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India's patent fix

While the government has been battling patents on traditional Indian remedies abroad, the Patent Office back home has granted a handful of such patents, causing an embarrassment of sorts

CAN THERE BE A PATENT ON TRADITIONAL KNOWLEDGE? Patents have been granted using indigenous plants and fruit like *amla*, *mehndi*, *kareta* (bitter gourd) and *ashwagandha*

SUSHMI DEY

The Department of Industrial Policy and Promotion in the Union Commerce Ministry recently revoked a patent granted by the Indian Patent Office to Avesthagen, the Bangalore-headquartered life sciences company, for a diabetes medicine made from extracts of *jamun*, *lavanpatti* and *chandan* (sandalwood) because these indigenous plants are an integral part of the traditional medicinal systems (Ayurveda, Unani and Siddha) and have been used from time immemorial for diabetes management. The government used a "rarest of rare" provision in the Patents Act to quash the patent because it was "mischievous to the state and generally prejudicial to the public". The company had argued, *The Times of India* reported, that the three plants were chosen from a long list of 100 plants and a short list of 10 plants, there was considerable research and innovation in the invention, the patent validates the traditional medicinal systems and farmers would benefit from it. But that didn't cut much ice with the department.

That's because the patent was turning out to be quite an embarrassment for the department. The government has for long been resisting attempts globally to patent traditional Indian knowledge. It has successfully fought attempts to patent *haldi* and *neem*, which have for centuries been used by Indians to cure wounds and diseases. For instance, in 1997, the Council of Scientific and Industrial Research had challenged and won a case against a US patent on turmeric given to a research group from University of Mississippi Medical Center. In fact, the government had got the European patent authorities to turn down a similar request by Avesthagen two years ago. A patent to Avesthagen on its home turf would have weakened India's case in international forums. That's why it had become essential to revoke the Avesthagen patent. After this case, the government has realised, there might be four of five such patents granted by the Patents Office using indigenous plants and fruit like *amla*, *methi*, *karela* (bitter gourd) and *ashwagandha*. It is not difficult to imagine what will be the fate of these patents.

India has argued that traditional knowledge cannot be patented because that will interfere with the lives of ordinary people. Those who use traditional medicine are often farmers and workers in villages, tribes or forest dwellers — poor people who cannot pay for patented cure. It is also a politically sensitive matter. Any government that allows such patents will in no time be accused of selling out to unscrupulous drug makers. Still, drug makers and life-sciences companies are always on the lookout for traditional knowledge. This is perhaps because the efficacy of these herbs and plants is already proven, and that cuts the go-to-market time as well as research costs. With the pipeline for new drugs almost dry, this helps in a big way. The Indian pharmaceutical market is pegged at almost ₹60,000 crore — it would be considerably bigger if the traditional medicines are included. Civil society activists call it bio-piracy.

India ventured pretty late into the world of intellectual property protection when compared to other countries. The country signed the World Trade Organisation's agreement on Trade Related Aspects of Intellectual Property Rights in 1994 and changed its patent law only in 2005 — a cushion of over 10 years. Till then, only process patents were valid in the country; thus, you could make any product in the world so long as you used a different method. From January 1, 2005, product patents also began to be recognised. Since then, India has been granting patents merrily: as many as 3,488 drug patents have been registered with the Patent Office between 2005 and 2010. The figure is huge as compared to other emerging economies like Brazil, Argentina, and Columbia. A research paper, Pharmaceutical Innovation, Incremental patenting and Compulsory Licensing, by Carlos M Correa, a professor at the University of Buenos Aires, points out that just 278 patents were granted in Brazil between 2003 and 2008, 951 in Argentina between 2000 and 2007, and 439 in Colombia between 2004 and 2008. However, in South Africa, where patents are simply registered without much verifications and patentability requirements, 1,426 were registered in 2008 alone.

The numbers suggest that India has become quite popular amongst patent seekers, though it may not always be for the right reasons.

Balancing the two objectives of promoting innovation and improving availability and affordability, India has in recent years granted a number of patents for products whose novelty can be questioned: a broom, a wound dressing, a permanent calendar, a toilet seat cover, a belt buckle and a sanitary napkin. The charge is that patents are often granted to known substances with minor modifications or a mixture of such substances, which is not really innovation. The Avesthagen case has brought the spotlight on the issue. In the past also, patent was granted to an edible herbal composition comprising mixtures of at least two Indian herbs selected from a group comprising *jamun, karela, baingan* (eggplant) and *gurmar* for their efficacy in reducing sugar levels. Strictly speaking, the Patent Office ought to consider each patent application on merit and need not pander to the whims and fancies of the Commerce Ministry. The issue is if the patent law explicitly lays down that traditional knowledge cannot be patented and if that condition is being flouted.

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"The Indian patent law does not allow patents on traditional and combination medicines but the patent examiners are influenced by jurisprudence of other countries and do not interpret the law in Indian public interest in the Indian context," says KM Gopakumar of Third World Network. Gopakumar points to Section 3 (j) of the Indian Patent Act which says that a plant or animal, in whole or any part of it including seeds, other than micro-organisms, is not patentable. "Even though there is no explicit exclusion of genes or DNAs under this section, it is clear that this exclusion includes gene, cell lines, DNA *et cetera*," he says. However, gene patents continue to exist in India, mainly because the patent examiners are of the view that a genetically modified gene sequence or amino acid sequence is novel when it involves an inventive step and has industrial application. This anomaly, or leniency, could be the source of the government's current embarrassment.

What could be termed another abnormality in the system is that through patents are examined and granted by the Patent Office, they cannot be revoked by the same. A patent in India can be revoked only by the government. According to intellectual property rights experts, there are various gaps — technical and legal — in the patenting system that permit such irregularities. "Even if a patent is granted by the Patent Office, there is no set mechanism to rectify it," says an expert. Earlier, there was a provision under the law which allowed the Patent Office to suo motu revoke a patent if within one year of the grant evidence against the patent is cited. However, this was deleted in the law which came into place in 2005. Besides, experts also complain that the training programme of patent examiners itself is flawed. "Our patent officers are being trained by officials from the US and Europe, then how can you expect them to look at things from Indian perspective?" says Gopakumar.

All of this has not gone down well with drug makers. Their genuine innovations, they allege, are unnecessarily being called into question by vested interests. Meanwhile, it seems this fight over patents will only get worse. The Intellectual Property Appellate Board, on Friday, struck down the patent given in 2006 to Roche's hepatitis C drug, Pegasys. The board cited lack of evidence that the drug was any better than existing treatments and its high cost as the reasons for its decision. This was the first product patent granted in the country. Sankalp Rehabilitation Trust, an advocacy group for inexpensive medicine, has had challenged the patent, saying the drug was costly and gave the Swiss drug maker monopoly in the market. Earlier, in March, India had given homegrown drug maker Natco the "compulsory licence" to make cheaper copies of Bayer's cancer drug Nexavar. Novartis is battling in the Supreme Court an earlier decision to refuse it a patent on cancer drug Glivec.

It could get worse.