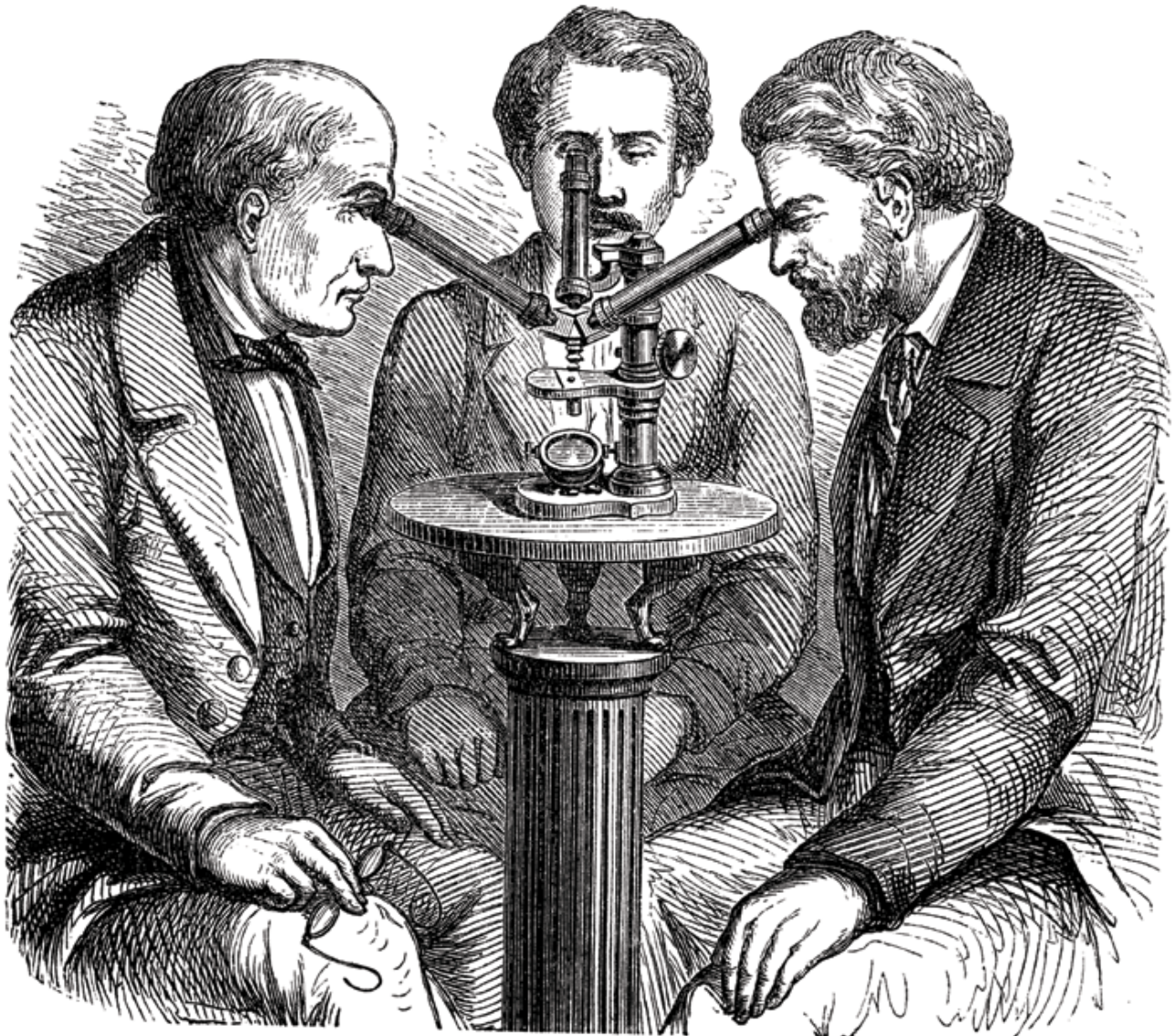


INDIA'S PATENT PREDICAMENT

INDIA IS WORKING TO IMPROVE ITS IMAGE AS A PATENT-FRIENDLY JURISDICTION. BUT WHO WILL TRIUMPH IN THE BATTLE BETWEEN INNOVATORS, MULTINATIONALS AND THE GENERAL PUBLIC? **VANDANA CHATLANI** INVESTIGATES



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ccording to data from the Controller General of Patents, Designs and Trademarks, 145,060 patent applications were filed in India over the past three years. Of these, 73% were filed by foreign inventors, applicants,

legal entities or organizations, while the remainder were filed by Indian parties.

The number of foreign patent filings reflects India's growing prominence for intellectual property (IP) owners, but also suggests a move to step up protection and clamp down on infringement. India is no stranger to IP controversies, particularly on the patent front, where it has come under fire for generic drug manufacturing and a few years ago for awarding a compulsory licence to domestic pharmaceutical company Natco in order to make Bayer's patented kidney cancer drug more affordable in India.

However, India's commitment to restricting the patentability of marginal innovations for the sake of providing affordable drugs and public interest is being questioned following reports in March that the Indian government had given private assurances to the US that it would no longer issue compulsory licences.

Srividhya Ragavan, a professor of law at Texas A&M University School of Law, says there was no legal reason for India to make such a pledge. "India has one of the most sophisticated compulsory licensing provisions which is fully compliant with the [World Trade Organization's] TRIPS [Trade-related Aspects of Intellectual Property Rights] agreement," she wrote in *The Hindu*.

Pravin Anand, the managing partner of Anand and Anand, points out that "private assurances made by anyone – be it a government body or anyone else – have no meaning in law". He explains that an application for a compulsory licence would first come up before the patent office. Any appeals from orders passed by the patent office are then referred to the Intellectual Property Appellate Board (IPAB). A writ against the IPAB is then heard at a high court, and in suitable cases, a special leave petition before the Supreme Court of India.

"These are the four fora which alone have the jurisdiction to decide compulsory licence cases," Anand says. "No assurance made by anyone, be it the central government, state government or anyone else, can bind these bodies in any manner whatsoever."

India does not grant patents for traditional medicine or for incremental innovations to existing drugs and substances, even if these small innovations produce huge benefits. The idea behind this is to foster greater competition among generic manufacturers thereby giving people access to cheaper medicines.

Some believe that India is changing its priorities with regard to patent protection, in response to intense pressure exerted by US industry and government bodies. In May, the Pharmaceutical Re-

search and Manufacturers of America along with 16 other US industry bodies expressed their reservations about India's patent laws and business norms in a letter to President Barack Obama.

That same month, the Indian Patent Office reversed an earlier decision denying US drug manufacturer Gilead a patent for its hepatitis C drug. The patent office initially said the drug, sofosbuvir, did not demonstrate sufficient improvement over an existing compound, but later concluded that it had satisfied the threshold of novelty and inventiveness. Gilead's drug costs US\$1,000 per pill, making it unaffordable to many in India and around the world.

Ragavan reflects the view of many critics when she writes in *The Hindu*: "It is best for the Modi government to stop engaging US bureaucrats as patent consultants and instead showcase the Indian patent statute as an exemplar for a balanced patent regime to the rest of the developing world."

ROOM FOR IMPROVEMENT

"India's position is that its laws are compliant with the requirement of the treaties to which it is a signatory," says Ashwin Julka, the managing partner of Remfry & Sagar, referring to the National Intellectual Property Rights Policy, introduced in May. He adds, however, that while the law may be adequate and sufficient, "clear guidelines and proper, uniform implementation ... in the processing of patent applications is needed so that 'positive predictability' may be attributed to the Indian patent system, which, in turn, will spur both domestic and foreign innovation."

Garima Sahney, a partner at Saikrishna & Associates, supports



Pravin Anand
Managing Partner
Anand and Anand

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Managing Partner, Remfry & Sagar

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this view. "Restrictions in Indian patent law do not actually hinder the pace of patenting in India, but the outdated understanding, procedures and practices at the Indian Patent Office do," she says. "Innovations will pick up pace automatically if the patent procurement procedure at the patent office is expedited and streamlined at each stage. Currently, there is a backlog of more than five years at the patent office, which severely affects the rights of patent holders."

In addition, Prabhakar Mani Pratap, a partner at Vutts & Associates, says guidelines on the prosecution and examination of innovations such as those relating to the biotechnology, computer and chemical industries are vague and unhelpful for those prosecuting applications in India.

Others advocate reforms to specific sections of India's Patents Act, 1970, including section 8. Under this section, applicants filing for patents in India are expected to provide details of patent applications they make for the same invention in countries outside India, while also keeping the patent office informed of the processing of those overseas filings. Compliance with these provisions is mandatory and failure to provide adequate disclosures of foreign filings has led to the revocation of patents in India.

"I do not think section 8 – in its current width and ambit – is necessary in today's day and age," says Adarsh Ramanujan, a director of the Geneva office of Lakshmikumaran & Sridharan. "If at all, perhaps, this may be diluted to allow the patent office to seek material information that is otherwise not accessible to it and that, too, only when necessary."

Patent practitioners agree that uniformity across India's IP offices is key to ironing out creases in the current regime. Pratap says the Indian Patent Office should be open to adopting best practices from IP offices outside India. "For example, the Indian file wrapper for a patent application is not organized," he says. "It is very difficult for a user to understand and confirm the sequence of events and chronology of the documents filed in a patent application. The file wrapper

should be arranged along the lines of those used by the European Patent Office, the US Patent and Trademark Office and the World Intellectual Property Organization."

KNOWING THE ROPES

Innovators and in-house counsel seeking to protect company inventions, even when familiar with India's patent filing system, still risk tripping on hurdles in preparation for and during the prosecution process.

From the outset, applicants should ascertain whether a patent is needed for a product or technology, or whether a trade secret would be a better option, suggests Sahney. "This determination should always be critically made for innovations that are evergreen in nature and for those which are short-lived since in both cases patenting might not be the right choice," she says. "Such evaluation must involve inputs from inventors along with teams from the commercial, delivery and market research teams."

Adarsh Ramanujan

Director (Geneva)

Lakshmikumaran & Sridharan

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SPICE ROUTE LEGAL

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The next step is determining the goal of a patent. “Very often, the final objective of procuring a patent is only brand value creation or to secure capital from venture capitalists,” says Sahney. “It is only the bigger companies which consider enforcement and deterrent-related end-objectives. As for the latter, a company must evaluate the practical feasibility of enforcement in India as well as other markets of interest considering the cost and complications involved with the legal battles.”

Ramanujan attributes many of the mistakes made by in-house counsel to “blind attempts at implementing strategies and techniques pursued elsewhere to the Indian context. This includes amending claims and pursuing divisional applications at will,” he says. “Pursuing Indian applications requires some special attention and careful thinking in many instances.”

DATA AND DETAILS

Jaya Bhatnagar, the managing partner of SiebenIP, warns that insufficient specification of a patent can lead to numerous objections during the prosecution stage and urges patent owners to diligently file all the necessary information and documentation. “In-house counsel and patent owners should always focus on novelty and patentability criteria so as to achieve well-drafted claims that may do away with attracting objections during the prosecution stage,” she says.

Bhatnagar says the best strategy is to conduct a thorough patent search; file an application as soon as the concept is conceived; follow and strictly adhere to timelines; carefully draft specifications with claims that are not too narrow or broad so as to avoid infringement actions; regularly track the application; take remedial measures to ensure that no pre-grant or post-grant oppositions are filed; and keep the Indian Patent Office well informed under section 8(1) and (2) of the corresponding foreign filings.

Julka has encountered in-house counsel who have pursued non-patentable claims such as method of treatment claims, second medical use claims and software claims, only to be denied a patent. For example, India prohibits patenting of software “per se” under section 3 of the Patents Act. Computer-related inventions which fully or partly depend on software to function can be patented and software may be patented in combination with hardware, but not on its own.

Julka advises in-house counsel to direct their agents to perform a basic claim review to confirm which claims are statutorily allowed in India. “This step is more necessary now, since the amended rules allow an applicant to delete claims at the time of entering national phase applications in India (no claim amendments are allowed at this stage), which may lead to filing a reduced set of claims and therefore avoiding extra claim fees.”

Naveen Varma, a partner at ZeusIP, recommends using experience acquired from patent prosecution in the other countries to amend pending claims and descriptions to negate and obviate anticipated objections. “As Indian examiners majorly rely on the examination results during the international stage or examination results in few major jurisdictions, [applicants should] evaluate the situation upfront and make necessary voluntary amendments to avoid any apparent prior art, novelty or obviousness rejections,” he says. Varma adds, however, that this advice may not apply to every case and suggests that counsel managing the patent application should evaluate the situation carefully.

SPEED, SPECIALISTS AND SUBMISSIONS

The Patents (Amendment) Rules, 2016, notified on 16 May by the Indian Patent Office, allow for expedited examinations, but these can only be requested if India was named as the international search authority (ISA) or the international preliminary examination authority



Jaya Bhatnagar
Managing Partner, SiebenIP

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in the corresponding international application. Startup companies are also permitted to seek expedited examinations or to hasten their patent registration process. An applicant that does not qualify as a startup can take advantage of the expedited examination by applying for a Patent Cooperation Treaty international application and choosing India as the ISA.

“As [of now], only Indian applicants can select India as the ISA, says Ramanujan. “If you do not fulfil either criterion, then the best advice is to enter the national phase into India at the earliest and file the request for examination immediately rather than waiting till the final day of the deadline.”

Most IP lawyers encourage applicants to keep in constant touch with patent examiners to ensure their applications are on track. “Upon receipt of the first examination report [FER] and submission of a response thereto, a regular email or follow-up phone call should be done with the examiner to enable them to allow or issue a hearing notice,” says Tarun Khurana, the managing partner of Khurana & Khurana. “Responses to FERs shouldn’t be delayed ... they must be submitted within two months from the issuance of the FER.”

Sudhir Ravindran, the managing partner of Altacit Global, advises patent owners to provide all of the information and documentation needed to support their applications. “Failure to submit a permission letter from the National Biodiversity Authority, or non-compliance in the deposit of biological material, for example, could cause delays,” he says. “The subject matter of the patent should be assessed for all requisite compliance and the same be made in timely manner.”

Patent owners and in-house counsel often engage outside lawyers for assistance with patent prosecution, a practice unsurprisingly endorsed by law firms. However, Ravi Bhola, a partner at K&S Partners, emphasizes the need for technical expertise as an additional

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Partner, Saikrishna & Associates

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Ravi Bhola
Partner
K&S Partners

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safeguard when attempting to patent an invention. “The drafting of patent specifications by lawyers registered as patent agents, but having no technical background, results in poorly drafted patent applications,” he says. “In-house counsel [should engage] professionals who are experts in the domain, familiar with the technology and capable of understanding it in detail.”

Lawyers also recommend budgeting in advance to estimate the financial commitment required to obtain the grant of a patent, which normally takes years. Vaibhav Vutts, the managing partner of Vutts & Associates, says in-house counsel should work with their lawyers to decide on a mutually beneficial budget. He points out that the maximum cost for patents is incurred after filing and during the prosecution stage.

“India is still a relatively affordable jurisdiction to prosecute patent application,” he says, “however foreign jurisdictions can be expensive. Ideally, identify the territories of business interest and prosecute an application only in those territories. An early decision on this might help in lowering costs.” For instance, he says, if fewer than five target countries are identified, applicants can consider the Paris Convention applications path instead of the Patent Cooperation Treaty route.

Equally important is the decision on the country, type (provision-

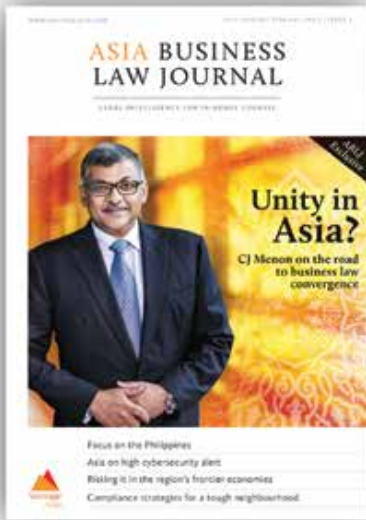
Vaibhav Vutts

Managing Partner, Vutts & Associates

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al or complete) and date of the first filing. “The first filing triggers several other deadlines, due dates and actions,” says Sahney. “Therefore, the timing of the first filing must be crucially decided based on the stage of product development, market entry, etc.” She adds that the country of first filing should similarly be chosen based on factors such as foreign filing permission, related laws of different countries, country of first launch, and import-export strategy.

While companies engineer plans to protect their inventions, India must assess its own patent predicament. “The fundamental issue with regards to intellectual property rights in India is how to create and sustain an environment that is consistent with the country’s ideological position on patents and balances innovation and protection,” concludes Julka. “There is still work to be done before we reach that point.” ▲



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