

## For IPR In India, A Time Of Sea Change

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*Wednesday, January 17, 2007* --- Nearly two years after implementing a massive overhaul of its patent laws, India is still struggling with legal and regulatory teething problems. But contrary to Western criticism, intellectual property rights are keeping pace with both the fast-tracked development of technology in the country and international laws, say Indian attorneys.

In fact, the Patent Act of 2005 – which adopted the product patent regime for food, drugs and chemicals, and embedded software – continues to be amended at such a rate that it is often a challenge for Indian patent attorneys to keep up-to-date with the law, says Archana Shanker, partner at New Delhi-based intellectual property firm Anand & Anand.

“Things are changing all the time,” she admits, pointing to a foot-high stack of amendment booklets on her shelf. “But that is a good sign. Where there is scope for interpretation, the government is taking steps for clarification by setting up task forces to create uniform guidelines. It is also constantly taking measures to upgrade the system and boost the technical qualification standards for patent examiners.”

Complicating matters is the Indian court system itself, which has acquired a reputation for being slow and dysfunctional – thanks largely to its massive backlog of some 21 million civil and criminal cases. That gridlock that has boded particularly poorly for patent matters, which often involve complex technical issues many judges aren’t equipped to handle.

Indeed, the numbers on the surface seem to indicate a system that is making dubious progress at best in terms of speed: Of the approximately 24,500 patent applications filed in India in 2005-2006, only about 4,500 were granted, according to research conducted by Anand & Anand.

But things are not as dire as they appear, says Shanker. Roughly half of those patent applications are in the process of being granted within one to two years – with 500 applications set to mature in the next six months alone, according to her research.

In addition, the choked courts – while problematic on a judicial level – have not deflected foreign interest in the Indian market, according to Pravin Anand, founding partner of Anand & Anand.

“These statistics show that while the number of patent applications overall has increased significantly in the last 15 years, the number of grants has

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gone down,” he says. “But they don’t show the reason, which is that now, people have faith in the Indian system.”

However, Anand points out that a large bulk of the newer patent applications are in the field of pharmaceutical and agro-chemicals, and these patents have not been granted partly on account of weaknesses in the law covering these products – such as Section 3(d) – and the pre- and post-grant opposition procedures, which can slow down the grant of a patent even if there is a frivolous challenge to it.

Anand adds that the government “has spent and is spending a huge amount of resources on modernizing the Patent Office” and that the positive effects of that process will begin to materialize in the next few years.

Thus, multinational companies should not be deterred from seeking patent protection in India on the assumption that doing so will be an unnecessarily time-consuming process, says Shanker.

“Every company needs to evaluate the importance of seeking a patent in India,” she says. “If it is important, the company should file an application immediately. We’ve now graduated into a faster system whereby the patent controller has to issue a first office action within six months.”

For multinational companies looking to move into the Indian marketplace, however, legal assistance on the ground in the country can be key, Shanker admits.

“We have a working relationship with many of the patent officers, and we use those connections to assist our clients in taking certain steps to avoid delays or glitches,” she says. “The system is not just purely traditional; you have to walk hand in hand with regulators in order to be able to move forward.”

And foreign companies looking to patent their drugs in India should be aware of several trends in IPR in India, Anand says.

For example, “generic pharmaceutical companies are currently trying to spread their message at a faster pace than the innovator companies and it is necessary for the innovator companies to neutralize this message,” says Anand. “They must understand who is being influenced by what thought and how that can be neutralized.”

Foreign companies should also be aware that there are still certain weaknesses in the patent legislation that may surface when cases come up, as evidenced in the closely watched legal battle by Swiss drug maker Novartis to patent its cancer treatment Gleevec in India, he adds. (Last year, the Chennai Patent Office rejected the company’s patent application on the grounds that Gleevec was not significantly different in properties from an already existing compound under a controversial section of the new patent laws that bars derivatives from being patented.)

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“The courts will be willing to interpret the law favorably particularly in writ and appeal jurisdictions but before Indian courts, apart from the facts and the law, a good litigation strategy is possibly the clincher,” Anand advises.

Indian courts also look to the E.U. and the U.S. for guidance, says Anand. The result is that India’s IP development mirrors that of the West – though not in all ways.

“The really great thing about Indian courts is that they are very protean – there is no ego factor,” says Anand. “High judges often look to the decisions of lower courts for guidance, which is unique about India.”

India has also caused waves on the intellectual property frontier by taking a strong stance against what it sees as misuse of patent laws, such as its recent successful bid to revoke a patent on turmeric.

In 1995, the New Delhi-based Council for Agriculture Research challenged a turmeric patent granted in March 1995 to two non-resident Indians associated with the University of Mississippi Medical Center. The U.S. Patent Office eventually yanked the patent after the CAR argued that turmeric has been used in India for thousands of years for healing wounds and rashes.

Though costly, the multimillion-dollar legal battle resulted in the decision to create an electronic encyclopedia of India's traditional medical knowledge, the Traditional Knowledge Digital Library, in a bid to stop people from patenting such information.

With many legal experts predicting that India will be the future battleground for intellectual property issues, U.S. companies looking to set up shop in the country needn’t be overly cautious, but should be aware of the legal pitfalls that still remain, attorneys say.

India’s current lack of a data protection law similar to that of the United States or Europe is one thing to keep in mind, particularly for multinational pharmaceutical companies. (India’s industry ministry, led by a committee headed by the secretary of the department of chemicals and petrochemicals, is mulling legislative action on the issue.)

In addition, India has come under both international and internal criticism as one of the only countries in the world to offer both pre- and post-grant opposition to patent applications. Critics say the provision is contributing to India’s massively backlogged court system and deterring multinational pharmaceutical companies from pursuing filings in the Indian marketplace.

But on the ground in India, that doesn’t seem to be the case. Intellectual property lawyers in the country say they are witnessing an unprecedented economic growth hand in hand with a steady increase in the IP sector.

“The scope of IPR protection in India has been widened, [making] the IP landscape in India inviting and exciting to IP owners,” says Jose Madan,

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head of the intellectual property practice at Mumbai-based Khaitan & Co. “The system is also much faster than it was before.”

For now, as Indian courts near the bottom of the barrel of patent applications filed in India since the implementation of its new patent laws, intellectual property attorneys in the country – and their multinational clients – are bracing for a wave of litigation. But the legal boom could become especially messy if Indian courts fail to take crucial steps to prepare for such an onslaught, some attorneys say.

There is a dearth of patent examiners, for example, and while judges in the high courts are generally qualified to handle complicated IP matters, judges in lower courts may still lack that kind of specialized knowledge, according to Vivek Kathpalia, partner at Mumbai-based Nishith Desai Associates.

The lion’s share of IP cases in the Indian court system are currently in the trademark area, says Kathpalia, but “patent litigation will be the next boom, and that is when the expertise of the judges will become a bigger problem.”

Still, there have been a number of successful steps in the right direction, Kathpalia says.

“The government is spending more money on training in the courts, and holding workshops on IP in conjunction with the U.S. and Europe,” he says. “The mindset has changed.”