brazil, the Philippines, Argentina and South Africa.

But despite such high standards for granting patents, our recent study reveals that there is an elephant in the patent office: of the IPO granting patents for things that should never have been granted. Our analysis of pharmaceutical patent applications suggests that the IPO is operating at an error rate as high as 72%, which corresponds to all secondary patents granted by the IPO. In short, seven out of 10 patents granted by the IPO are likely granted in error.

In the last two decades, the IPO has granted 1,654 secondary patents, of which 91% were directed to formulations, compositions and combinations. Much of these would come under the purview of Section 3(d), which covers “combinations and other derivatives of known substance”, as well as under Section 3(e), which covers “substance obtained by a mere admixture resulting only in the aggregation of the properties of the components or a process for producing such substance”. Whenever an objection is raised under these sections, the law requires the applicant to submit efficacy data for the former and demonstrate synergism for the later. However, the applicants bypass the stringent requirements under Section 3(d) by presenting their inventions as a composition or combination of known substances and steering away the objection from Section 3(d) to Section 3(e). The possible explanations are: demonstrating synergy under Section 3(e) is a relatively easier exercise compared to the requirements of efficacy data under Section 3(d), as mandated by the Supreme Court in the Novartis case. Second, Section 3(d) is being interpreted narrowly by the courts and the IPO to apply only to a new form of a known substance, and not to combinations and compositions involving known substances.

To remove the applicability of Section 3(d) in cases where combinations are involved, patent applicants rely on the decision of the Intellectual Property Appellate Board (IPAB) in *Ajanta Pharma Ltd v. Allergan Inc*, which also finds mention in the 2014 IPO guidelines for examination of pharmaceutical patent applications. However, in this case, the issue of applicability of Section 3(e) was not considered as the patent was rejected on other grounds. Moreover, a mere passing observation made by the IPAB cannot be considered as a binding authority as such a narrow interpretation of Section 3(d) would defeat the objective of the section. Keeping in mind the widespread practice in the pharmaceutical industry of creating new compositions/combinations, it should be given an expansive meaning to cover combinations with other substances.

Another disturbing finding pertained to patents for methods of treatment, a category that is statutorily barred. A total of 63 patents were granted for methods of treating an individual for a disease, specifying a particular dosage regimen or a mode of administering a drug. Section 3(i) of

the Act categorically excludes methods of treatments from the purview of patent protection. However, though statutorily barred, such patents were granted by clever drafting and legal argument. For instance, in application No. 267/KOLNP/2007 filed for “compositions and methods for treating neurological disorders”, the applicants had initially claimed for “a method of treating a neurological disease or disorder in a mammal, which method comprises administering to said mammal in need of such treatment a therapeutically effective amount of a proteosome-based composition”. However, when an objection was raised under Section 3(i), the applicant later amended it to “a composition in the form of a medicament for a neurological disease or disorder comprising a proteosome based composition”. It is evident that the applicants by clever tweaking of the language have managed to get over the initial objection; in the case mentioned, by merely removing the words “method of treating”. The grant of patents to method of treatment claims shows the focus on form over substance.

Given the IPO’s unacceptable error rate, we have recommended a standardised mechanism for examination of patent applications. As the grant of patents create property-like rights in intangibles, the IPO should steer its focus towards grant of quality patents than on the quantity.

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