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Stepping on corns?

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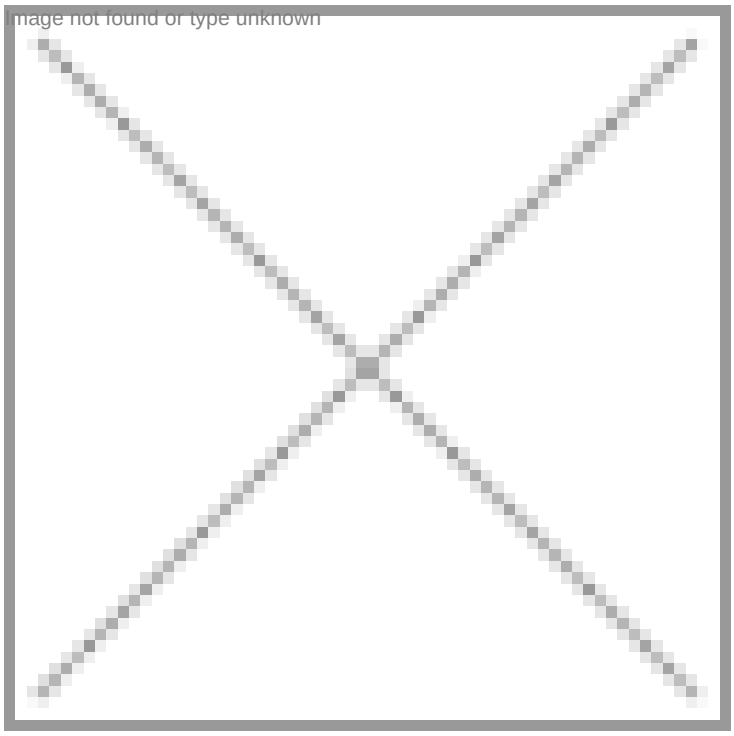

Agriculture or planned cultivation of crops is probably as old as the civilization itself. Even today, scientists have an insatiable desire to develop the perfect crop: disease resistant, high yielding, consuming less nutrition yet robust; but the techniques vary from hybridi-sation, tissue culture, genetic engineering and what-have-you.

Attempts at hybridisation (producing cross between two in-bred lines) may be traced to early 1920s when American farmers had started experimenting with corn in their fields. Capitalizing on such developments, an Iowa farmer Henry Wallace founded the Hi-Bred Corn Co., now one of the largest seed companies and carved out a niche market for hybrid seeds. The passing of the Plant Patent Act 1930 in the US and awarding patents for plants marked the era of commoditization of agriculture.

Now, it is the age of Vitamin-A fortified rice protected by over 150 patents, suicide seeds, species-wide patent of Agracetus to all transgenic cotton, patent on brassica obtained using agro-bacterium techniques to Calgene and so on. Fortunately, most of these patents do not operate in India and Indian farmers and scientists are free to use the technology for further research, possible improvements and commercial production within India.

At one extreme end are countries such as the US wherein protection for plants is regulated by nearly three legislations (Utility Patent, Plant Patent and Plant Variety Protection Act) and at the other extreme are developing countries wherein plants or parts thereof are not protected at all. While not everyone is convinced that patents should be issued for plants, it appears to be one of the popular methods of protecting one's intellectual efforts invested in commercial agriculture.

In the Indian context, the idea of seed companies selling suicide seeds may not appeal given the size of the farm and farming practices. However, the contribution of the Indian farmers and scientists in plant breeding to international pool is tremendous and such knowledge deserves protection.

In India, plants and plant parts such as seeds are not protectable under the Patents Act, 1970. Similarly, agricultural and horticultural practices cannot be protected. In a post-2005 scenario also, this is not likely to change drastically. That opens the arena for protection of plant specific-DNA sequences, virus-detection methods, methods for preparing constructs to be expressed in plants, method of coating seeds to make them herbicide resistant, etc. It is expected that post-2005, the product patent regime may permit patents for sequences, expression cassettes, plasmids and vectors. It is not known yet whether plant cells could be patented.

Therefore, currently, genetically engineered crops cannot be protected by patents. But, it may be possible to protect some essential parts of the technology. Let us take for instance, Monsanto's RoundUp Ready technology. The technology involves production of a chimeric-glyphosphate gene consisting of a promoter sequence, a sequence encoding EPSPS (a chloroplast phosphate synthase fusion peptide) and a sequence for expression of the fusion peptide, plasmid, a plant transformation expression vector comprising the chimeric sequence, a plant cell transformed and containing the chimeric sequence and of course, the method of producing the glyphosphate resistant plant. Of all these aspects, only the method of producing a chimeric sequence may be patented in India under the existing law. The chimeric sequence, vectors, plasmids could be protected after 2005. There are no precedents to establish that transformation techniques to produce genetically engineered plants are patentable. This is one issue warranting judicial intervention, since such methods may be interpreted as falling under "methods of agriculture".

Monsanto has obtained patents in Canada, the US and other countries for this technology and has also licensed the RoundUp seeds to various farmers. A controversy seems to have arisen with a Canadian farmer who is alleged to have deliberately planted the patented seeds whereas the farmer claims it is a case of contamination. The dispute is yet to be resolved by the Canadian courts.

The Bt-technology (wherein the transgenic plants are engineered to counter the bollworms by producing proteins that kill them) is also protected by a whole array of patents, right from the gene sequence, vector, methods of transformation techniques, etc. But none of these are so far patented in India.

Similar is the case with Flavr Savr tomatoes, patented originally by Calgene, now purchased by Monsanto. It was one of the first "genetically modified" food to hit the market. Traditionally, tomatoes are picked from the vine while still green in order to maintain their firmness during transport. Once harvested and transported the green tomatoes are chemically ripened by ethylene gas. Flavr Savr tomatoes are so designed that they can ripen on the plant itself while maintaining a firmer skin, thus producing a fuller flavoured tomato on the shelf. Scientists found that ripe tomatoes are soft because an enzyme, polygalacturonase, which is present in the fruit breaks down the fruit pectin that is responsible for stiffness of the fruit. To counter the early ripening and softening problem of the tomatoes, Calgene's scientists genetically engineered the tomatoes whereby the expression of polygalacturonase in the fruit is reduced.

The Flavr Savr patent claimed tomato plants wherein the expression of the polyglactouranase gene is reduced and a method of reducing the expression of a polyglactouranase gene in a plant: none of these patents are made in India nor are they tenable under the existing law.

However, crops such as the Bt cotton, Flavr Savr and Round-Up may be protected under the Plant Variety Protection Act, which is expected to be triggered into force post-2005. Until then, it would not be illegal to use the technology of these patents for research and development or even for commercial purposes in India. It would be nothing less than asking for trouble should these products be exported to countries where patents exist.

Salient Features of the Plant Variety and Farmer's Rights Protection Act

Registrable varieties

- Any new plant variety that conforms to the criteria of novelty, distinctiveness, uniformity and stability (DUS) may be registered, provided it does not contain any sequence involving terminator technology.
- Essentially derived varieties that differ from the parent variety by one or more characteristics may also be registered.

Criteria for registration

To be registrable, the variety should be novel, i.e., the propagating or harvested material should not have been sold or disposed of by the breeder before the date of filing of the plant variety application, except under the following circumstances:

- Within a year from the date of first sale, the material
- Outside India, four years, from the date of first sale of the material

Application for registration

May be filed by a breeder or an assignee of the breeder. The Applicant may be an Indian or foreign national. Applications from foreign nationals whose country grants plant variety rights to Indian citizens would be entertained.

Is there any way to crawl out of the complex web woven by patents? The answer may not be a simple yes or no. Proprietary science may be needed to be deconstructed to its last bit to arrive at a stage of selective use.

Some possible solutions to break the patent-barrier include:

- Designing around existing patents:

A scientific approach, wherein all the patents surrounding the technology are unearthed, thoroughly analysed and alternatives

beyond the scope of the patents are designed to make "improvements", which may then be patented and used. For instance, the constructs may be redesigned with different and new promoters or different sequences.

- Make improvements and offer to original patent owner:

Every technology suffers from certain drawbacks. These may be analysed scientifically and the invention may be improved to eliminate them, thus arriving at a new invention. It may be patented, but for commercialisation, one may require the permission of the original patent owner.

When biotechnology enters the realm of agriculture, sky is the limit for the milestones it may set. Patents just reward the inventor, but are not its ultimate goalposts. Golden rice would mean real gold for the developing world: patented or not.

J Sagar Associates is a leading national full service law firm and K& S Partners is an IP focused law firm. Both the firms provide legal services to several domestic and international biotech clients. Henceforth senior people from these companies will write on the patent issue.