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Pharma cos lose out in patent office-judiciary stand-off

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MUMBAI: FOR the patent office, the past three years have been like the past three overs of a Twenty20 match. It cleared 1,911 patents in 2004-05, but stepped up the pace to make more than 40,000 patent grants in the past three years. On the face of it, this should be great news for innovators in the country. But it isn't.

At the heart of the problem is a brewing dissonance between the patent office, which wants to nurture innovation, and the judiciary, which is keen to protect the interest of Indians who can't afford expensive medicines.

To make matters worse, the patent office's slog overs-styled strategy is coming under scrutiny. At the end of March 2005, the patent office had 170 staffers. That number hasn't changed since, but it still managed to grant eight times more patents in 2008-09. The question on everyone's mind: but how? (About 40% of 16,000 patents granted that year were for chemical, drug, or biotechnology products. Patents in other sectors don't quite have the complexities common in drug research.)

And yet, innovators want the patent office to move faster. Today, the office has a backlog of 70,000 applications, which it hopes to clear in around three years, said PH Kurian, controller general of patents, designs and trademarks. This has pushed the country's innovation ecosystem to a precarious position—the office grants patents, but the courts routinely overrule them, or at least refuse to limit copycats during the litigation process.

“Our job is to promote innovation, so we can't be conservative about granting patents,” said a senior patent officer who asked not to be named. That is a stark contrast to the stance of the courts. “The judicial system takes a counterview in upholding patents and considers the cost of medicine to masses first,” said Krishna Ella, chairman and managing director, Bharat Biotech.

The net result: the cutting edge of innovation is often blunted in the process of patenting, and researchers stand to lose the most, say companies. Moreover, things have come to a place where people are beginning to wonder if the thousands of patents being granted are of any worth at all. A group of Indian pharmaceutical firms recently said they will oppose as many as 90 drug patent applications sought by global rivals and some local companies, terming them as frivolous patent claims. Despite the patent office's best intentions, systemic flaws within are hampering its work.

The number of patent examiners, people with expertise to judge whether the patent being sought is novel, is 126. On an average, an examiner can verify 10 patent applications a month, Mr Kurian said. That makes the office's capacity to research 15,120 applications a year.

Approvals in 2008-09 already exceed that number. In contrast, the US employs 6,242 patent examiners. The US office had 1,207,794 pending applications in end-2009. For biotech products alone, the US cleared 7,750 patents from 23,738 applications last year, a spokeswoman of the US patent office told ET. Despite the flux of applications, the Indian patent office completed an exercise to digitise all records only last year.

Prior to that, the research to grant a patent comprised manually flipping through ledgers. "This leaves a lot of scope for human error in everything that was approved before 2009," a pharmaceutical company official who files patent applications said. Therefore, the patent office relied heavily on patents that were US-approved, he added.

Patent officers vehemently deny the charge. Patent grants are being challenged routinely, and courts have been ruling against the innovator and in favour of the challenger. For example, Swiss pharmaceutical company Novartis AG was unable to prevent generic manufacturers from making its cancer drug Glivec in India. In the case of drugs, the drug controller's office can approve launch of generic versions even during a patent litigation.

The office is responsible for ensuring the safety of the drug, and is a counterpart of the US Food & Drug Administration, or USFDA. Earlier this year, Germany's Bayer moved court to create a link between patent litigation and approval of generic drugs. Its appeal was denied, and the company has an ongoing patent infringement suit against India's Cipla over its drug Nexavar.

Cipla has already launched a cheaper version after it got permission from the drug controller's office. The USFDA, in contrast, restricts approval of drugs to 30 months if the innovator files an infringement suit with 45 days of the generic application.

"It provides time for the patent litigation to take place," said the USFDA in an email to ET. "The 30-month stay provision is beneficial because it provides the name brand company with a reasonable period of time to litigate the patents in question prior to a potentially infringing product entering the market."

It also allows a generic company to determine if its products will infringe the original brand prior to potentially selling an infringing product and being liable for damages, the US regulator said. The regulator approves drugs tentatively during this 30-month period after which companies can launch a generic version at the risk of paying legal liability.

Indian innovators are frustrated. "It is in India's interest to show the world it can protect patents," Biocon chairman and managing director Kiran Majumdar Shaw said. Big drugmakers are opting for low-cost centres. "The world's Big Six (pharma companies) have set up research centres in China and not India," says Ranjit Shahani, vice-chairman and MD, Novartis India. In the US, unlike in India, the legal risk is big. "The mindset of judges in the US is to uphold the patent, because the grant is part of an established process," said Nilesh Gupta, group president and executive director, Lupin.

Yet, a third of the suits filed in Delhi today are intellectual property-related, said Pratibha Singh, renowned patent lawyer. "There is hardly any good biotech patent lawyer in India," Dr Ella of Bharat Biotech said. Ms Singh says for a better patent environment, the country needs more lawyers trained in intellectual property, a government and judicial regime that understands patents and has specific skills to assess them, and better administration. Yet, training judges is not the answer, she said. "In the US, these cases are heard by judges like other routine cases. It is the lawyers who have the knowledge to present cases," she said.

The US patent office spokeswoman said American business sectors that rely on IP protection account for \$5 trillion of gross domestic product and employ 18 million workers. Dr Ella suggests that the patent office seek the help of academia and industry to strengthen its systems. Patent controller Mr Kurian, however, said there is no way for industry to help. The office is currently working on a plan to hire 250 more people for

patent examination through the CSIR.

The staff will be recruited over the eight months, he said. The Indian patent office is also looking to outsource some technical research for novelty in patent applications to CSIR, he said. “We should start doing that in another one or two months.” The office also has a better database and electronic research methods for a more thorough examination for future patents, he added. Meanwhile, patents that have been granted in the last five years continue to hang in the balance.