

PERSPECTIVES

IP: No room for banana peels here



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BILL Gates once said "Intellectual property has the shelf life of a banana". Can't blame him for saying that! In his field, very often, the inventor gets only a short time to reap the commercial benefits from his invention before another genius discovers a better product or someone else brings in a non-infringing product.

In the pharmaceutical industry, intellectual property (IP) would normally enjoy a market exclusivity of 10 years or more. It is indeed a good sign that Indian companies today are not only IP-compliant but are becoming IP-savvy. Although at a nascent stage, our companies have started to create, own and exploit IP. A welcome catalyst has been the amended Indian Patents Act, currently in force. It will provide an impetus to protect and promote innovations.

The Indian pharmaceutical industry is fortunate to have a vast pool of scientists with astute skills, capable of creating IP in all branches of drug discovery and development. They have also begun the journey to discover New Chemical Entities (NCEs). This, combined with the unfettered Indian entrepreneurial spirit, provides Indian pharma companies undeniable opportunities in owning valuable intellectual property. The time has come to climb up the ladder. And at this stage, we cannot afford to be mired in scepticism and ambiguity that have typically hounded our Indian patent laws.

However, let us not forget that 300 million people live in grinding poverty in India. Deprivation and alienation make this section of our population a breeding ground of social unrest. Indian IPR laws and regulations must, therefore, balance the need to reward the innovator, with the need of meeting public health priorities.

Burning a hole in the issue of incremental innovations has been the hotly debated Section 3 of the

Indian Patent Act. We must understand that one of the key strengths of our Indian scientists and companies lies in innovation that adds true value to existing products. Hence incremental innovations that result in new forms of existing drugs should be allowed to be patented, but only, if they meet the patentability criteria of novelty, non-obviousness (inventive step) and industrial utility. This section includes a clause (d) that defines 'Inventions Not Patentable'. This clause limits the patentability of new forms of existing products, unless there exists a significant difference with regard to efficacy. Thereby, frivolous inventions will not get patents. The extant law takes care of this but rigorous examination of the patent applications is essential.

Indian pharma companies have so far tasted considerable success in the area of Novel Drug Delivery Solutions, like improving upon thrice-a-day medi-

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cines into once-a-day, so as to significantly enhance patient compliance and convenience. Here lies an enormous opportunity. It will be a travesty of truth to say that such inventions are frivolous in nature. Restricting patentability to New Chemical Entity only would be retrograde. This would take away the opportunity for Indian pharma companies to move up the pharmaceutical value chain through incremental inventions. It's almost akin to 'throwing the baby out with the bath water'.

Genetically modified micro-organisms form the technological basis of most biotechnology compa-

nies. Allowing patents for genetically modified micro-organisms will protect the investments that biotech companies make in development of such organisms. Hence the current law that permits the patentability of micro-organisms needs no modification. Let us remember that the future line of treatment for diseases could be through biotechnology, and innovation in this area would definitely need patent protection. In fact, we are seeing a convergence in the two technologies — biotech companies are embracing conventional chemistry-based pharma companies and vice-versa, in order to succeed in delivering the latest and most effective medication to people.

Another area where a gap needs to be filled is in data protection laws. To give an impetus to innovation efforts, the government should allow data protection for new chemical entities and phyto-products for a period of five years, subject to safeguards. This will inspire companies to invest more in R&D as they will feel comforted by the fact that the intellectual capital they create can be secured. The data generated by a company for getting market approval is inherently valuable and, like IP, deserves protection against 'unfair commercial use'. However, data protection should not be used as a means to impede generic competition by extending the period of market exclusivity enjoyed by the innovator company beyond the term of the patent.

It has only been a little over two years since the new patent regime came into force in India. Areas like capacity building for patent examination, enforcement of IPR and upgrading of patent office infrastructure need immediate attention. We should have a curriculum and modules for our patent offices and organise exchange programmes on IP with countries having experience in this area.

What we need is a strong yet simple, IP regime that would act as a spring-board for Indian companies to unleash their inherent strengths. In his book, *24/7 Innovation*, Stephen Shapiro, says, "Innovation emerges when people are allowed to give free rein to their creative talents within a set of simple rules." This now holds true than ever before. We should take care that we do not slip once again on that proverbial banana peel!

(The author is executive director, Ranbaxy Laboratories Limited. Views are personal)