Seed money

Neha Srivastava discusses the litigative landscape in India surrounding sustainable agriculture and seed patenting

Seeds are the basic and most critical input for sustainable agriculture, and production of high-quality hybrid and genetically modified (GM) seeds has boosted yields around the world. Valued at more than $500m, the Indian seed industry is the fifth largest in the world, and accounts for 4.4% of the global seed market after the US (27%), China (20%), France (8%) and Brazil (6%).

To promote this sector, the Indian government has taken several steps in the last three decades including the implementation of an effective intellectual property rights (IPR) framework, thereby stimulating investment in research by private players, development of public-private partnerships and growth of the domestic seed market.

Legal framework

For plant varieties and seeds, Article 27(3)b of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) obligates member states to provide protection either by patents or a *sui generis* system like plant variety protection (PVP), or a combination thereof. Several countries have joined the Union for the Protection of New Varieties of Plants (UPOV), established in 1961, revised in 1978 and 1991. However, India is not a UPOV member.

For instance, the US provides protection to plant varieties through utility patents and PVP. Under the European Patent Convention (EPC), plant varieties *per se* are not patentable, but may be protected through Community Plant Variety Right (CPVR). In both cases, PVP laws conform with UPOV 91.

India provides IP protection through the Protection of Plant Varieties and Farmers' Rights Act (PPVFRA), but without accepting the framework of UPOV 91 since it severely limits farmers' freedom to reuse farm-saved seeds and exchange them with their neighbours.

Under PPVFRA, farmers may save, use, sow, re-sow, exchange, share or sell seeds of a protected variety. However, reconciling this legislation to GM seeds is sometimes challenging, for farmers must enter into licensing agreements with seed companies (for biosafety data etc) that impose restrictions on post-harvest saving and using of GM seeds.

Seed patents in India

Seeds, including GM seeds, have been excluded from patentability through the insertion of section 3(j) as a part of the 2002 amendment of the Indian Patent Act, 1970. Section 3(j) bars patenting of plants and animals in whole or any part thereof except microorganisms, but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.

A plain reading suggests that while non-biological processes for production of plants/seeds are patentable, plants/seeds *per se* and conventional methods for their production and propagation do not constitute patent-eligible matter in India.

Despite this basic clarity, there is contention around the interpretation of section 3(j), particularly with regard to GM seeds. Should a recombinant gene be considered 'part' of a plant/seed? Can a non-biological, biotechnological, process of producing GM seeds be equated to an 'essentially biological process'? Would a patent on a gene indirectly allow seed manufacturers to exercise exclusive rights over seeds and plants containing such genes in a manner contrary to the statutory exclusion under the Indian Patents Act?

Under the TRIPS agreement, Article 27.1 requires that "... patents shall be available for any inventions… in all fields of technology…" Article 27.3 goes on to state that "[m]embers may also exclude from patentability… (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes." A combined reading of Article 27.3 with Article 27.1 therefore suggests that biotechnological inventions in agriculture constitute patentable subject matter.

In terms of listing 'what are not inventions' under the Indian Patent Act, the Ayyangar Committee Report of 1959, based on which the patent statute was enacted, expressly clarified that the prohibition under section 3(h) which excludes "methods of agriculture or horticulture" from patentability, was intended to apply only to "inventions in the field of plant propagation by asexual methods".

Further, the term 'plants' was consciously deleted from section 3(i) of the statute as a

part of the 2002 amendment, implying the legislature's intention to make the treatment of plants (to render them free of disease or increase their economic value) as patentable subject matter. In addition, section 3(c) excludes only "discovery" of naturally occurring living things or non-living substances from patentability, thus leaving the window open for patenting of biotechnological inventions involving substantial human intervention.

Based on the foregoing, one may conclude that methods relating to biotechnological inventions ought to constitute patentable subject matter. The Intellectual Property Appellate Board (IPAB) has also affirmed this in the case of *Monsanto Technology LLC v Controller General of Patents*,[1] wherein it was held that a method of producing a transgenic plant involves substantial human intervention, and could not be considered as an "essentially biological process" prohibited by section 3(j).

The applicability of this provision is best illustrated through the example of Bt cotton wherein no patent protection is available over the cotton seed containing the Bt gene, but the process of introducing the gene and producing transgenic seed/plants would be considered patentable.

With respect to what is covered under 'any part of a plant' under section 3(j), the grey area lies in terms of its interpreting whether 'part' is limited to roots, leaves, flowers etc. or if it can be extended to plant cells and recombinant DNA constructs. As per the current position of the Indian Patent Office, plant cells fall within the exclusion and therefore plant cells including transgenic plant cells are not patentable. On the other hand, a recombinant DNA, which is a synthetic product, constitutes patent-eligible matter. However, this aspect has been challenged in the case of *Monsanto Technology LLC And Ors v Nuziveedu Seeds Ltd & Ors* (2018) at the Delhi High Court, but it is yet to be seen how it would be finally interpreted by the courts.

Patent enforcement

In the US case of *Monsanto Co v McFarling*[2] involving a transgenic plant and gene for herbicide resistance, Monsanto sued farmers who had purchased and planted its patented soybean and subsequently saved and replanted the seeds from the initial soybean crop. Since Monsanto's contract with the farmers specified that their purchase only covered one planting season, saving and replanting was alleged to be patent infringement. One of the farmers challenged the validity of their contract, however, the Federal Circuit upheld the contract. In similar vein, even though Canada does not offer plant patents, Monsanto has been successful in preventing Canadian farmers from saving and replanting Monsanto seeds.

In *Bowman v Monsanto Co,*[3] the Supreme Court of the US held that the defence of patent exhaustion (which gives the purchaser of a patented article, or any subsequent owner, the right to use or resell that article), does not permit a farmer to reproduce patented seeds through planting and harvesting without the patent holder's permission.

In India, where patents on plants/seeds are not available, similar enforcement trends can be seen. In the first of its kind case of *Monsanto Technology LLC v Nuziveedu & Ors AIR 2019*[4] Monsanto had entered into licensing arrangements with Nuziveedu Seeds and other Indian seed companies engaged in using Monsanto's patented Bt cotton technology, involving use of a recombinant DNA construct to keep the deadly bollworm (a pest) away from their cotton crop. The genetic fragment was derived from *Bacillus Thuringiensis* (BT), a bacterium, and inserted into the plant genome. Donor seeds with this artificial gene construct (integrated in their genome) were then delivered by Monsanto to seed companies who used these as carriers to produce their own 'BT gene infused' hybrid cotton varieties, which were subsequently sold to farmers.

In late 2015, a dispute broke out between the parties on account of non-payment of royalties. Monsanto terminated their licences and sued the seed companies asking for restraining orders against the continued use of their patented technology. Nuziveedu claimed that the patent in question was itself invalid.

The single judge did not rule on patent validity at the interim stage – it merely restored the licences granted to seed companies and said royalties would have to be paid. The matter was then appealed, and as an outcome of cross appeals filed by Monsanto and Nuziveedu, the division bench of the Delhi High Court invalidated Monsanto's patent for violating section 3(j), raising two key questions: whether human intervention in fundamentally altering the genetic make-up of a seed should be considered an 'essentially biological process' and whether a recombinant DNA- a modified synthetic molecule conferring transgenic trait should be considered as a 'part' of a plant?

It was Monsanto's argument that the 'DNA construct' satisfied all the conditions of patentability. It was indeed a product, novel (not anticipated by use or publication), non-obvious to a person skilled in the art and was in fact capable of industrial application. It was a result of human intervention and not an essentially biological process.

Nuziveedu claimed that the 'DNA construct' on its own was not capable of industrial application – it was only after insertion into the seed that it produced the desired result. Further, once inserted into the seed, the DNA construct could not be separated from it subsequently – it became an integral part thereof and self-perpetuated in 'progeny seeds' via an 'essentially biological process'. Thus, it was outside the purview of patent protection under section 3(j).

On appeal, the Supreme Court remanded the matter back to the Delhi High Court saying it had erred in passing a judgment on complex technical issues in a summary manner, and invalidating Monsanto's patent without examination of expert evidence (thereby upholding Monsanto's patent). Also, seed companies were permitted to continue using the technology on payment of royalty rates as fixed by the government.

Summary

This case is still pending before the court of first instance. Since Monsanto's patent expired in November 2019, the only issue at hand now concerns damages. But deciding the quantum of damages will require an assessment on whether Monsanto's patent was infringed, so the decision ought to be instrumental in clarifying the patentability of biotechnology related inventions. Given the importance of the farming sector to the Indian economy and the legislative intent captured by the PPVFRA, the court is likely to keep broader public policy objectives in mind to deliver a judgment that balances the rights of all stakeholders.

Footnotes

1. IPAB Order No. 146 of 2013 dated 5 July 2013.
2. 363 F.3d 1336, 1338 (Fed Cir 2004), cert denied, 125 S Ct 2956 (2005)
3. 569 US 278 (2013).
4. SC 559.

Author

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