

Patents choke innovation in India

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In India, the in-vitro diagnostic (IVD) industry is considered as a part of the biotech sector and is often referred to as the 'sunrise sector'.

IVD, being a relatively nascent yet fast growing industry, is adversely affected by the intellectual property issues, especially after the amendments to the Indian Patents Act of 1970 in 2005, which was effected to make the Indian Patent Act Trade Related Intellectual Property Rights (TRIPS) compliant.

It is well known that the objective of patenting system is to foster innovation and technology in order to bring new inventions to the market for the benefit of the society, with the innovator being granted a monopoly for a limited time-period to commercialize and practice the invention through its industrial applicability.

However, if rogue corporations, lawyers and individuals hijack the patent system by filing frivolous patents, the core objective of patenting is affected. Instead of encouraging R&D and nurturing science the filing and granting of these frivolous patents persecute competition and thwart the industry growth. And that is what is happening in India.

Some IVD companies in India have been systematically filing frivolous patents. The most unfortunate part is that these patents are being granted, and that too on a fast track by the Indian Patent Office, in many instances against what is provided for by law.

Most of these patents are blatant copies of existing patents, or mere rehash of what is available in the public domain since decades. Till date most specifications that have been published, fail the basic tenets of patentability i.e., inventiveness, obviousness and anticipation. It is absolutely beyond comprehension as to how such blatantly frivolous and bad applications are allowed to escape the search and scrutiny process.

While it is true that the number of patents filed by inventors is a barometer of any country's technological progress and

prowess; on the flip side the number of frivolous patents that are granted in a country is a barometer of the ethical standards, the inventors themselves uphold, and the competence and independence of the examining process itself.

The pre and post grant opposition process has to be objective and ethical and has to play by the set rules. If unscrupulous companies are favored and the patent office insists on granting such patents at amazing speed it only serves to undercut the industries' future and incurs a grave cost to the customers and society at large.

In India, typically while the cost of filing a patent is about \$6000-\$8000 (Rs 3-4 lakh) per patent, if a patent attorney is engaged; the cost of fighting an infringement and revocation petition in high court is pegged anywhere between \$100,000 and \$200,000 (Rs 50-100 lakh) per patent. And the average time to settle an infringement suit could be anywhere between five-10 years, provided the legal process works without time delays.

Fully aware of this, unscrupulous individuals, corporations and patent agents have spawned a multi-crore litigation industry that frustrates and punishes ethics and rewards brazenness. This group serves the interest of individuals and companies that plan to use litigation to thwart competition and deflect the attention of the industry from the productive engagement in running technology intense business to running from pillar to post, in order to find justice.

The Association of Diagnostic Manufacturers of India (ADMI), in March 2007 and subsequently in December 2008 has already represented to the Ministry of Commerce and Industry and to the Controller General of Patents in this regard, with copies to all stakeholders. Unfortunately, these representations seem to have fallen on deaf ears.

While the industry and the ADMI, contemplates future course of action and want to stress that the patenting process in India must:

- Ensure that patents are granted to only those applications that qualify for the same.
- Eliminate and discourage false, fraudulent, frivolous, excessive and repetitive claims.
- Provide an effective, quick and economical method for revocation of frivolous patents.
- Provide a mechanism for punishing companies/individuals that habitually file frivolous patents.

It may be pertinent to add that since grant of patents to a patentee is without presumption of its validity, in case of an infringement petition no action should be taken by the courts until the validity of the patent is established in the counter revocation petition.

Biotechnology being a relatively new and evolving area, adequate and appropriately qualified examiners are needed to supervise the pre-grant examination process in order to understand the art comprehensively.

Just as the IVD industry has woken up to the rude shock of the new patent regime and its unexpected consequences, it is time that the biotech fraternity wakes up to this situation and proactively moves towards a solution to protect the interests of all the stakeholders. After all—forewarned is forearmed.