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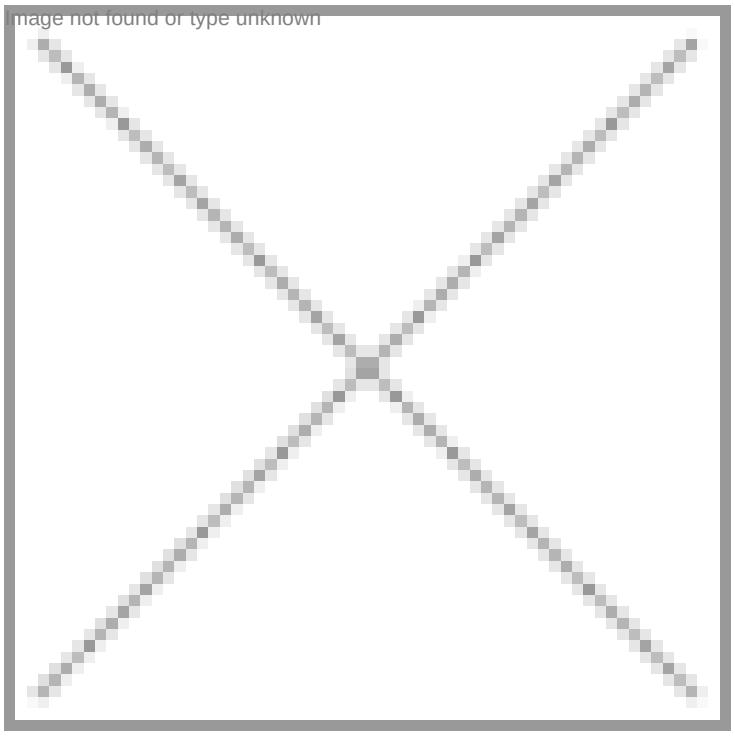

Indian Agri biotech industry in credibility crisis

The debate around the safety of genetically modified crops hits a new roadblock.

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India is on the verge of approving its first genetically modified (GM) food crop, Bt Brinjal. Brinjal was first transformed in 2000 and has made its way clearing each regulatory step and is now in the final stages of large scale field trials.

As Bt Brinjal reaches the end of the regulatory assembly line and nears the market, one issue has raised a lot of debate. Should information submitted to the regulator be kept a secret? Should that information be considered an intellectual property? Or precisely, does safety tests conducted on GM crops be reserved for private eyes of the official in the Department of Biotechnology (DBT) or the Ministry of Environment and Forests (MoEF) and not be allowed for independent public scrutiny before the approval of the product?

These questions are inevitable and form the core of a legal case at the Delhi high court. The case has been filed by the biotech crop developer Mahyco and the Central Information Commission with the DBT and Divya Raghunandan of Greenpeace as respondents.

Let's take a closer look at what can be an intellectual property. Intellectual property right is the provision of certain rights over the utilization of an invention to the inventor. Such rights include copyrights as well as patents and trade marks. Some of these rights, like patent rights are always given for a finite period, say 20 years. They are conferred only after a registration of the invention and in the case of a patent the process of registration also ensures the disclosure of the invention to public, while protecting the unauthorized use of the invention. Thus, the spirit of an intellectual property right is to endow benefits to the society while ensuring an incentive to the inventor.

Arguments by crop developer

The argument held by the industry is that while regulatory information is not an invention it has some aspects of trade secrets and thus if disclosed could affect the privacy of the individual firms and could cause commercial loss.

This is not true, and the best example is pharmaceutical patents where the regulatory information, which is clinical trial data, is available after submission for any introspection, under Right to Information and similar acts across the world. The commerce is not affected in this case, because, the data by itself, even if it has sensitive information on the formulae of the production processes, is not of any use to a competitor as the utilization of that data to produce a successful marketable product requires the permission and recognition of the regulator.

In fact, in the case of pharmaceuticals, the growth of inexpensive generic pharma drugs, which has brought health care to reaches of the economically deprived masses of our country, has been possible because product patents were not recognised (till 2002) by the Indian patents Act 1970. Additionally the provisions under the Drug and cosmetics Act 1940, requires only equivalence of the generic drug molecule towards an approved version of the drug molecule and permits the use of clinical trial data submitted by the inventor to approve the bio safety of the generic drug, thereby making the generic drug free of the expensive and time consuming tests required for bio safety.

Such a provision does not exist in GM crop regulation because, unlike the case of a medicine where a purified form of a drug is consumed, in a GM crop, an entire organism which has been subjected to genetic modification is consumed, necessitating bio safety, as well as morphological, physiological and metabolic assessments of each variety that is genetically modified.

The current regulations for GM crops, for reasons to disallow unsafe approvals and to protect the right of the technology holder of a GM crop, has already adopted the recommendations of the Sub committee for Streamlining the Current Regulatory Framework for Transgenic Crops in June 2006. It included the clause to procure an "authorization/ NOC from the technology provider in the case of sublicense" as a requirement to be fulfilled before any new Bt cotton hybrids for the Mon 531 event is approved.

Thus, neither in the case of a life saving pharmaceutical compound nor in the case of a genetically modified crop, can the data submitted to the regulator for bio safety or agronomic assessments be misused. In fact such a misuse can be penalised under law. This means, the disclosure of the data for public introspection only increases the credibility and transparency of the process of regulation while in no way affecting the commercial prospects of the crop developer.

Chronology of events leading to the Delhi High Court case:

Feb 2006: Biosafety data of Brinjal, ladies finger, mustard and rice is sought under the RTI act by Divya Raghunandan of Greenpeace.

March 2006: The public information officer, of the Department of Biotechnology, refused information under Section 8 .1.d RTI act which states

"information including commercial confidence, trade secrets or intellectual property, the disclosure of which would harm the competitive position of a third party, unless the competent authority is satisfied that larger public interest warrants the disclosure of such information;"

May 2006: The Appellate authority of the department reiterates the information officer's order.

April 2007: The central information commission heard the case on 13th April 2007. It ordered the data to be disclosed immediately on the grounds of public interest in the issue

May 2007: DBT provided only the result summaries of the data that are derived from the data for genetically modified brinjal. It directed the appellant to go to the ministry of environment and forests and take down the thousands of pages of data under supervision of an officer. There was no data given on the other three crops, (i.e) rice, Okra and Mustard.

November 2007: The Central Information Commission (CIC) heard the case again on the basis of a non- compliance petition. The CIC also made an observation after going through the acts and rules related to the genetically modified organisms (under the EPA, 1986) of the fact that,

"From a perusal of these rules it is quite clear that genetically engineered organism or cells are recognized by government as an item potentially hazardous to public health. It automatically follows that full compliance with these rules is a matter of public interest. In light of this we cannot agree that inspection of this information can be provided only in a restricted environment to members representing Civil Society"

The commissioner ordered the DBT to provide the information within ten days in a CD format.

December 2007 till August 2008: Mahyco Seeds, the developer of Bt Brinjal approached the Delhi High Court and obtained a stay on the order of the CIC on December 6, 2007. It has also has seeked to quash the order of the CIC on the grounds that:

1. The order is contrary to articles 14 and 21 of the constitution (denial of a right to hearing and make submissions) and thus does not constitute due process under law, and

2. The disclosure of the bio safety information of transgenic crops affects the commercial interests of the company as the information involves IPR.

Does the Trade Related Intellectual Property Rights (TRIPS) regime of the WTO prevents disclosure of regulatory information?

TRIPS does not interfere in data disclosure, provided protection against unfair commercial use is assured by governments.

Article 39.3, section 7 of the TRIPS regime states

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Three arguments emerge from this clause. One, a member country need not protect information pertaining to agribiotech but only related to pharmaceutical or agricultural chemical products. Second, the data needs to be protected from unfair commercial use and not mere disclosure; third, in any case, public interest can override the reasons to protect the data.

Furthermore it is a norm that the provisions of an international treaty like TRIPS can only by read into the municipal law where there is a lacuna in the law and where the treaty does not run contrary to the municipal law in force. In this case, the RTI Act 2005 being a law in force in India is applicable to any case, regardless of the provisions of the TRIPS agreement.

Does the disclosure of data affect commercial prospects of the crop?

The data in question is the biosafety assessments of a transgenic crop. The contention by the industry is that the data contains protocols, event Id information, data generated under biosafety studies, methods, testing locations and the kind. Apart from the inconceivable argument that is not separable, it is quite an erroneous claim that protocols which are stipulated by the government are sensitive business information; event Id's which are anyway provided by the crop developers post the approval to the various laboratories under the Biosafety protocol and is now also one of the preconditions stipulated by the Supreme Court order for conducting field trials cannot be disclosed; methods for protein estimation and evaluation which have to be standardized methods that have been published in leading journals and accepted worldwide are actually secrets or that locations of field trials that are conducted, which need a prior permission from the panchayat or local administration officials of the area, are confidential and can affect the business adversely.

If the information is not protected by the present intellectual property laws in the country, then, it's a deplorable and unethical practice of the company to provide unprotected information to the regulator for approvals and then holding the regulator ransom for disclosing information to the public. It is not the duty of the GM regulator to protect patent rights, and if the information submitted to the regulator contains patentable information, then the crop developer should approach the patent authority first to grant a patent on the contentious information and then apply for a crop approval. What cannot be granted an intellectual property right cannot be held from public disclosure under any circumstances.

It needs to be noted that information has been generated for a statutory requirement under rules of the Environment Protection Act 1986 and has been submitted to the authorities under the same requirement. Thus the information is not that of the crop developer but belongs to the government specifically created and submitted to the Government for the purpose of obtaining clearances. The notion of 'ownership' of the information is a polemic argument, as the protection against unfair commercial use is anyway being guaranteed by the government.

However, there is only one case where it might affect the commercial prospect of the product. If the information disclosed is found to have a faulty assessment of health and safety, then the disclosure of this might stop the commercial release of the product. But, if the product is really unsafe, then there cannot be a commercial prospect for it anyway.

The debate of open access to safety test data has been growing stronger with cases of faulty assessment of drug as well as genetically modified crops.

Here are two such cases which have raised doubts on the credibility of assessments by the authorities primarily because the data in question was prevented from public disclosure.

Prozac, an anti depressant drug belonging to the multinational pharma giant Eli Lilly, belonging to the category of drugs collectively known as selective serotonin reuptake inhibitors (SERI's) was found to be ineffective and no better than a placebo, in February 2008. The study was done by Dr Irving Kirsch of the university of Hull and colleagues in the US and Canada. It is one of the world's best selling drugs and has been used by more than 40 million people. The study was a complete analysis of almost all data available on the drug, including the results from the studies that manufacturers chose not to publish at the time of approval. Some of the trial data were still not available for the reanalysis, and was prevented by the United States Food and Drug Administration to be disclosed under the Freedom of information Act, possibly under pressure from the industry.

In April 2004, the French paper Le Monde, reported that the French genetic engineering commission (CGB) expressed safety

concerns in the bio safety assessment of the maize MON 863. Following this, Greenpeace fought a case at the Cologne administrative court to access the controversial rat study MSL â€“ 18175, which was opposed by the multinational seed corporation Monsanto. In June 2005, the court ruled that the study be given to Greenpeace. An independent expert in toxicology, Dr. Gilles Eric Seralini of the Committee for Independent information and Research on Genetic Engineering (CRIIGEN), studied the report and in contrary to the European Food Safety Authority's (EFSA) decisions found kidney and liver toxicity in the rats that are fed with this maize. He later publishes a peer reviewed paper in March 2007.

The fact that it took almost 19 years after the launch of the drug Prozac by the USFDA, or more than two years after the submission of the study of the Maize Mon 863 by EFSA (to merely procure data because it had been kept undisclosed by the industry, should surely not be the kind of unethical and irresponsible behaviour that we should emulate.

The proposed National Biotechnology Regulatory Authority has suggested a single window system to fast track approvals by bringing risk assessment into the system with a dedicated unit. These measures, while on one side centralises decision making on a matter that has implications on matters of health, safety, trade, socio economic conditions, agriculture and ethics of the public, will raise no more than distrust in the authority if transparency and accountability for the decisions are not in incorporated. While many in the agribiotech industry may not support the position taken by the crop developer in the Delhi High Court, and might support the idea of free and open assessment by independent experts as a part of the regulatory regime, much needs to be done to gain trust on the regulator and the assessments. There are no short cuts to gain quick approvals. At the same time risking public credibility by choosing to stall a public disclosure of information at a court is the least advised route and is ill productive in the long run.

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