Bt Cotton and India's Policy on IPRs

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The commercial cultivation of *Bacillus thuringiensis* (Bt) cotton in India has led to enormous debate on the benefits and costs of genetically modified crops. The promoters of Bt cotton have tried to demonstrate its yield potential and reduction in pesticide use but opponents have argued against the environmental effects and disputed claims of high yields. While the cost-benefit calculations of Bt cotton performance in India have been analysed in numerous studies, the linkage of the Bt cotton issue with India's policy on intellectual property rights (IPRs) has not been given adequate attention. The case of 'unauthorized' varieties of Bt cotton being sold without severe punishment in India has also led many to dismiss IPR as a factor in policy-making. However, such an omission would be shortsighted as IPR issues are set to figure in the agenda in the days ahead. It is a crucial period for review of India's policy on genetically modified crops with the conclusion of the initial three years period for the commercial release of Bt cotton in India. The review process must not overlook IPR issues relating to Bt cotton if India is to frame a long-term rational policy on genetically modified crops.

Bt cotton is a genetically engineered variety of cotton designed by Monsanto, a company based in the US, to reduce or eliminate the need to spray for bollworms. Monsanto created the variety by introducing the Bt gene into the cotton plant. The cotton variety so developed,

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Bollgard, produces the toxin in all parts of the plant such that major insect pests of cotton are controlled, and when bollworms feed on the Bt cotton plant, the protein stops the larva from feeding further and causes its subsequent death.[1]

Bt Cotton is the first and only transgenic crop approved initially for commercial cultivation in India in six states, namely, Andhra Pradesh, Gujarat, Karnataka, Madhya Pradesh, Maharashtra and Tamil Nadu for three Bt cotton hybrids (Bt MECH 162, Bt MECH 184, Bt MECH 12) in March 2002 for a period of three years. The government in April 2004 approved a fourth transgenic crop RCH 2 Bt developed by Rasi Seeds for commercial cultivation in central and southern parts of India.[2] Recently, the government approved new cotton varieties to be produced in the northern states of Punjab, Haryana and Rajasthan.

Bt Cotton and IPRs under India's Law

Bt cotton varieties being sold in India are not currently protected by IPRs nationally. However, this situation may soon change with the various revisions in India's IPR system. It is important for Indian policy makers to analyze the Indian case and the global IPR position relating to Bt cotton and evaluate the implications of granting IPRs in India on such technologies. Two IPR systems are relevant in the case of agriculture: patents and plant breeders' rights.

Patents

India's policy has generally been restrictive in terms of granting IPRs related to agriculture. India's Patent Law of 1970 did not allow patents on products including plant varieties, tissue culture, etc.[3] India also had no system of plant variety protection for decades. Thus, Bt cotton could not be protected under IPRs under this system. However, as mentioned before India's policy is currently undergoing a transition that would affect the Bt cotton issue as well.

India has undertaken major revisions in its patent regime by amending the Patent Act of 1970. The first amendment took place with the Patent Amendment Act of 1999, the second with the Patent Amendment Act of 2002, and India has currently passed the Patent Amendment Act of 2005. The major thrust of these amendments has been in the field of pharmaceuticals but the changes have implications for the agricultural sector as well.

The legal regime relating to patents for plants and particularly for transgenic crops is still evolving in India and also globally. There is enormous controversy on what should be the standard according to Trade Related Intellectual Property Rights Agreement (TRIPs) and among countries on the scope of such patents. In the case of plants, India's patent laws have been amended under the Acts of 1999 and 2002 to allow for process patents in the case of plants but not plants per se. Protection can be granted for treatment of plants, which renders them free of disease or increases their economic value .[4] Some authors point out, however, that this may *de facto* end up in patent coverage for plants.[5] Regarding biotechnological inventions in the case of plants it is not clear if the same would apply.[6]

The Patent Amendment Act of 2005 being passed in April, it is difficult to understand its full implications on agricultural inventions. It is reported that product patents for agricultural products are provided for while the question of patentability of micro-organisms and seeds has been referred to an expert committee.[7] The ordinance that preceded the Act did not categorically exclude seeds developed by novel means thus leading to speculation on the possibility of patenting transgenic seeds.

Clarity is lacking in this area, which may provide benefits diplomatically, but must eventually be sorted out in practice. To focus on some of the actual developments in the area of patents we can refer to some of the recent patent applications in India both with relation to cotton in general and patent applications filed by Monsanto.

Six patent applications related to cotton have been filed in India till December 2003.[8] Monsanto has filed seven patent applications related to plants in the same period.[9] A search in the patent database of TIFAC reveals that Monsanto has filed a total of 72 patent applications in India. The following table lists some of the significant plant related patent applications by Monsanto. Although none of the patent applications mention cotton in the title, Monsanto has filed one patent related to Bt.

Plant Breeder's Rights

India, for decades, had no system of plant breeders' rights. Thus no varieties of plants could be protected under plant variety protection in India, including Bt cotton varieties. India introduced the Protection of Plant Varieties and Farmers' Rights Act in 2001 to allow for plant

Table: Selected Crop Related Patent Applications Filed by Monsanto in India, January 1995-December 2003 (Abstract from Online Search on TIFAC Database on Patent Applications in India at www.tifac.org.in)

Title	Year of Application
Method for reducing pest damage to corn by treating transgenic corn seeds with pesticide	2003
Method for reducing pest damage to corn by treating transgenic corn seeds with Thiamethoxam	2003
Seed Treatment with combinations of insectides	2003
Seed Treatment with combinations of Pyrethins Pyrethroids Clothiandidin	2003
Seed Treatment with combinations of Pyrethins Pyrethroids and Thiamethoxam	2003
Nucleic acid molecules and other molecules associated with soyabean cyst nematode resistance	2002
Method of enhancing biological effectiveness of plant treatment compositions	2001
Compositions promoting chemical substances in plants	2001
Corn event PV ZMGT32NK603 and composition and methods for detection thereof	2001
Transforming plants to express Bacillus Thuringiensis Delta Endotoxins	2001
Expression of Fructose 1.6 Bisphosphate aldolase in transgenic plants	1998
Fungicides for the control of take-all disease of plants	1995

breeder's rights in India. One reason for introducing this Act was to conform to TRIPs by granting protection for new varieties. India also attempted to protect farmers' varieties and other varieties and designed a unique legislation. The Act enables registration under four categories: new variety, extant variety, farmer's variety and essentially derived variety. Under this Act, the Bt cotton variety marketed by Monsanto could be protected as a new variety. Applications under the Act are yet to be made public.

IPRs and Bt Cotton in the Global Context

Two patents relating to Bt cotton varieties called 926 B Pima and 930 B Pima have been acquired in the US as the box illustrates.

Implications of Granting IPR Protection on Bt Cotton Related Inventions in India

India must carefully weigh the costs and benefits of granting Bt cotton related inventions IPR protection in India. Implications of such IPR

Box: Patents on Bt cotton in US

Patent Numbers:
6,093,876 July 25, 2000
6,102,971 August 15, 2000

Sections from the Abstract:

The present invention relates to a method for rapidly introducing genes into germplasm which involves the use of crossing, backcrossing, intense selection and agronomic trait selection. The present invention further relates to two new and distinctive high yielding Pima Bt Bollgard.RTM. cotton cultivars, designated 926 B Pima and ***930 B Pima,*** which have been prepared in accordance with the method of the present invention.

Claims include:

Claims on Seed, Plant, plant parts, pollen, ovule, tissue culture, method for producing cotton cultivar seed.

Source: USPTO at www.uspto.gov; Purushothama, 2002

protection on farmers, public sector institutions and domestic companies require analysis. Measures to overcome any negative implications must be devised.

Extent, Scope and Nature of IPR Protection

It is important to evaluate what should be the scope of IPR protection. Broad patent claims may lead to difficulties in acquiring or negotiating many aspects of the plant in question. For example, if India permits similar type of patents which exist in the US related to Bt cotton, the broad nature of the claims would restrict our access to technology. According to Purusotama, "if we carefully try to analyse different claims, the inventors have all the rights on almost all the aspects of these plants. In the first place the varieties are patented, and even if we buy these, we are not free to use any part of this plant (leaf ovule, pollen) for further research without obtaining the original inventors permission. Even the technology to generate tissue culture plants of these varieties is patented and the seed which is developed by growing this variety is also patented".[10] A careful examination must be made when granting patent claims and mechanisms for transfer agreements and negotiations must be looked into.

The nature of the protection granted is also important in the case of plant breeders' rights. Under India's current law, claims could be

made by firms, public sector institutions, NGOs or farmers on other varieties of cotton provided they can meet the set criteria. The interpretation of these categories could prove crucial in the coming years. In the case of Bt cotton varieties or varieties used in developing Bt cotton, a situation could arise where there are overlapping claims and disputes over ownership. This could block access and sharing of resources required for innovation.

Ensuring Access to Technology

Public sector initiatives to develop local Bt cotton varieties also must be kept in mind in deciding future policy. The public sector institutions in India have undertaken two major initiatives to produce Bt cotton locally.[11] These programmes utilized *cry 1a (b)* gene and the *cry 1a (c)* gene but were not very successful in developing Bt cotton.[12] Yet the Indian government wants to develop Bt cotton in the public sector because of the fear that private companies may neglect cotton varieties, may not fully meet the needs of the Indian farmer, and that the price of Bt cotton sold by firms may be too high for the small or medium farmer.[13] The *cry 1A (b)* and the *cry 1Ac* genes are proprietary and are being allowed for use for research purposes only.[14] Indian government must therefore address the issue of how to negotiate or develop agreements for ensuring that commercial varieties of Bt cotton can be sold by the public sector in future.

Private sector has also been attempting to produce Bt cotton in India. The IPR issues relating to Bt cotton may also affect the initiatives of domestic companies to produce Bt cotton. Swarna Bharat Biotechnics Private Ltd (SBBPL), Hyderabad, India, a consortium of seven Indian seed companies is attempting to develop Bt cotton.[15] The consortium has received licences for two genes derived from Bt from the National Botanical Research Institute (NBRI), Lucknow, India, for Rs. 7.5 ($ 0.16) million over a three year period and a royalty of 3 per cent.[16] With the introduction of novel Bt cotton varieties, SBBPL, which has a 30 per cent share of the total Indian cottonseed market, expects to claim some of the Rs 30 ($0.66) billion market per year that is at present monopolized by the joint-venture company Monsanto-Mahyco Biotech, Mumbai, India.[17] In order to promote indigenous efforts to commercialize Bt cotton, steps will be required to ensure access to technology in the future.

Farmers' Rights

The extent and scope of IPR protection should be closely evaluated in terms of its impact on farmers. India's plant breeders' rights law contains a crucial provision that farmers are allowed to save, exchange, use, and sell seeds of a protected variety but not under the breeder's registered name. India has attempted to make a provision to take care of farmer's rights to save and sell seed under the clause on Farmers' Rights, but this should not be negated either through amendments to the Patents Act, other policies such as the Seed Acts or through membership in international bodies such as UPOV. Some analysts have pointed out that the definition of 'branded' seed is unclear and since firms can identify a seed by its genetic makeup rather than the brand name, firms who intend to assert their IPR over their varieties could do so.[18] Although it would be difficult or impractical for multinational companies to attempt to restrict farmer exchange through legal means in India at present, it does not preclude such cases from arising in the future, nor does it mean that there are no other means of enforcing their proprietary rights if the situation so demanded.

Legal System in Practice

The actual functioning of the legal system must also be carefully observed. An interesting case of a patent on cotton being granted in India, though the law did not permit such patents, is illustrative. In 1987, Agrecetus, a multinational corporation, applied for a patent in India titled, "Genetic Engineering of Cotton Cells and Lines" and after examination the title was changed to, "Methods of Producing Transformed Cotton Cells by Tissue Culture". The patent was awarded in India in 1992. The patent created enormous controversy raising questions about the broad claim granting a monopoly on all genetically engineered cotton cells. It also raised a debate on whether genetic manipulation could be considered novel and therefore patentable. The Government of India initiated action after the patent was granted to get it revoked listing commercial and health reasons. After a hearing before the Joint Secretary in the Ministry of Industry the government issued a notification in 1994 revoking the patent noting that it was prejudicial to the public but not providing any further elaboration on the point.[19] In order to avoid such mistakes, the legal system must be monitored and redressal mechanisms must be workable.

Company Strategies

Finally, the reality on the ground on IPR issues will be shaped by how companies pursue their rights, and it is important to analyze these factors. It is reported that Mahyco has filed a case against Navbharat—the seed company that sold Bt cotton varieties without government approval while Mahyco-Monsanto awaited clearance for their variety—for infringing its intellectual property rights.[20] Yet, the case of these 'illegal' sales may have actually speeded up the clearance for Monsanto-Mahyco's Bt cotton. Monsanto has already co-licensed the *Cry 1Ac* gene to nine more Indian companies and Ranjana Smetacek, the company's spokesperson in India, says Monsanto welcomes the widespread usage of Bt cotton.[21] Since Monsanto is already concluding licences with various domestic companies, India could focus on ensuring that technology transfer takes place through careful negotiation. However, this should not blind us to the fact that Monsanto may contest the commercialization of indigenous Bt cotton in future, particularly if sales of Bt cotton from other sources or other cotton varieties cut into their market share.

The current focus on regulating the entry of genetically modified crops in India should not deter policy makers from paying close attention to the intellectual property aspects. The main reason for granting IPRs is as an incentive to invest. In the case of Bt cotton, investment is already underway, but steps are required for ensuring further investment and technology transfer. Whether this could be achieved through careful negotiations or IPR protection should be looked into. It is the right time to analyze what would be the real benefit in allowing IPR protection on Bt cotton related inventions at this stage, and ensure that in case IPRs are granted, such benefits materialize.

Endnotes

1 http://www.monsantoindia.com/monsantoin/literature/what_is_biotech/btcotton_traits.html
2 Indian Express, April 16, 2004.
3 Subbaram, 1995.
4 Ramakrishna, 2003.
5 ibid.
6 ibid.
7 Indian Express, March 23, 2005.
8 TIFAC, IPR Bulletin, 2004.
9 ibid.
10 Purushothama, 2002.
11 Alam, 2004.

12 ibid.
13 ibid.
14 ibid.
15 Krishna, 2004.
16 ibid.
17 ibid.
18 Ghose, 2003.
19 Rao, 1999.
20 Lalitha, 2003.
21 Krishna, 2004.

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