

## Ambiguity related to IPR and access to technology in *Bt* cotton seed and trait case

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The fixation of country-wide uniform seed price of *Bt* cotton, including the determination of trait value royalty by the Central Government in May 2016, could not resolve the differences within Indian seed industry. The complexity of underlying issues and apprehensions was large and less understood. The issuing authority withheld the control order and invited stakeholders' and public opinion within a period of 90 days. This note analyses a unique difficulty emerging in the Indian seed and agri-biotech sectors.

Cotton production scenario in India has transformed since the adoption of *Bt* cotton in 2002. Respective increases in area, production and lint yield from 2000–01 to 2014–15 were over 52%, 271% and 143.6% respectively (area from 8.53 to 12.99 m ha; production from 9.52 to 35.33 million bales; lint yield from 18.96 to 46.20 kg/ha)<sup>1</sup>. The process of transformation include acquisition and import of *Bt* cotton technology, extensive licensing of technology to Indian seed industry, development of cotton hybrids expressing the *Bt* trait, seed production of these hybrids in sufficient quantity by seed companies, and continuous supply of seed input to farmers across the country. This resulted in increased cotton production and enhanced farm incomes, including the income of small-holder cotton-growing farmers who adopted *Bt* cotton.

Further adoption and diversification of agri-biotech/genetically modified (GM) products in agrarian India will depend on an improved regulatory environment, authentic biosafety data, and public acceptance of GM technology. Therefore, it is important to understand gaps in awareness and sensitize concerned stakeholders about the realm of IPR and innovation.

### Gazette notification for regulatory reforms

A gazette notification dated 18 May 2016 (ref. 2) issued by Central Government to provide 'Licensing and Formats for GM Technology Agreement Guidelines, 2016' may be broadly seen as an appropriate and sequential step taken

well within norms. It was a follow-up of the Cotton Seeds Price (Control) Order 2015 (ref. 3) which was in turn based on the Seeds (Control) Order 1983 (ref. 4). Again, considering the complexity arising from various immediate reactions in public, the decision to withhold the notification for 90 days and ask for comments by concerned stakeholders and public is also justified. Further, it would be critical to again put on track the regulatory reforms process in seed sector vis-à-vis equilibrium in cotton farming sector. The issue is particularly discussed here with regard to the IP subsisting in cotton seeds and *Bt* trait, their access for commercial use and related implications.

### Patent grant and access to technology

The Indian Patents Act provides for grant of IP right on traits *sensu* genetically modified gene sequence wherein independent claims of different categories may relate to a single inventive concept<sup>5</sup>. 'Trait' for specific manifestation of a protected gene sequence in a plant/plant variety of single or multiple species according to the 'claim(s)' can be regulated as per Sec. 83(c) of the Patents Act and working of patent (Chapter XVI) to promote, transfer and disseminate the technology for mutual advantage of producers and users, social and economic welfare, and balance of rights and obligations.

The patent grant in India also obligates the patentee u/s 83(g) of the Patents Act to make the benefit of the patented invention available to public at reasonably affordable price. The owner and licensee/s must furnish the progress on working of patented invention on commercial scale in the country to the Controller in Form 27 every six months. There are provisions (Sec. 84 to Sec. 94) to deal with cases where working of patents is not complied with. Grant of compulsory licences to third parties at the level of controller or the Central Government is one such option made.

The Patents Act excludes grant of patent on 'seeds', and also on plants in

whole or parts, varieties and species of plants, and essentially biological processes for their production (Sec. 3(j)). This exclusion is in conformity with Article 27.3(b) of the TRIPS Agreement. Methods of agriculture and horticulture are also not patentable in India as per Sec. 3(h). Therefore, further question of regulating trade and commerce in seeds and plant varieties under the Patents Act does not arise *per se*.

The regulation for marketing/trade of seeds/varieties having embedded 'trait(s)/modified gene sequence(s)' protected/protectable by patents is a wider question outside the domain of the Patents Act. Access to such technologies irrespective of whether patented or not, may be governed by assignment, licences and contracts, whereas regulation of other aspects like quality/efficacy, pricing, etc. may be controlled under other Acts and policies such as the Seeds Act, various Seeds (Control) Orders, competition law, common law, national seeds policy, etc.

### Protection of and access to plant varieties

The Protection of Plant Varieties and Farmers' Rights (PPV&FR) Act, 2001 provides for registration and protection of new, extant and farmers' varieties and also essentially derived varieties of notified species and genera (Sec. 14 to Sec. 23). There is no provision for protecting seeds *per se* but such protection of seeds of protected varieties is implicit. 'Seed' is the essential plant part by which the protected varieties would be propagated ordinarily. Also, there is no provision to protect the 'trait' *per se* in the plant varieties protected under the Act. Rather, the distinctiveness, uniformity and stability (DUS) of varieties for the traits (characteristics) listed in the DUS Test Guidelines constitute essential criteria for the candidate varieties to qualify for protection under the Act.

This grant can be regulated (*sensu* IPR) as commercial/tradable variety. Unlike patents, some of which may be held by inventors for certain strategic purposes to advance their future technological

innovations, all protected plant varieties are intended to be available for use in commercial terms. The PPV&FR Act, however, does not have any explicit provision for the working of protected plant varieties in corollary to Sec. 83 of the Patents Act, i.e. general principles applicable to working of patented inventions.

It is implicit that protected plant varieties could be exclusively used for commercial purposes throughout the term of their protection. The breeder owner and licensees would intend to harness maximum possible benefits from marketing of their proprietary seeds. It is also perceptible that the breeder owners would not prefer any situations for grant of compulsory licenses for protected varieties (Chapter VII) to arise. In the instant *Bt* cotton case the seed industry including the owner and licensees of *Bt* trait ensured that the seeds of protected *Bt* cotton hybrids are made available to farmers in reasonable quantity. Also, for many years the issue of price affordability was hardly brought in by different states or licensees of the *Bt* trait. Thus, it was not a fit case to be considered for the grant of compulsory license.

The PPV&FR Act provides for determining benefit sharing with the breeders of protected varieties under Sec. 26. The authority based on the extent and nature of genetic material of the claimant party used in the development of a protected variety as well as its commercial utility and demand is to decide a benefit-sharing amount, which the breeder has to deposit in a gene fund. There is no provision to regulate *per se* seed pricing of varieties protected under the Act by PPV&FR authority in normal circumstances, i.e. except compulsory licensing.

### Access to unprotected intellectual property

Both Patents Act and PPV&FR Act do not determine or regulate access to IP which is not protected under these laws, but commercialized under some licensing contract or as undisclosed information. Thus access to such unprotected technology for commercial use will be governed by other business principles (assignments, licenses, contracts, etc.), legislations, common law, and marketing regulations. Its availability in sufficient quantity, quality and affordability, and market competition, etc. will be broadly determined as a matter of policy admini-

stration by the government. Business in good faith should prevail, but the technology holder and licensor must take adequate steps from time to time to trigger demand and maintain market goodwill.

### Evolving the policy dimension

The new IPR policy recently announced by the Central Government calls for administering the implementation of all IPR Acts, except the PPV&FR Act under a single, unified domain, whereas the implementation of this Act should also be harmonious with other IPR legislations<sup>6</sup>. A real-time application of key balancing elements of the IPR policy vis-à-vis industrial policy and promotion in agriculture, particularly the plant variety domain may alone help in creating a level playing field for the seed industry to operate more competitively yet synergistically for agricultural development and farmers' welfare.

### Conclusion

The gazette notification for fixing seed price and trait value in *Bt* cotton should not have heavily relied on construing re-interpretation of patent and plant variety laws. In fact, issues like trade, public welfare or competition are extraneous to the IPR domain *per se*. This was a routine case of marketing regulation. Availability of technology to farmers was never a constraint. Pricing for seed and trait value royalty was an issue of conflict within the seed industry and not a concern raised by cotton-growing farmers. Thus *prima facie* there was hardly any issue of determining the exclusive ownership of the *Bt* trait or that of farmers' welfare. The Indian seed R&D industry rather needs to generate competitive IP on its own merit, and discourage considerations of such extraneous elements.

In this case, the imported *Bt* technology was a monopoly. There was no competitor having specific trait-based technology for the large Indian market. All licensee seed companies gained monetary benefits from *Bt* trait licensing contracts signed by them with the technology provider company. This arrangement fairly ensured the seed quality standard and efficacy of trait manifestation with regard to the target pest for sufficiently long duration of more than a decade. The Central Government decision for late intervention was not backed

up by adequate background analysis or confidence building.

New IPR policy provides an opportunity to the PPV&FR authority and the agricultural ministry to capture precedence, principles and processes from other intellectual property offices/nodal departments for handling future challenges of this sort, which must be available. Our national obligations and opportunities in handling business in plant varieties and agri-biotech require that the IPR regime in the country ought to evolve through efficient and apt institutions and capacity building<sup>7</sup>.

The ambiguity in interpreting Indian law for IPR over seeds and traits may continue to prevail unless the stakeholders are aptly sensitized with pros and cons of being due diligent or negligent, and farmers/end-users educated and empowered to strategically contribute to national decision making in larger agrarian interest. Functional uniformity of Indian IPR domain shall also help.

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2. Licensing and Formats for GM Technology Agreement Guidelines, 2016. The Gazette of India Part II Section 3 Sub-section (ii) No. 1236 SO1813 (E) of 18 May 2016.
3. Cotton Seeds Price (Control) Order, 2015. The Gazette of India Part II Section 3 Sub-section (i) No.756 GSR 936(E) of 7 December 2015.
4. Seeds (Control) Order, 1983. GSR 932 (E) of 30 December 1983 issued in conformity with the Essential Commodities Act, 1956 and the Seeds Act, 1966.
5. Controller General of Patents, Designs and Trademarks. 2011, Manual of Patent Office Practice and Procedure. Version 01.11, as modified on 22 March 2011, Chapter 08: Examination and grant. Clause 8.3.7.d) 7, p. 96.
6. Kochhar, S., *Agric. Today*, 2016, **XIX**(8), 42–44.
7. Kochhar, S., *J. Intell. Property Rights*, 2008, **13**(6), 605–611.

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