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From the Director's Desk

K.T. Chacko

Shortage of food and food crisis has speedily vindicated the importance of biotechnology in recent years. Its proliferation has justified that in the wake of an impending food crisis, world hunger will be mitigated to a large extent through Genetically Modified Organisms (GMOs), especially by producing a wide variety of agricultural products. As GMOs are produced through adequate involvement of technology and traditional knowledge, patenting such technological process and knowledge becomes essential for the world as a whole to benefit from an economic or trading activity that is currently witnessing high growth. Developing countries argue, the TRIPS regime which is operating today is not equipped to address this problem. They insist that amendment to TRIPS merits immediate attention of the WTO to check the problem of bio-piracy and misappropriation of traditional knowledge taking place in producing such products.

Developing countries are taking keen interest in bringing the issue of TRIPS and Convention on Biological Diversity (CBD) to the forefront of the WTO negotiations. India along with Brazil, China and other African countries have suggested that implementation of the two major elements of the CBD such as the sovereign rights of the states over biodiversity and protection of traditional knowledge may be ensured. In recognition of such rights of the sovereign states over biodiversity, the CBD provides that the users of biological material must seek prior informed consent (PIC) from the designated authority identified by each member state of the convention.

Moreover, users are expected to enter into fair and equitable benefit sharing arrangements emanating out of the utilization of genetic resources. Developing countries to that extent argue that though TRIPS recognizes protection of technologies that are being used to develop biological material; the rights of countries providing the material are conveniently ignored under the present system.

With a view to rectifying such lacunae and ensuring implementing of both TRIPS and CBD in a mutually supportive manner, developing countries have been insisting for an amendment in such TRIPS regulation. The proposal to amendment initiated by like-minded countries such as India, Brazil, China, ACP countries centers around certain pressing issues like disclosure of biological resources, and/ or associated traditional knowledge, providing evidence of PIC and benefit sharing.

Though the proposal faces stiff opposition from developed countries, who emphasize that disclosure is not the most effective way of addressing bio-piracy, developing countries with the increasing support of many other developing countries propose it to be a part of future negotiations in WTO. If world is to benefit from the issue of biotechnology, then the collective responsibility of developed and developing countries is important to bring a breakthrough on disclosure requirement under TRIPS.

Biotechnology and Trade: Issues and Concerns

Nitya Nanda*

Issues surrounding the biotechnology and its benefits have created some amount of controversy in world market. Genetic Modification (GM) of food products continue to feature in WTO negotiations and are hitting up different parts of the world. Many proponents of GM issue believe that the Sanitary and Phytosanitary (SPS) measures and the Technical Barriers to Trade (TBT) agreements fully cover the regulatory approval processes for biotech products and therefore to a large degree are safe whereas opponents have different view. It is recognized that consumers hold the ultimate power of a dynamic and free marketplace and they need to be informed well about the pros and cons of these products. This paper makes an attempt to analyze the issue in detail. In view of the huge prospects of world trade in this area, the WTO may need to examine, cooperatively and collaboratively, the implications of biotechnology issues for international trade.

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Introduction

DEVELOPMENT of biotechnology and the growth of biotech trade have generated serious debates on related trade policy issues. There are several aspects of biotechnology that have implications for trade policy. The regulatory challenge of biotechnology is a current subject of debate in the WTO. This is the most controversial aspect of biotech trade as long term health and environmental impacts of biotech materials are not fully known. Given this, opponents argue that extreme caution should be exercised while allowing trade in biotech materials in general and genetically modified organisms in particular. However, the proponents argue that given the benefits of biotechnology, such extreme approach is better avoided.

The *second* aspect of the debate is about the access to technology. While it is argued that biotechnology can make immense contribution to agriculture and medicine and thereby helping fight against poverty, hunger, malnutrition and environmental degradation, the lack of access to technology can keep the potential benefits out of reach for a large part of the population, especially those who need it most. Since access to patented knowledge is governed by the rules under the TRIPS Agreement of the WTO and similar provisions of several other trade agreements, there is a trade angle to access to biotechnology that needs reconsideration.

The *third* aspect relates to issues surrounding traditional knowledge and bio resources which are often useful in the development of biotechnology. The terms of access to such resources and sharing of the benefits of such technology developed from bio resources are currently embroiled in controversy. This is because these resources have been maintained by community over the centuries and are mainly traditional in nature. Exploitation of such traditional knowledge and resources is attracting the centre stage of trade negotiations at the WTO. Another related issue that has often been highlighted is the ethical question related to manipulation of microbes, plants, and animals, as well as the commoditization and exchange of living organisms.

Biotechnology: Benefits, Risks and Concerns

The UN Convention on Biological Diversity (CBD) defines biotechnology as "any technological application that uses biological systems, living

organisms, or derivatives thereof, to make or modify products or processes for specific use". Genetically modified organisms (GMOs) can be defined as organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally. The technology is often called "modern biotechnology" or "gene technology", sometimes also "recombinant DNA technology" or "genetic engineering". It allows selected individual genes to be transferred from one organism into another and also between non-related species. While traditional biotechnology improves the quality and yield of plants and animals through, for example, selective breeding, genetic engineering is a new aspect of biotechnology that enables direct manipulation of genetic material (inserting, removing or altering genes). The new technology speeds up the development process and brings more certainty in the process.

The proponents argue that genetic engineering entails a more-controlled transfer of genes because the transfer is limited to a single or just a few selected genes, whereas traditional breeding risks transferring unwanted genes together with the desired ones. In genetic engineering, genetic traits from any species—bacteria, virus, fungi, plants or animals— can be introduced into a desired plant species; this is different from conventional breeding in which plant breeders can only work with closely related plant species. For example, the "Bt" widely used in genetically modified crops is *Bacillus thuringiensis*, a common bacterium that produces insecticidal proteins. By introducing the bacterium's gene for toxin production into cotton, for example, BT cotton acquires the ability to intrinsically repel insects, reducing the burden on farmers to use insecticide against pests, and consequently a better environment.

It is well recognized that biotechnology has the potential to provide a wide range of products and leverage the existing production skills both in the pharmaceuticals and the agricultural sector. In biotechnology, organisms can be designed with the aid of genetic engineering so as to introduce desirable traits into a species, creating a specialized organism with specific traits. Genetically modified products include various types of medicines, vaccines, food products, food ingredients, fibre, and feeds. Specific examples range from pest-resistant crops to synthetic insulin to genetically modified algae for use in biofuel. It is also accepted that the farming sector in the developing world will require large scale biotechnological interventions to deal with the impending climate change that is likely to affect agriculture in the developing world disproportionately. Proponents of biotechnology argue that it has the potential to bring crops with better yields and nutritional values; resistance to diseases, pests, and herbicides; higher tolerance to climatic variations; reduced consumption of pesticides/other agricultural chemicals.

Against these advantages, there are many potential side effects in terms of possible adverse impacts on the environment and human health that are unknown. Although many studies claim that there is no evidence that genetically modified (GM) foods are unsafe, it is also true that there is no evidence that GM foods are safe. To provide a reasonable certainty that no harm will result, several types of data and long-term studies are required which are not available. An experiment reinforced concerns about the possible adverse health effects after exposure to transgenic foods. In this case, Losey, Raynor and Carter (1999) reported that Bt corn, a kind of GM plant, may be a hazard for monarch butterfly larvae. They deposited some unspecified Bt corn pollen onto milkweed leaves and made the larvae feed on these leaves. After a four-day period, the researchers found a lower survival rate of larvae feeding on leaves deposited with Bt pollen than larvae feeding on control leaves without pollen. Although this report only used monarch butterfly larvae as its target organism, it indicated that GM foods might pose a potential health risk to humans.

Some simple experiments and tests have attempted to demonstrate that the protein in GM foods breaks down into small peptides or amino acids in in vitro-digestion. However, the tests provide no information on toxicity and the result from the aggregate exposure to these proteins. Even specialists who

support the spread of GM foods have noted that it is impossible to provide assurance of absolute-zero risk because of the inadequacy of methods to screen for toxicity and allergenicity.

While the debates and discussions have covered a broad range of aspects, the four main risks debated are allergic reaction (allergenicity), toxicity, gene transfer and outcrossing. As a matter of principle, the transfer of genes from commonly allergenic foods is discouraged unless it can be demonstrated that the protein product of the transferred gene is not allergenic. Gene transfer from the GM foods to cells of the body or to bacteria in the gastrointestinal tract would cause concern if the transferred genetic material adversely affects human health. This would be particularly relevant if antibiotic resistance genes, used in creating GMOs, were to be transferred.

Another issue is the movement of genes from GM plants into conventional crops or related species in the wild (often referred to as "outcrossing"), as well as the mixing of crops derived from conventional seeds with those grown using GM crops. This could create health problems in humans, anti-biotic resistance in plants and associated insects, long-term damage to ecosystems, loss of biodiversity, and lack of consumer choice. This risk is real, as was shown when traces of a maize type which was only approved for feed use appeared in maize products for human consumption in the US. Several countries have adopted strategies to reduce mixing, including a clear separation of the fields within which GM crops and conventional crops are grown. However, this might not be feasible in many countries where there are large number of small farms side by side.

GM foods currently available in the international market have passed risk assessments, and no effects on human health have been shown as a result of the consumption of such foods by the general population in the countries where they have been approved. However, critics argue that "Franken foods" are the wrong answer to the problems of hunger and malnutrition, which they claim are the outcomes of distributional problems.

Biotechnology seems to have some serious concerns relating to the access to patented knowledge. The concern of access to existing patented knowledge got deeper in the 1990s with the production and patenting of knowledge tools. This became particularly prominent in the field of biotechnology when several companies started developing and patenting technology knowledge such as DNA sequences, to sell these to companies who would actually use these to develop actual products. This change also brought a far reaching change in the way patents are used. While traditionally patents have been used as a protection against imitation by competitors, the tool companies sought was broader patents for methods and data. Then they entered into contractual arrangements with the companies for their eventual use to produce end products (OECD 2004).

Access to patented knowledge in biotechnology is thus crucial for addressing the problems of poverty, malnutrition, food security and environmental sustainability. An example is the development of Vitamin A "Golden Rice". This technology can improve nutrition in developing countries as millions of people in poor countries suffer from Vitamin A deficiency. Marketing of Golden Rice would require dealing with a huge "patent thicket" made up of 70 patents originally held by 30 different patent holders (Schimmelpfening 2004). Monsanto, which holds the largest number of patents among those, agreed to give royalty-free licenses for marketing golden rice in developing countries. Syngenta, which received the right of golden rice patent, also agreed to provide golden rice to developing countries without any patent fees and expects to recover the costs by marketing golden rice in developed countries. However, such a solution cannot be expected in all situations. In fact, it has been also argued that Monsanto and Syngenta agreed for these, essentially to make GM technology more acceptable.

The ethicists worry that there are no limits to the possibilities of gene transfers, even between plants and animals, which leads to discussions about whether limits to the use of this technology should be drawn based on ethics. In the arena of trade policy, these ethical questions pose a unique economic dilemma: to what

extent should commoditization and exchange of living organisms be allowed? This also links intellectual property rights issues to biotechnology trade. These concerns relate to fears that biotechnology will transfer resources from the public sphere to private ownership. Firms that have invested in the development of genetically modified varieties want to protect their proprietary knowledge, but many farmer groups have protested that enforcing intellectual property rights will disrupt their access to seed. Farmers accustomed to harvesting and replanting their seeds are not willing to pay for GM seeds year after year. These debates draw attention to the controversial TRIPs Article 27.3(b), which exempts certain life forms from patentability but requires countries to establish some form of protection for plant varieties.

Spread of Biotechnology

Genetic engineering techniques and their applications have developed rapidly since the introduction of the first genetically modified plants in the 1980s. In 1999, genetically modified crops occupied less than 3 million hectares of land which rose to 40 million hectares in 1996. Currently, it accounts for about 160 million hectares of land spread over 29 odd countries making up about 14 per cent of the world's total agricultural area. The US is by far the biggest GM farmer and North America (including the US, Canada and Mexico) accounts for about half of the global agricultural land under GM crops. Outside North America, GM technology has been enthusiastically adopted in Latin America where most countries are cultivating GM crops. The technology is vehemently opposed in Europe where most countries have severe restrictions on growing GM crops. In Asia, only a few countries like India, China and Pakistan have adopted it, while in Africa GM technology is largely opposed in many parts except South Africa, Egypt and Burkina Faso.

As of now, developing countries are planting GM crops at a more rapid rate than rich countries. Interestingly, in Africa, the technology is opposed not due to domestic concerns but due to the fear of losing the European market on which these countries are highly dependent for their agricultural exports. They have even refused to accept food aid that included GM foods. Cultivation of transgenic crops has so far been most widespread in the production of soybeans accounting for about half of total transgenic crop production, followed by maize (corn) and cotton. Interestingly, cotton is the crop where GM technology penetration is the highest with 82 per cent cotton produced globally is of GM variety followed by soybean and maize with 75 and 32 per cent of penetration respectively (James 2011).

Genetic engineering in agriculture has mainly been used to modify crops so that they have improved *agronomic* traits such as tolerance of specific chemical herbicides and resistance to pests and diseases. Biotechnology is also making significant contribution to pharmaceutical sector by way of providing innovative medical solutions both in medicines and also medical diagnostics in terms of facilitating treatment of life threatening diseases like AIDS, diabetes, etc.

International Regulations of Biotech Trade

The right for a country to set its own environmental and food safety regulations at the national level is provided for in Article XX of the GATT. But members of the WTO have trade obligations under other GATT Articles (MFN, national treatment, customs transparency), and under other WTO agreements (most notably the SPS and TBT Agreements) that restrict the extent to which trade measures can be used against GMOs without risking a case coming before the WTO's Dispute Settlement Understanding (DSU). In 2006, WTO Panel issued a Report of the case in which Argentina, United States and Canada claimed EC regulations and practice to be inconsistent with SPS Agreement (also TBT Agreement and GATT). The Panel found out that GMO may be treated as pests and therefore they fall within a scope of SPS, but not within a scope of TBT and GATT. The Panel made wide interpretation of SPS Agreement provisions, especially the level of risk assessment (Slok undated).

While, there are no specific international regulatory systems currently in place under the WTO, some other international

organizations are involved in developing protocols for GMOs. The Codex Alimentarius Commission (Codex) is the joint FAO/WHO body responsible for compiling the standards, codes of practice, guidelines and recommendations that constitute the Codex Alimentarius: the international food code. The Codex Alimentarius Commission at its 26th session in 2003 adopted Principles and Guidelines on foods derived from biotechnology. These are overarching principles on the risk analysis of foods derived from modern biotechnology and guidelines for food safety assessment of foods derived from recombinant-DNA plants and micro-organisms. The premise of these principles dictates a premarket assessment, performed on a case-by-case basis and including an evaluation of both direct effects (from the inserted gene) and unintended effects (that may arise as a consequence of insertion of the new gene). Codex principles do not have a binding effect on national legislation, but are referred to specifically in the Sanitary and Phytosanitary Agreement of the World Trade Organization (SPS Agreement), and can be used as a reference in case of trade disputes.

The Cartagena Protocol on Biosafety (CPB), to the Convention of Biological Diversity, signed in Montreal on 29 January 2000, an environmental treaty legally binding for its Parties, regulates transboundary movements of living modified organisms (LMOs), which is defined in Article 3 as any living organism possessing a novel combination of genetic material obtained through the techniques of modern biotechnology. GM foods are within the scope of the Protocol only if they contain LMOs that are capable of transferring or replicating genetic material. Thus, while LMOs for use in food, feed and processing are included, GM products derived from but no longer containing GMOs are not covered.

The cornerstone of the CPB is a requirement that exporters seek consent from importers before the first shipment of LMOs intended for release into the environment. As of now, 141 nations have ratified Cartagena Protocol. Countries such as the US, Australia or Russia are not parties to this convention. Moreover, Canada and Argentina, despite signing the Protocol in 2001 chose not to ratify it. Since 2002, the EC is also a party to the Cartagena Protocol. The Protocol regulates import and the whole procedure of decisions permitting to import LMO. Although it concentrates on a transboundary movement of LMO and technologies, it also regulates the information procedures concerning LMO which are intended to direct use in food or feed.

At the WTO, efforts have also been made to address the issues of access to bio resources and traditional knowledge as well as benefits to communities maintaining them. At the TRIPS Council meeting on 8 March 2004, Brazil, Bolivia, Cuba, Ecuador, India, Pakistan, Peru, Thailand and Venezuela called for greater urgency in resolving possible conflicts between the TRIPS Agreement and the Convention on Biological Diversity (CBD). The Convention was established with the three main goals of conservation of biological diversity, sustainable use of its components and the fair and equitable sharing of the benefits from the use of genetic resources. The US and Japan have opposed it and suggested that the World Intellectual Property Organization (WIPO) is the right forum to discuss this. Meanwhile, free trade agreements continue to change the contours of the relationship between trade law and biotechnology as many of them include TRIPS plus provisions including plant patentability.

Biotechnology and India

In India, biotechnology industry started a humble beginning in the late 1980s as low end biotech ventures in the form of tissue culture companies and ELISA or other formats of in vitro diagnostics. But the real beginning came much later in the mid-1990s when some pharmaceutical companies expanded their operation into biotechnology. Very soon new biotech companies also started as dedicated ones which were small and had narrow focus with a couple of products. Traditionally, Indian pharmaceutical companies have a strong presence in generic drugs market and this has helped many of them enter the market for biogenerics – generic therapeutic products.

Agro-biotech is another important area where a number of products have been introduced in the Indian market. However, this segment of the market is dominated by foreign companies or their affiliates. In terms of area cultivated, India is the fourth largest country (after the US, Brazil and Argentina) with 10.6 million hectares of land under GM crop but has adopted only one crop, cotton. In contrast, China has only 3.9 million hectares of land under GM crops but produces cotton, papaya, poplar, tomato and sweet pepper of GM varieties.

India's strong skills into the IT sector have played an important role for some Indian companies to diversify in bioinformatics. Many Indian companies are also offering attractive cost benefits to foreign companies through outsourcing, including contract research activities. At a broader level, the Indian biotechnology industry is still at a nascent stage more of generic-focused rather than innovative research-oriented. Some companies have however moved on from being generic focused to innovation oriented.

One defining feature of Indian biotechnology industry is its high export orientation as it earns about 60 per cent of its revenue from the export markets. Export orientation is however not similar across different segments of the industry. Among the products, biopharma earns about 60 per cent from the export markets while for bioagri and bioindustrial products, export orientation is quite low. Biotechnology related services are however more or less entirely dependent on the export markets (TERI 2010a).

In India, the Ministry of Environment and Forests (MoEF) has notified the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/ Genetically Engineered Organisms or Cells in 1989 under the umbrella legislation, Environment (Protection) Act, 1986. Several institutions were created to establish policy guidelines, monitor and review experiments, and issue approvals under the 1989 Rules. They are: IBSC – Institutional Biosafety Committee; RCGM–Review Committee on Genetic Manipulation; MEC–Monitoring-cum-Evaluation Committee; GEAC – Genetic Engineering Approval Com-mittee. IBSC provides initial recommendation/approval, and has to be informed of all proposed recombinant DNA experiments. RCGM conducts field trials, recommends generation of appropriate biosafety and agronomic data from larger multi-field trials. Prior permission from RCGM is required for high-risk experiments wherein the escape of transgenic traits into the open environment could cause significant alterations in the biosphere. MEC analyzes data from multi-location large scale field trial sites and recommends agronomically viable transgenics to GEAC through RCGM. ICAR – Indian Council of Agricultural Research is also involved in the process which generates complete agronomic data to ensure compliance with Seeds Act and recommends commercial release of GMOs. GEAC collates information from the RCGM, MEC, and ICAR and approves large scale use and open release into the environment.

The *Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts* (1994, revised in 1998) approved by the RCGM cover areas of recombinant DNA research on plants including the development of transgenic plants and their growth in soil for molecular and field evaluation (DBT 1998). The guidelines also deal with import and shipment of GM plants (for research use only). Clearance for import of transgenic material for research purposes is provided by the RCGM, which will issue an import certificate after looking into the documents related to the safety of the material and the national need. While no labelling scheme for GMOs exists as such, GMOs do need to be labelled, whether as importer or domestically approved, due to the conditions on the approvals granted by the GEAC on each application for environmental release. Each approval may have different labelling requirements, depending on what is being approved and for what purpose (Baumüller 2003).

Most of these institutions operate under the Ministry of Science and Technology (MoST), with the notable exception of the Genetic Engineering Approval Committee (GEAC), which is housed within the MoEF. The Biotechnology Regulatory

Authority Bill (2009) seeks to rationalize the regulatory space for biotechnology in India. As per its preamble, this is done with a view to making existing regulatory procedures more efficient while ensuring that biosafety norms are not compromised (TERI 2011).

In India, the Ministry of Health and Family Welfare (MoHFW) is the oversight authority for food safety. For nearly five decades the Prevention of Food Adulteration Act (PFA), which was enacted in 1954, has been the sole legislation on food safety in India. The primary objective of this legislation was to ensure consumer safety through preventing fraud and deception in food manufacturing and marketing. In 2006, the entire food safety law in India was overhauled through the enactment of the Food Safety and Standards Act. This provides for a one point regulatory oversight over the entire food chain. This illustrates a shift away, in many ways, from the earlier regulatory ethos of focusing on enforcement mechanisms on the end of the food chain sold in the market to a more preventive approach to risk assessment and reduction of such risk. Nevertheless, though the food regimes is to be under the Food Standards and Safety Authority (FSSAI), the Ministry of Environment and Forests (MoEF) continues to be in charge of the environmental health impacts of food safety regime specifically with reference to the genetically modified foods. This follows from the parameters set up within the Environmental Protection Act 1986, through the notification setting up of the entire regulatory apparatus of approval of GM crops. The Union health ministry had issued a gazette notification in 2006, making it mandatory to label GM food. The notification was not operationalized and the onus of implementing it was put on FSSAI.

Conclusion

Biotechnology and its products have opened up huge opportunities, but also created some risks to human and environmental health. The moral dimension of causing injury to human health also becomes a cause for concern for the government. While, it is difficult to sustain a ban on GM food import in view of the 2006 WTO ruling and the Cartagena Protocol, in markets like EU, GM foods are not able to get much of market access as consumers are still not attracted to GM foods. It is of course natural as consumers do not get any price advantage with GM foods and hence they might not like to face the unknown risks. Consumers are far more receptive when it comes to medical biotechnology where benefits are significant and outweigh the risks. On the other hand, farmers across the world are embracing biotechnology quite rapidly forcing some to believe that in future consumers in some cases might not have the choice other than GM food when it is imported.

Given the scenario, it may however be worthwhile to have an appropriate labeling regime so that consumers can make an informed choice. An issue that becomes crucial here is the burden of the costs of labeling. It would be more effective to have a labeling regime where conventional food producers are asked to put a label saying that it does not contain GM foods. However, it would put an unfair burden on the farmers using conventional technology. In countries like India of course there is another concern if labeling would be of much help as consumer awareness on these issues is quite low.

Given the risks attached with GM materials and food, continuous use of risk assessments based on the Codex principles and, where appropriate, including post market monitoring and surveillance should form the basis for evaluating the safety of GM foods. Different GM organisms include different genes inserted in different ways. This means that individual GM materials and foods and their safety should be assessed on a case-by-case basis. Small and developing countries however will face enormous challenge to put in place such a regime as they might lack financial, institutional and human capacities.

Apart from the moral issues surrounding biotechnology, critics also fear a kind of divide where rich will use organic foods and the poor will be forced to have GM foods. Moreover, the medical potential of biotechnology to prevent and cure several diseases will remain

outside the reach of the poor people as they will remain expensive due to complex intellectual property rights arrangements. This, along with the issue of access and benefit sharing in the context of traditional knowledge and community bio resources, will hold the attention of the global community in coming years.

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Biosimilar Products Development Gets A USFDA Norms Boost

ROBERT SIMINSKI, a Detroit-based patent attorney specializing in pharmaceuticals and biotech issues, recalls how anxiously biotech experts at Indian firms - whom he had met at the India Bio Conference in Bangalore early February 2012 were looking forward to the US Food and Drug Administration's (FDA) draft guidelines for biosimilar product development.

He will be consulting nearly 10 Indian companies, communicating to them what these draft guidelines mean. They need expert help because the draft guidelines are neither specific nor clear and are full of open questions.

But they form the basis for Indian companies to attack a market that would open up by 2015 and could reach $11 billion by 2020. A biosimilar is a product that is similar to a biologic, which in turn is any drug produced through a biological route rather than chemical synthesis.

"It is a pretty good set of guidelines from our point of view," says Sumant Ramachandra, Chief Scientific Officer of Hospira, the only US company that has an approved biosimilar in Europe.

"The ambiguity is about the flexibility of the FDA to judge on a per case basis." Indian and US biotech companies have been largely silent on the guidelines, but they are all studying them at the moment.

The FDA has allowed till 16 April to provide comments; most of the objections of biotech companies will be sent as comments by then.

"We are still assessing the impact of these guidelines on the overall development plans of our company," says Rajesh Jain, joint managing director of Panacea Biotech.

Biosimilars need high investments and long periods of development when compared to generics, and so the Indian companies needed to know in advance what the US regulators will ask when they submit their applications. Many attorneys find the draft guidelines vague.

"The United States FDA did emphasize the importance of highly similar structure," says D'vorah Graeser, who heads a biomedical-focussed healthcare intellectual property firm called Graeser Associates International.

"However, the standard of acceptable similarity itself is not clear, as the guidelines only feature general statements."

It the US issues a final set of general guidelines and nothing more, as is possible, there is more work to be done on a per case basis for Indian companies.

"A question that everybody had which went unanswered is whether biosimilars are going to be interchangeable, the way it is with generic drugs," says Frost & Sullivan Industry Analyst Deborah Toscano.

Interchangeability could become the focus of the debate on biosimilars. Interchangeability means that a pharmacist can substitute a generic version of the biological in a prescription, without checking with the physician, as in conventional generics.

Generics get much of their power and reach because of interchangeability. Innovators of biologics argue that interchangeability is not possible because it is not possible to make a true copy of the original biological. There are minor

variations in the molecule between batches from even the innovator, and so there are bound to be differences between the original molecule and the biosimilar.

"Biological products are so complex and individual product is so diverse that even with the finalized guidelines, there will remain a lot of ambiguity because of the nature of the product itself," says IBISWorld Lead Healthcare Industry Analyst Sophia Snyder.

The biosimilar opportunity is so big that big pharma giants don't want to miss it. Merck has established Merck BioVentures (MBV) to develop biosimilars. Pfizer has tied up with Biocon to globally commercialize Biocon's bio-similar insulin and better its own biosimilars portfolio.

In India, companies like Cipla, Panacea, Dr Reddy's, Intas, Wockhardt, Reliance Life Sciences and of course, Biocon are making big investments on developing manufacturing processes for biogenerics. A $60 billion of biologic sales are slated to lose patent protection by 2017.

(*The Economic Times*, 1 March 2012)

Time to Give Biotech A Boost

EVEN as our country — and the rest of the globe — fights killer diseases such as cancer, diabetes, immune disorders and heart disease, biotechnology has the weapons to win this war. New-age biologic medicines that help control and cure such diseases are fast emerging as a result of our progress in biotechnology. To deliver better and faster on this promise, the Indian biotechnology industry must create cost-effective global scale in biomanufacturing.

With Indian companies making significant investments in biomanufacturing to enter global markets, and global pharma entities looking to India as their manufacturing base, biomanufacturing holds tremendous potential. It offers a stream of additional benefits such as high-end employment generation, multiplier effect on ancillary industries, and opportunity for large engineering and industry, even as it leads to inclusive development. As biomanufacturing takes root, a cluster effect is likely to follow — as it happened in Bangalore — which must be encouraged.

Global professional services firm Ernst & Young stated in a recent report that life sciences and automotive are two manufacturing segments to watch out for in India. As many biopharmaceuticals go off patent, biosimilars, or simply put, generic versions of Biologic medicines are being developed — resulting in a significant opportunity for biomanufacturers. Policymakers need to take steps to nurture biomanufacturing to help India attain leadership in this area. It is encouraging that the government is coming out with a draft biomanufacturing policy with the Association of Biotechnology Led Enterprises. Additionally, the Government is working closely with Indian industry to come up with Biosimilar Guidelines that address cost and time of development, making sure that high standards of quality, safety and efficacy are delivered to patients globally. It is also looking to strengthen the regulatory framework by setting up a regulatory training school.

Advantage India

India has an innate advantage in this sector. It has a significant capacity in generics, and the largest number of USFDA-compliant manufacturing facilities outside the US. According to BioPlan's recently-released Top 1000 Global Biopharmaceutical Manufacturing Index, China holds 8.5 per cent of the global concentration of capacity and employment, India 8 per cent, and Japan and some other Asian countries 9.2 per cent; these areas are growing more rapidly in biomanufacturing capacity than the global average. Leading Indian biotech companies are focusing on biomanufacturing, spurred by the realization that they must build scale to enter the international market.

Biomanufacturing is the fastest-growing industry segment. The rising number of products in development — the proportion of biologics in new medicine approvals has risen by more than 30 per cent during the last decade — and the growth of the biopharmaceuticals industry are driving biomanufacturing. With biotechnology companies' pipelines having more than 5,600 candidates currently in clinical trials, this pattern is set to continue. Larger global companies are also outsourcing their manufacturing to Indian

contract manufacturers. Globally, there is a shortage of biomanufacturing capacity, and India's low-cost-high-value proposition offers an edge.

We have seen how India has emerged as a preferred global destination for the cost-competitive production of active pharmaceutical ingredients (APIs) and generic formulations. Hence, there is no reason why we cannot capitalize on the biomanufacturing opportunity and develop leadership in this sector, too.

Develop Infrastructure

A recent survey of 352 global biomanufacturers ranked China as the ultimate destination for outsourced biomanufacturing — with 17 per cent of the respondents identifying it as their top destination. India was the choice of 13.2 per cent of respondents. One of the primary concerns for biomanufacturers with regard to India was infrastructure. The success of biomanufacturing is dependent on land availability, uninterrupted power supply, supply of large volumes of potable water, and effective effluent treatment. Even as infrastructure develops, we need to create biomanufacturing hubs with a cluster approach. The Bangalore bio-cluster developed owing to the congregating intellectual capital, the presence of leading research institutions and availability of raw material. The city's growth as a hub began in 1978, when Biocon was set up. By the 1990s, attracted by our success, bio-entrepreneurs started flocking here to set up new units. The cluster outsources what it requires rapidly and at low costs, spurring the growth of ancillary biotech companies. Hyderabad became the next big cluster. A cluster brings growth to the region — in terms of employment, investment, and a wide range of socio-economic services that spring up to support the cluster.

Enhance Capabilities

Biomanufacturing demands high standards in terms of technology, human capital, and regulatory aptitude. India's weaknesses associated with biomanufacturing include problems associated with quality management, perceived weaknesses around protection of intellectual property, inadequate financial support, and an unclear regulatory environment. While Indian companies are well-positioned to move ahead, they need rigorous quality control and regulatory compliance to meet global standards. Biomanufacturing is done under current good manufacturing practices (cGMPs); regulations that require well-trained and highly skilled personnel. Adherence to cGMPs is non-negotiable for India to become a global biomanufacturing leader. India also needs to be able to provide a host of capabilities such as fill-finish capabilities, as well as assay and product-characterization testing to their offerings.

Nurture Skills

Biomanufacturing demands a high level of skills and technical expertise. We still don't have a large-enough and growing pool of well-trained manpower to realize the industry's potential. It is important to fill this gap in skills by making sure that students are employable and industry-ready and also by setting up the required educational infrastructure. We must also think creatively in terms of locating clusters. Biomanufacturing hubs can be nurtured near top engineering institutes like IIT Kharagpur or BITS Pilani, giving industry access to high-quality talent. Bangalore is home to some top-class academic and research institutions which have been critical to the city's pre-eminence in biotechnology.

Financial Support

Biomanufacturing is a complex and expensive proposition. It costs between $350 and $900 million (depending upon the product) to build, equip and validate a biomanufacturing facility. And once the facility is up, it can be as long as four years for it to become operational. The government needs to provide a range of tax benefits — extending, until at least 2017, the 200 per cent weighted deduction on R&D to provide an impetus to research, extending the 100 per cent tax-free status for Biotech Special Economic Zones (SEZs), exempting SEZ Biotech units from MAT, and continuing tax incentives on STP exports for an additional 5 years.

(www.thehindubusinessline.com, 29 February 2012)

Neighbours Set for a BT Harvest, What about India?

IN the next 24 months, genetically modified food crops will enter India's neighbourhood. And that will trigger changes in our own agriculture, like it or not.

Between now and 2014, Bangladesh will introduce BT brinjal; Pakistan will introduce biotech corn; Philippines, that already grows biotech corn, will also adopt BT brinjal and biotech rice; Vietnam will adopt biotech corn; and Indonesia will allow biotech corn and biotech sugarcane, according to International Service for the Acquisition of Agri-biotech Applications, a non-profit think tank that monitors adoption of biotech crops globally.

These new crops are designed to attract farmers. The seeds fight off pests, diseases, and yield more from the same farm. In short, they reduce the risks and raise the returns - every farmer's dream.

Not too long from now, families in West Bengal and Bihar will see pest-free brinjal flourishing across the border while they struggle with a dozen pesticide sprays. They will see their Bangladeshi cousins make ten times more money from the same acre. What are the chances that some BT brinjal seed will not be 'borrowed' and sown in India? Nil. Such 'borrowing' is commonplace in farming. Farmers routinely exchange seeds with each other to ensure varietal health. When the borrowing becomes large-scale, the impact on the market and local agriculture can be dramatic.

Two instances in the last decade are classic. Farmers in Punjab liked Super basmati, a popular variety in Pakistan and started growing it in their own fields. Within a couple of seasons, Super basmati (now lovingly called Shabnam) had replaced many of the government-authorized basmati varieties. That's when agriculture ministry and the Punjab Agriculture University woke up to the 'illegal' crop growing under their noses.

Since it was impossible to make farmers give it up, government took the practical approach. Super basmati can be legally exported from India as a basmati (else farmers would be on the warpath) but it is still not recognized as a basmati by the agriculture ministry, much to Pakistan's consternation.

BT cotton, introduced in 2002, is another case. Initially no variety was approved for north India. But that didn't stop Punjab farmers from planting it. Helpless against BT cotton's tide of popularity, by 2005 government had 'released' 60 varieties just for Punjab.

Pakistan found BT cotton borrowed from India flourishing so widely in Punjab and Sind that in 2010 it was forced to officially approve it. Such borrowing is universal. Brazil's biotech soyabean spread to neighbouring Argentina before it was officially permitted. Argentina's law was forced to catch up. Examples abound.

India last year shelved BT brinjal after loud opposition by activists and state-level politicians. But once Bangladesh introduces BT brinjal, no chief minister can guarantee it won't sneak in. Instead of becoming wiser after the event, the smart option is to introduce the biotech brinjal varieties designed by India for India. Else, the stealth and ignorance could be more harmful to the cause of food safety and consumer choice.

Resistance to biotech crops is anyway out of sync with rest of the world. Sixty countries, including fastidious Japan, now allow import and use of biotech food and feed crops. Even in the EU, often upheld as the last bastion against GM food, eight countries — Spain, Portugal, Czech Republic, Poland, Slovakia, Romania, Sweden and Germany — grow BT corn or biotech potato.

Like corporate managers, farmers exchange seeds and tips on cultivation because it helps business. Such exchanges possess enormous economic and social value. Across the world, farm input and consumer goods companies, agronomists and district administrations harness the power exercised by progressive farmers to spread their message. Social media, mobile phones, and agri tourism have accelerated the exchange of ideas, followed by exchange of seed.

(*The Economic Times*, 20 February 2012)

Implications of Recent Proposals on WTO and Biotechnology

THERE are some potentially serious implications of the recent proposals of some developed countries (as part of the Seattle process) to set up a working group in the WTO (or to consider additional disciplines in WTO) to deal with biotechnology.

These proposals have now been included in the revised Ministerial Text of 19 October in two parts:

(a) There is a Para 71 (in square brackets) entitled "Working Party on Biotechnology" which states: "We agree to establish a Working Party on Biotechnology. The Working Party shall have a fact-finding mandate to consider the adequacy and effectiveness of existing rules as well as the capacity of WTO members to implement these rules. It is appropriate for this Group to deliberate within an X period of time."

This proposal has come from Canada and Japan, which had submitted papers proposing to set up a working party or a forum to deal with biotechnology (details are given below).

(b) In the draft Declaration's section on Agriculture, there is a Para 29 (vi) on improving the rules and disciplines (of the WTO). Under this section are listed various proposals. One of the proposals is: "Disciplines to ensure that trade in products of agricultural biotechnology is based on transparent, predictable and timely processes."

The language of this paragraph is similar to the US proposal (in its paper WT/GC/W/288 dated 4 Aug 99) in the context of future agriculture negotiations.

The proposals could have serious effects on the efforts made by developing countries in the Biodiversity Convention to establish a Biosafety Protocol which is aimed at preventing the indiscriminate export to developing countries of potentially hazardous genetically-modified organisms (GMOs) in products such as seeds, food and animal feed.

The GMOs could have adverse effect on agriculture in developing countries (as the genetically-engineered genes could inadvertently contaminate local plants and crops) and could also pose health hazards. To avoid these problems, almost all developing countries of the G77 have taken the lead in fighting for a Biosafety Protocol with an "advanced informed approval" (AIA) system in which GMO products can only be exported if the importing country is first informed and gives approval.

A small number of countries (which are the main producers of GM crops and food) are trying to delay and water down the protocol. They have proposed only a limited scope for products covered, and that instead of an AIA procedure (where exporters are obliged to get the importing countries' permission), exporters should only put information on an internet website and it is up to the importing countries to seek the information themselves and to restrict imports (if they so wish) within a specified period, after which the product should be allowed to enter.

They are also insisting on a clause that the Biosafety Protocol be in line with other international agreements (meaning the WTO).

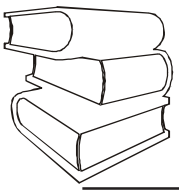
The proposals in the WTO are in line with these efforts to subject the biosafety protocol to new disciplines in the WTO that would restrict the ability of importing countries to regulate imports of GMO products.

If the proposals are adopted in Seattle, they would adversely affect the efforts of developing countries' delegations in the Biosafety Protocol to adequately regulate the (now unregulated) trade in GMOs and GM products.

At present, GMOs and genetically-modified seeds and other materials are already entering developing countries, often without the knowledge of importing countries' authorities. There is grave concern among environmental, agricultural and health authorities in many developing countries over the potentially serious problems this may cause. They are thus pushing hard for a good biosafety protocol, which is now scheduled for completion next year.

There are strong grounds to believe that the recent proposals in the WTO are aimed at countering the Biosafety Protocol, or to prevent it from being able to adequately regulate the trade in GMO products, or to seriously limit the scope of national laws regulating imports.

(www.iatp.org)



BOOKS/ARTICLES NOTES

BOOKS

Genes, Trade and Regulation: The Seeds of Conflict in Food Biotechnology by Thomas Bernauer, Princeton: Princeton University Press, 2003.

THE complexity of international negotiations is best captured in the debates where the US and the European Union take on each other. The book entitled *Genes, Trade and Regulation: The Seeds of Conflict in Food Biotechnology*, authored by Thomas Bernauer provides an interesting analysis of how politically heated discussions between the US and the European Union over the regulation of genetically engineered (GE) crops.

The author has focused on the US and the EU precisely because they are the two "regulatory poles" – the United States has the world's most biotechnology-friendly regulations while the EU regulations are the least biotechnology-friendly. Most importantly, their regulations have the most impact on other countries.

Chapter 2 provides historical account of the emergence of the debates concerning agricultural biotechnology. The differences in the approached opted by the US and EU and their origins are elaborated in following chapters. Chapter 3 explains the differences in approach between the EU and United States. Chapters 4 and 5 provide a detailed analysis of the causes behind these differences. The attempts made towards resolving these differences have been examined in chapter 6 and finally, in chapter 7, the author argues that these efforts do not address the reasons underpinning the differences and goes on to list his own suggestions for "coping with diversity".

The central premise of this book is the argument that the debates pertaining to the use of biotechnology are causing delays and as a result denying the world, particularly the developing countries, the opportunities offered by potentially useful crops. The major contention made by Bernauer is that such deadlock situations arise essentially due to the profound differences in the ways different political approaches regulate the technologies and how they address various trade related issues.

In this book the author has emphasized the role of 'interest groups' in international discussions. He argues that the different approaches to regulating agricultural biotechnology in the United States and EU reflect the interaction within each polity of interest group competition (a "bottom-up" process) and the dynamics of regulatory federalism (rather confusingly called a "top-down" process). He argues that the two processes tend to push in the same direction within each polity, but if the interest groups from two countries compete with each other than the direction of evolution of regulations in one polity move in the opposite direction from those in the other polity.

In other words, the anti-GE technology interest groups in Europe have been more influential than their counterparts in the United States. This has been further complemented by the greater regulatory autonomy of the EU's member states (relative to the US states). Together, these two factors have enabled those, who are pessimistic about the biotechnology, to "ratchet up" the EU's rules. Central to the influence of anti-GE groups in the EU has been the "public outrage" which emerges out of distrust in agricultural biotechnology and a lack of trust in regulators.

Another critical observation, contrary to the general perception, that Bernauer has made in this book is that anti-GE nongovernmental organizations (NGOs) in the EU did not create this distrust but capitalized on it as a means of

mobilizing members and financial resources. This claim, however, can be criticized for the insufficiency of data, to which the author himself concedes. Nonetheless, the book offers an interesting read for those who are interested in agricultural biotechnology and want to understand the transatlantic dispute. The weaknesses in some aspects of the analysis may ignite interest in further research.

Biotech Patents: Equivalency and Exclusions under European and US Patent Law by Li Westerlund, Kluwer Law International, New York, 2002.

IN this book, the author examines the relationship between biological and technological realities with legal approaches and concepts. He develops a patent law theory with respect to biotechnological inventions so as to grasp the substantive law suitable for biotechnology.

Biotechnological inventions and patents – this issue not only challenges law, but is also the focus of much debate. The author's focus is on the scope of patents and the subsequent requirements for granting a patent and determining infringement when applied to biotechnology. Other issues discussed include mandated exclusions from patentability under the European patent law of categories of plant and animals subject matter and certain biological processes.

The text of the book explores modern patent law issues including theory and practice, with respect to the European Patent Convention in the UK, Germany and the US.

Three main issues of biotechnological patenting are analyzed in this book. The patenting of these kinds of inventions has been questioned although they are patentable in principle and therefore, the issues of eligibility, the disclosure requirements and the actual protection given into a granted patent should be of central interest.

The first part, Chapter 2, concerns eligibility issues, which are analyzed from an explanatory theoretical basis relative to the development that has taken place in the biotechnological field of patents. The following parts then bring into focus the issue of patent scope, meaning the actual protection that comes with the exclusive right. Chapter 3 addresses the disclosure requirement of patent law, a requirement with actual effect on the scope of a patent right, by scrutinizing the case law of the granting procedure. Because patent scope is not really determined until there is an infringement suit, the study in Chapters 4 and 5 focusing on this issue is mainly based upon case law. The reason being that from those decisions can be deduced the framework in which the scope of protection is determined, while from that assessment the actual protection afforded biotechnological patents can be more or less predictably inferred. Under European patent laws for biotechnological inventions, certain kinds are explicitly debarred from patentability. This particular aspect, being relevant only to the bio technological field, demands comprehensive analysis in order to clarify where the law stands in this respect in Europe, and all these details are analyzed in Chapters 6 and 7. In the last chapter the exclusions from patentability in context, followed by concluding reasoning regarding the main issue, namely the scope of the patent right, are analyzed.

Patents: Myths & Reality by Dr. Vandana Shiva, Penguin Books India, New Delhi, 2001.

IN today's world, patents affect all of us – whether we are farmers whose right to save seed is threatened, or consumers whose right to food and medicine is eroded, or researchers whose freedom to exchange knowledge is blocked. This book examines the myths associated with the universalization of the Trade Related Intellectual Property Rights (TRIPs) Agreement in the context of trade liberalization, and the real consequences of implementing such a regime.

Dr. Vandana Shiva details how under IPR laws natural resources are taken by western corporations without recognition or payment; how local communities are prevented from using their centuries-old knowledge by corporations who have patented that knowledge; and how the Third World countries are forced to buy products based on their indigenous knowledge at much higher prices than if they were produced locally. The book also explains the historical role of patents and provides an analysis of the way forward that should be taken by governments and individuals for a more balanced patent regime.

Thus, today, companies, commercial laboratories, universities, researchers and more

particularly governments – all seem to be in a "high-stakes scavenger hunt" to collect "patent" which can be sold for billions of dollars. As a result, the end of the twentieth century saw patents being granted for indigenous knowledge and plants and also for micro-organisms, genes, animals, and even human cells and proteins.

The TRIPs Agreement of GATT/WTO has globalized US-style patent laws. This has far-reaching consequences and impacts not only on our capacity to provide for our basic needs of food and medicine, but also on democracy and sovereignty. The universalization of patents to cover all subject matter, including life forms, has resulted in patents invading our forests and farms, our kitchens, and our medicinal plant gardens. Patents are now granted not just for machines but for life forms and biodiversity; not just for new inventions but for the knowledge of our grandmothers. Indigenous knowledge which India has used over centuries for everyday needs – *neem, haldi, karela, jamun, kali mirch bhu-amla* and hundreds of other plants.

The International Biotechnology Handbook, Euromonitor Publications Ltd., London (UK) 1998.

THE biotechnology industry has had its fair share of teething troubles and financial disappointments in recent years but prospects are beginning to look up. The opportunities for these exciting new technologies to make a real contribution to industry and agriculture are now very real.

In this new business series handbook industry experts analyze various key aspects of the growth development and current structure of the biotechnology industry. The book describes the scientific progress being made in biotechnology and offers a layman's guide to some of the main terms and definitions. But the emphasis is on practical current economic issues – the products on the market, the major companies and the major world markets. The current structure of the biotechnology industries of the US, Japan and Western Europe are examined and there are chapters on current trends in research and market prospects. Other practical issues include the state of government regulations and the patenting of biotechnological products.

Part one gives an introduction to biotechnology for layman who may have only a vague idea, if any at all, of what this new science means. Chapter one briefly traces the historical developments which have led to man's imperfect but growing understanding of microbiological processes in the late twentieth century. Chapter Two follows this by outlining the main industrial products and processes with which biotechnology is involved today – again in simple terms for the non-expert reader.

Chapter Three examines in more detail (and necessarily in a more complex language) the products and processes which are the focus of current research in international biotechnology laboratories.

Part Two turns the spotlight on the national development of biotechnology in the major countries which are most likely to be the moving force in the next decade. Individual chapters are devoted to the US and to Japan, while Chapter Six summarizes developments in Western Europe. These chapters also provide profiles of the major companies involved in biotechnology, whether they be small, research-based (or "start-up") companies or the large industrial combines best able to exploit commercialization of biotechnology.

Part Three, in contrast, examines the broader issues of the biotechnology industry – which confronts researchers and commercial enterprises in all countries – with the main focus on regulatory issues (Chapter Seven) and patents (Chapter Eight). This part of the book concludes with a chapter on market trends and prospects, a chapter which is a natural sequel to Chapter Three on current research. An individual chapter (Nine) is devoted entirely to the impact on medicine of biotechnology, because this is the sector of the economy which is already beginning to feel the impact of new products and processes based on this "new" science.

Finally, Part Four is a reference section containing seven different sources of information on biotechnology, including a bibliography, press section, databases and, in line with the economic stress of the book, a section on current market surveys. The source lists are introduced by a guide to finding out more about biotechnology using these different sources.

Each chapter of the book has been researched and written by an expert contributor who

specializes within the particular field concerned, whether it be market research, scientific research or information science. This means that each chapter has its own "flavour", or a style suited to the topic being covered, whether industrial, scientific or commercial.

Q and A on BT-Cotton India, by T.M. Manjunath, (*www.hindu.com*/holnus)

BT COTTON has neither caused any negative impact related to safety of human or animal or environment nor has there been any crop contamination or pest resistance anywhere in the world for the last 11 years, an expert in the field and a key member of Mahyco-Monsanto team has claimed.

In fact, safety had been accorded the highest priority in biotechnology and in the last five years of its commercial cultivation in the country and for 11 years in thousands of hectares in several other countries.

The detractors of biotechnology did not seem to take cognizance of the facts that a number of experts drawn from various reputed institutions of India, used their collective wisdom in scrutinizing the scientific data from various perspectives before approving any product as safe, the author Manjunath, a former Director of Central Institute for Cotton Research, Nagpur, and a key member of the Mahyco-Monsanto team which was responsible for the introduction of Bt cotton in India, said.

Despite the continued opposition by "a small section", Indian farmers, who have been haunted by bollworms for more than three decades, had accepted this technology, he claimed.

This was reflected by the fact that area under Bt cotton, which was about 29,000 hectares in 2002, the first year of approval, has steadily increased from year to year to reach about 3.8 milion hectare grown by more than 2.3 million farmers in nine states by 2006, author says.

Presently, with the approval of more than 60 Bt cotton hybrids developed by various Indian seed companies and also newer and improved versions of Bt-cotton, there would be an increasing demand for these transgenic seeds, Manjunath claims.

Making an attempt to clear a lot of doubts and enable people to develop more confidence in crop biotechnology, Manjunath in his book says that coincidental with its steep increased adoption, the average yield of cotton in India increased from 308 kg per hectare in 2001-02 to 450 kg per hectare in 2005-06 with most of the increase in yield of up to 50 per cent or more, attributed to Bt cotton.

The book, which described as very cruel the allegation that Bt cotton was responsible for farmers' suicides, said it had no empirical basis. On the contrary, Bt cotton has come as a big relief to farmers and has saved their crops and enabled them to reap a better harvest and profit, Manjunath says.

In fact, an International Market Research Bureau survey in 2004 indicated that for every rupee spent by the farmers, they received Rs.5.80 in value for reduced insecticide cost and increased yield over conventional cotton, he said.

Agriculture and Intellectual Property Rights: Economic, Institutional and Implementation Issues in Biotechnology, edited by V. Santaniello, R.E. Evenson, D. Zilberman, G.A. Carlson, CABI, June 2000.

THIS book presents the perspectives of policy-makers and economists on a highly topical subject. Plant breeding patents, the ownership of biological innovation and associated intellectual property rights (IPRs) are the subject of increased attention worldwide. They are particularly relevant in the field of agricultural biotechnology, but until recently evoked little policy analysis.

IPRs are particularly relevant in the field of agricultural biotechnology. They are issues affecting public and private sector organizations and companies, and are significant for developing as well as developed countries.

This book is useful to agricultural economists; policy-makers; legal advisers; researchers in plant and animal breeding and biotechnology. It covers Chapters such as Patent and Other Private Legal Rights for Biotechnology Inventions (Intellectual Property Rights - IPR); Intellectual Property Rights of Plant Varieties and of Biotechnology in the European Union; Intellectual Property Rights under the Convention on Biological Diversity; An

Economic Approach to Identifying an "Effective *Sui Generis* System" for Plant Variety Protection under TRIPs; Recent Intellectual Property Rights Controversies and Issues; Economics of Intellectual Property Rights for Agricultural Technology; The Market Value of Farmers Rights; International Crop Breeding in a World of Proprietary Technology; Knowledge Management and the Economics of Agricultural Biotechnology; Comparing Allocation of Resources in Public and Private Research; Biotechnology Inventions: What Can We Learn From Patents?; Biotechnology Inventions: Patent Data Evidence; Property Rights and Regulations for Transgenic Crops in North America.

Biotechnology Update, Internal Coordination Group for Biotechnology (ICGB)**,** OECD, No. 19, 30 April 2008

THIS Newsletter provides up-to-date information on OECD activities related to biotechnology. It is mainly intended for delegates participating the OECD meetings. This Newsletter is informative for the wider biotech community. The contents of this Newsletter have been provided by those members of the OECD secretariat who are responsible for various activities concerning biotechnology. Some of the areas taken from the Newsletter are mentioned below.

Industrial Biotechnology

The ability of biotechnology to transform industrial processes and deliver profitability and environmental benefits go hand-in-hand. The Application of Biotechnology to industrial sustainability prepared by the OECD Task Force on industrial biotechnology, has prompted action in several countries towards delivering a more resilient, more sustainable and more bio-based economy. The OECD focuses on how industrial biotechnology can contribute to sustainable growth and development, and tries to identify and appraise policy options for supply and demand side interventions that can drive an efficient transition towards bio-based economy.

In February 2008 the Task Force on Industrial Biotechnology received a new mandate and a new focus on eco-innovation and the opportunities for sustainable economic growth within the context of developing bioeconomy. The new Task Force will advise on policy issues related to industrial biotechnology, including science and technology; the provision of supportive environments for efficient delivery of innovation and access to such innovation; the policy responses to novel developments in science and technology, including convergence with other technologies; and the impact of such developments on policy, as well as the sustainability and eco-efficiency of industry. The Task Force on Industrial Biotechnology will develop methodologies for the evaluation of bio-based products and processes. It will also address issues related to R&D and the application of environmental biotechnology.

Economic Instruments for Biodiversity

The OECD Working Group on Economic Aspects of Biodiversity (WGEAB), a subsidiary body of the Environment Policy Committee (EPOC), has focussed for over the last ten years on incentive measures, valuation and market creation for the sustainable use and conservation of biological diversity. Reflecting the main outputs of the Group, OECD countries agreed in 2004 an OECD Council Recommendation on the Use of Economic Instruments in Promoting the Conservation and Sustainable Use of Biodiversity. In 2007-2008, the WGEAB is undertaking a review of the implementation by OECDs 30 member countries of the Council Recommendation on the use of economic instruments since its adoption in 2004. While this review is still in process, initial findings suggest that most of the countries responding to the OECD questionnaire do have in place a national biodiversity strategy or framework, a number of which provide a comprehensive and over-arching framework across policy areas. Nearly all noted further progress in the last few years in the application of economic instruments within their biodiversity strategy or framework, although the use of market based instruments is often still limited to specific instruments and policy areas. The most commonly noted economic instruments used in the responding countries were positive subsidies for biodiversity friendly behaviour, with the application of fees, charges and taxes fairly widely used as well. Instruments that create markets for sustainable use of biodiversity resources were also relatively less developed in biodiversity management, for example tradable permits

schemes, although there were some examples such as with fishing quotas and hunting permits. In terms of application of biodiversity related incentive measures to specific sectors and ecosystems, the survey indicated that the areas covered most comprehensively by such measures in responding countries were inland waters, agriculture and forest biodiversity, while the use of such instruments was more partial or limited in mountain areas and species management.

OECD Biotechnology and the World Wide Web

OECD's web site includes much information on biotechnology, biosecurity, biosafety and related topics. The web site allows individual users to tailor the OECD site to their needs. By selecting the themes that interest them, visitors can personalize their homepages at My OECD to present the news, events, and documentation related to their chosen themes. Visitors can also choose to receive automatically future editions of Biotechnology Update through My OECD.

- OECD's portal is: http://www.oecd.org
- OECDs biotechnology portal: http://www.oecd.org/biotechnology
- For more information on industrial, scientific and health applications of biotechnology, and Biosecurity, see: http://www.oecd.org/sti/biotechnology under the theme – Biotechnology Policies.
- The BioTrack information system (which covers biosafety) is found at: http://www.oecd.org/biotrack/
- For information on Biosecurity codes of conduct, see: www.biosecuritycodes.org

Intellectual Property Protection of Biotechnology, ISNAR Research Report No. 3, (*ftp://ftp.cgiar/isnar/publicat*)

THE legal protection of biotechnological innovations has now been under consideration for more than a decade. New bioprocesses and manufactured living organisms did not fit in existing systems for the protection of intellectual property rights (IPRs) and raised many questions with respect to their legal protection. Except for plant varieties, living material was generally not within the purview of any IPR system until the 1970s. In many industrialized countries this situation changed with the extension of patent coverage to microorganisms which, by the beginning of the 1980s, were major vehicles for pharmaceutical innovation. Patent protection of higher organisms, including plants, animals and human tissue and cell cultures followed.

With respect to agricultural biotechnology, the Report states that two IPR mechanisms are relevant: patents and plant breeders' rights. A *patent* is a right granted by the government to inventors to exclude others from imitating, manufacturing, using or selling a specific invention for commercial use during a certain period. In industrialized countries this is usually 17-20 years. In order to be eligible for patent protection, the subject matter has to be:

- novel and inventive;
- not obvious to a person skilled in the art; and
- industrially applicable and useful.

Final receipt of a patent in turn requires that the inventor disclose his invention to the public. Once awarded, patents are *territorial*, which means that they can only be honoured in countries where the patent is awarded. It is the patent claim itself that defines the actual scope of the patent.

On Plant Breeders' Rights (PBRs) the Report explains that PBRs are granted by the government to plant breeders to exclude others from producing or commercializing material of a specific plant variety for a period of, minimally, 15-20 years. In order to be eligible for PBRs, the variety must be novel, distinct from existing varieties, and uniform and stable in its essential characteristics. The legislation for both patent and PBR systems contains provisions for limited unauthorized use of the protected matter. Patent legislation includes a *research exemption* which allows others to study the protected subject matter without reproducing or multiplying it for commercial purposes. Under PBR law, the Report says, the use of material of a protected variety for creating new varieties, and the commercial exploitation of these new varieties remains, to a certain extent, free. This so-called *breeders' exemption* is the core principle of the PBR system. Furthermore, under the PBR system, governmental authorities often leave farmers the freedom to use their own harvested material of

protected varieties for the next production cycle on their farm. This privilege is referred to as the *farmers' privilege*.

Towards an International Agreement on the Legal Protection of Biotechnological Innovations, ISNAR Research Report No. 3 (ftp://fpt.cigar/isnar/publicat)

THE level of IPR differs widely among nations. In many developing countries the duration of protection is much shorter than it is in industrialized countries. Even in the latter group of countries, some exclude specific processes and products from patent protection. For example, half of the signatories of the Paris Convention for the Protection of Industrial Property, including most Western European countries, exclude plant or animal varieties, and biological processes for the production of plants and animals. Many developing countries also exclude pharmaceuticals, food products and processes for pharmaceutical and food production from their patent legislation, the Report mentions towards legal protection of biotechnological innovations. The Report further gives reasons for this situation that the Paris Convention does not provide for minimum standards, in terms of patent coverage or duration, that the laws of member countries should meet. The Convention is based on the so-called "national treatment" principle, which requires signatories to offer equal protection to both foreign and national applicants. While over 100 countries have acceded to the Paris Convention, only 24 (industrialized) countries are members of UPOV. Under international law, countries that do not adhere to either of these conventions have no obligations with respect to IPR for biotechnological innovations.

The Report refers two routes have been used to try to harmonize IPR legislation:

(a) Multilateral negotiations in the World Intellectual Property Organization (WIPO) and in the Uruguay Round of multilateral trade negotiations under the aegis of the General Agreement on Tariffs and Trade (GATT); and

(b) Bilateral negotiations initiated by the US, and to a lesser extent by the EC and Japan.

To the extent that they are related to bio-technology, these negotiations are discussed below.

Protection of Biotechnology in WIPO, the Report says WIPO is the United Nations' specialized agency which administers most IPR conventions. WIPO's role in the debate on IPR in biotechnology has been twofold. *First*, the International Bureau of WIPO has undertaken several initiatives to discuss proper protection mechanisms for biotechnology, and *second*, WIPO has been the main forum for talks on the international harmonization of patent laws.

Protection of Biotechnology in GATT, the Report states that when the Uruguay Round commenced in the mid-1980s, the US, supported by Japan and the European Commission (EC) successfully insisted that IPRs should be included in the GATT negotiations. Their reasons were twofold. *First,* developed and developing countries had not been able to reach agreement in the WIPO negotiations. In GATT, however, negotiations on IPR were linked to international trade negotiations, making developing countries' access to export markets in industrialized countries contingent upon advances on IPR. *Secondly*, GATT contains an effective dispute-settlement mechanism, the use of which would facilitate relatively quick, enforceable action against countries violating any GATT agreement on intellectual property.

IPR have been discussed in the GATT negotiations on Trade-Related Aspects of Intellectual Property, including Trade in Counterfeit Goods (TRIPs). The industrialized countries brought forward proposals which would lead to a new international IPR standard for advanced technology, including biotechnology. They also proposed provisions for enforcement and the settlement of disputes between states concerning international trade in protected matter. Dispute settlement was perceived as taking place under the authority of an envisaged Council on Trade-Related Aspects of Intellectual Property Rights as part of the proposed Multilateral Trade Organization of GATT.

Because of the linkage between trade and IPR in the GATT forum, the Report says that the TRIPs negotiations have been used by developed countries to put pressure on developing countries to accede to proposed legislation giving stronger legal protection to the products of advanced technology.

Select Provisions of the Final Draft TRIPs Agreement under GATT Having Impacts on Biotechnological Innovations

- Biotechnological inventions are to be protected under patent law. Excluded from patent protection may be: plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals, other than non-biological and microbiological processes. Plant varieties should be protected either by patents and/or by an effective *sui generis* system. This provision shall be reviewed four years after the entry into force of the new GATT;
- A minimum patent duration of 20 years from filing;
- Extension of the protection of a patented process to the products directly obtained by that process.
- No discrimination against certain fields of technology or against foreign inventions;
- Reversal of the burden of proof in case of alleged infringement of a process patent.
- Use of compulsory license only under specific conditions;
- Developing countries are not required to apply the provisions of the agreement within a period of five years, except for general provision of non-discrimination. For product patents on pharmaceuticals, and foodstuffs, including biotechnology, developing countries may benefit from a transitional period of ten years. Least developed countries benefit from renewable open-ended periods. The transition period is restricted for the protection of pharmaceutical and agrochemical products. Patent applications can be filed for these product categories, but are pending until the expiration of the transitional period. Instead, for the products covered by these pending patent applications, there will be a five-year marketing exclusivity period.

Apart from the multilateral route, the US, and to a lesser extent the EC, have put bilateral political pressure on individual countries to strengthen the legal protection of advanced technologies, including biotechnology, the Report mentions. The Special 301 provisions of the US Omnibus Trade Act of 1988 provide that the US Administration must take retaliatory measures against alleged shortcomings in foreign IPR legislation. For this reason, about 40 countries have been targeted by the US Trade Representative in the past few years, and some have had sanctions imposed on them.

The EC has also exerted pressure on several developing countries to adjust their IPR legislation both through diplomatic initiatives and commercial policy measures linked to its New Trade Policy Instrument.

The threat of trade sanctions and suspension of technological cooperation in bilateral negotiations have had a much greater impact than the IPR negotiations in WIPO or GATT. From the point of view of industrialized countries, the Report says that the advantages of the bilateral route over the multilateral framework are threefold. *First*, IPR legislation in developing countries has been upgraded as quickly as possible when agreed to bilaterally. Many countries have accepted the US and EC demands while the talks in GATT and WIPO have still to be concluded. *Second*, changes in IPR which have been agreed to bilaterally take effect almost immediately, without transition periods as envisaged in the draft TRIPs Agreement. *Third*, the level of IPR which has been agreed upon is higher than is envisaged in GATT or WIPO.

From the standpoint of the developing countries, the trade pressures being applied by the industrialized countries are sometimes seen as leading to infringements on national sovereignty, the Report adds.

ARTICLES

India Should Oppose Biotechnology in WTO

by Suman Sahai (http://www.genecampaign.org)

NEGOTIATIONS on the Agreement on Agriculture, part of the built-in agenda of the WTO are scheduled to commence some time in March this year. India has a great interest in this negotiation for the obvious reasons of our vulnerability in food. Apart from the need to protect our agriculture sector and the livelihood base of small farmers, India must also take a view on the new and emerging issues in agriculture, particularly biotechnology.

The last is a subject which has not attracted much attention in India or for that matter in other developing countries. In the context of the WTO specifically, this issue deals with trade in genetically modified crops. Genetically Modified or Genetically Engineered crops are those foods or crops, which contain a foreign gene. Genetic engineers can cut

out a gene from anywhere, not even necessarily another plant, and put it into any crop. This way traits that are not present in the particular crop can be brought in from anywhere; another plant, an animal or even a bacteria. In the case of transgenic cotton, the gene that can provide protection against the dreaded cotton pest bollworm, is brought in from a kind of bacterium found in the soil.

Transgenic plants are being made in both food and cash crops. The food crops include cereals, fruits and vegetables. The most prominent food crops are corn, soybean, potato, mustard and tomato. The main cash crops that are being grown are cotton and tobacco. The US is the main producer of transgenic or GM crops followed by Canada, Australia and Argentina and to a smaller extent, Japan.

There are a lot of apprehensions associated with GM foods chiefly relating to the safety aspects, both for the environment and for human health. It is feared that novel genes and genetic constructs could escape into the environment and create monster plants like weeds that cannot be destroyed or new, recombinant pathogens like bacteria and virus. Scientific evidence is thin that this has happened or is likely to happen. However, even if the fears are unwarranted, this new technology undoubtedly needs to be tested and appraised cautiously before it is accepted as a safe source of food.

Consumer groups in countries like the US, UK, Canada and Australia have demanded that all GM foods and processed foods made from GM crops should be clearly labeled so that the consumer can decide whether s/he wants to buy these products. The most resistant to mandatory labeling is the United States which still does not label processed foods. A major conflict has arisen between the EU and the US on trade in GM foods specially with reference to labeling of these foods.

The public perception of GM foods is highly negative. A near hysterical resistance is building up in Britain against these so-called "Frankenstein foods". Everybody from Prince Charles and the ex-Beatle Paul McCartney have chimed in against GM foods. Europeans, conservative and deeply suspicious of the science of genetics have rejected genetic engineering in a resolute way. Rather strong views against GM foods are now being heard across the Atlantic in America. This makes the American government and the multinational industries pushing GM technology, very nervous indeed.

Large investments have been made by the so-called Life Science corporations like Monsanto and Novartis on this technology. Money has been spent on buying up smaller competing firms, on field testing, on obtaining licences & clearances and on promotions and sales pitches for farmers. Farmers on the other hand have planted large numbers of acres with GM crops . If they cannot sell their produce because of hostile public reaction, they will vent their spleen on their government. No wonder then that the American government pushed by the gene technology corporates need to find markets for these controversial, frightening foods that nobody seems to want.

It is in this context that the Americans have been pushing for international trade in GM foods using the WTO as a platform where they have been attempting to force the inclusion of this new subject. No less a person than the American president plugged for GM foods. In a speech before Seattle, Bill Clinton took a strong stand on biotechnology products and made the US position clear , " America leads the world in agricultural products developed with biotechnology……We are committed to ensuring the safety of our food and environment through strong and transparent, science-based *domestic* (*not international !*) regulatory systems ….In Seattle we will continue to insist that market access for agricultural biotechnology products be based on strong science." (Italics mine).

The strategy to introduce biotechnology products like GM foods is to first set up a Working Group to discuss the subject and then its possible implementation framework. In the WTO, normally once a working group is set up, the subject is certain to be included in the final trade agenda. If that were allowed to happen, GM foods could be dumped as part of food imports in countries like India, without our even knowing. Given the American resistance to labeling, developing countries could end up being unwilling consumers of GM foods, with no choice in the matter.

Consider this. The way that negotiations have proceeded in the Agreement on Agriculture, we have significantly lost our ability to protect our

farmers against imports and our discretion for providing subsidies for production have been eroded. We seem to be moving towards zero duty in agriculture, we are already committed on rice and other cereals. The dismantling of quantitative restrictions on agricultural products has already begun and by April 2001, over 1400 products, most of them agricultural, will not be protected by quantitative restrictions. Imports are expected to flow in. With that the specter of every ton of safe and unsafe GM food landing in India begins to look real. In fact, there are reasons to fear that GM corn was part of a consignment of American corn that we imported recently. We did not import this consciously and slipping GM corn into a consignment in this way is clearly unethical. This however is what we will have to gear ourselves for on a large scale if trade in GM foods and other biotechnology goods becomes part of the WTO trade regime.

Once the negotiations on Agriculture start again, India should strongly oppose the setting up of a Working Group on Biotechnology in the WTO. It would in any case be too premature considering we have scarcely done any homework on this new and controversial area. Our government departments are largely unprepared and uninformed about the ramifications of this rather technical subject. People concerned with the negotiations should start collecting information and preparing a well thought out India position. As a first step we should draw up and articulate our domestic policy and identify our priority areas.

With the conclusion of the Biosafety Protocol in Montreal, the framework is clear. The US and the Miami Group have succeeded in diluting the requirements for labeling. India's domestic law should correct for this, stipulating strongly that food imports into the country will have to be clearly labeled as 'No GM Food '. In fact we should require an undertaking to be signed by the importing agency that the consignment does not contain genetically modified foods.

We should craft sensitive and just Intellectual Property legislation, which will protect our scientists and our communities. We should satisfy ourselves on the basis of scientific evidence about the long-term safety of these crops for human health and for the environment. And, most of all, we should carry out an awareness generation program and gain public acceptance for this technology and these foods should we decide to adopt them.

At present there are four major players in the WTO, each of who have taken divergent approaches on introducing GM foods and products. The European Union favours a clarification of the Agreement on Sanitary on Phytosanitary Measures (SPS Agreement); Canada has proposed the establishment of a working group 'with a factfinding mission to consider the adequacy and effectiveness of existing rules as well as the capacity of WTO members to implement these rules effectively'; Japan seeks 'an appropriate forum to address new issues, including GM organisms as a subgroup of an independent negotiating group on agriculture; and the United States wants 'transparent, predictable, timely and science-based' approval systems for genetically modified crop varieties to be among the objectives of the agricultural negotiations.

Both Japan and the EU support the 'precautionary principle' and take a cautious approach to genetically engineered products. Japan goes further and proposes that the biotechnology sub-group consider, among other items, whether 'the relevant WTO Agreements, such as SPS, Technical Barriers to Trade (TBT) and TRIPs ... are capable of responding to (GMO-related) matters'.

The EU advocates a clarification of SPS rules - which require trade restrictions to be based on sound science, so as to give WTO members more leeway in rejecting GM products on the basis of scientific uncertainty. The SPS Agreement already recognizes that temporary trade restrictions may be taken to protect human, animal or plant health/ life even 'where scientific evidence is insufficient', but these measures must be based on 'available pertinent information' and, to make them permanent, members must carry out a 'more objective assessment of risk [...] within a reasonable period of time.' A reference to the precautionary principle would undoubtedly lessen the degree of scientific proof needed to justify trade restrictions, as well as extend the 'reasonable period of time' during which scientific evidence must be presented to maintain provisional measures.

The United States and Canada are aggressive about opening markets for their genetically modified crops because both are large producers and are having difficulties getting buyers. Both favour a less stringent approach to GM foods and are keen to see it in the WTO without further delay. To make their case for dispensing with EU guidelines, they claim that the European Union's approval system for new varieties has 'broken down' - it is, indeed, likely that no new varieties will be approved until 2002 - and that the EU's existing and planned labeling requirements for foods that contain genetic modification are both unnecessary and technically unfeasible on a commercial scale.

The US is opposed to opening up the SPS Agreement for discussion, saying that renegotiations or fresh interpretation of its provisions would weaken rather than strengthen it. The US also finds the proposed working group's mandate too broad, and fears that the group's deliberations could slow down market opening for genetically engineered products. Instead, the US has proposed that the objectives for the agriculture negotiations should include addressing disciplines to ensure trade in agricultural biotechnology products is based on transparent, predictable and timely processes.

The Cairns Group is still trying to develop a common stand on biotechnology. This is proving to be a difficult task as the group's 15 members have widely divergent approaches to GMOs at the national level.

Developing countries have not made proposals on biotechnology, but most of them are in favour of stringent rules for trans-boundary movements of genetically modified organisms in the Biosafety Protocol. In these negotiations, they want provisions that would protect their regulations on GMO imports from WTO challenges, while the so-called Miami Group (consisting of the US, Canada, Australia, Argentina, Chile and Uruguay) favours a treaty narrowly-focused on biodiversity conservation and containing the fewest possible trade restrictions.

Informal discussions in Geneva during the first week of November revealed that the majority of WTO Members were against creating a WTO working group on biotechnology and WTO rules. Most developing countries said that genetically modified organisms should be discussed under the Convention on Biological Diversity and not in the WTO. The US appeared to have overcome its objections to a WTO working group, which was generally supported by the Miami Group, while the EU and Brazil declined to take a position. At Seattle, some discussions took place on biotechnology but these will have to be resumed since the talks collapsed. The place where biotechnology will return to the agenda is the negotiation on agriculture. India will need to tackle the situation with sophistication, not losing track of what constitutes its national interest.

GMOs in the WTO: A Critique of the Panel's Legal Reasoning in EC – Biotech by Caroline Henchkels, *Melbourne Journal of International Law*, Vol. 7, 2006.

THE safety of genetically modified organisms ('GMOs') is a highly sensitive issue in the European Union. The dispute over European Communities – Measures Affecting the Approval and Marketing of Biotech Products in the World Trade Organization implicated technical concerns about barriers to trade, scientific concerns about a technology's potential for harmful effects and political concerns about the extent to which the Agreement on the Application of Sanitary and Phytosanitary Measures restraints the regulatory autonomy of sovereign actors. The decision on this dispute by the Panel under the dispute settlement mechanism of the WTO is critical as it not only deals with the complexity of adjudicating a science based domestic regulation by an international authority but it also addresses the debates about the intersection between international trade and international environmental law. This article examines the WTO decision on the dispute in this context.

The article begins with providing an institutional and legal context of the dispute and goes on to explain the nuances of the EC-Biotech dispute locating it inside the SPS Agreement. The core of the article constitutes an examination of the reasoning of the WTO Panels regarding the role of non-WTO rules of international law and its interpretation of the obligations that Article 5.7 of

the SPS Agreement places on WTO members. The article then concludes that the Panel did not give enough respect to the non-WTO international law in interpreting the SPS Agreement and by doing so, "it missed the opportunity to situate its decision within the broader context of international environmental law, which negatively impacts on the legitimacy of the decision."

Apart from the analysis of WTO Panel's decision, the point highlighted here is the complexities involved in international regulations and the need for coherence among various national and international laws. The central claim made by the author is that the abidance to Vienna Convention in the decision making would provide more legitimacy to the WTO's dispute resolution process. The author argues that the WTO is not a "self-contained" legal regime as the relationship between the WTO dispute settlement system and other rules of international law is still evolving. It is, therefore, necessary for the WTO Panel to follow the guidelines of treaty interpretation as per the Vienna Convention which prioritize interests and values other than trade liberalization, such as the protection of human rights, which would further strengthen the link-up between trade related international institutions with those that are concerned with other social and political issues.

GMOs, Food Safety and the Environment: What Role for Trade Policy and the WTO?
by Kym Anderson and Chantal Pohl Nielsen
(siteresources.worldbank.org/INTTRADERESEARCH/Resources)

THIS Paper refers to the current debates about genetically modified organisms (GMOs) in agriculture which reveal substantial differences in perception of the associated risks and benefits. Genetically modified crop varieties promise benefits to both farmers and consumers, and can lower damage to the natural environment, for example by reducing pesticide use. But some other environmental issues, together with food safety and ethical concerns with the production and use of GMOs, are being raised as potential negative aspects of GMOs. Hence the recent Biosafety Protocol with its endorsement of the use of the precautionary principle. However, if that Protocol were to encourage discriminatory trade barriers or import bans, or even just long delays in approving the use of imported GM seeds, it may be at odds with countries' obligations under the WTO.

The first part of this Paper provides a brief overview of the trade policy issues which hold great significance. The distributional consequences of adopting GMO technology in agriculture within and between countries, and of proposed trade-related policy responses, cannot be determined *a priori*. Hence the need for empirical modelling of the economic effects of GMO adoption.

The second part of the Paper illustrates how such policy or consumer responses can alter significantly the potential size of the global GMO dividend and its distribution. This is done using a well-received empirical model of the global economy (GTAP) to quantify the effects on production, prices, trade patterns and national economic welfare of certain countries' farmers adopting GM maize and soyabean crops without and with trade policy or consumer responses in Western Europe (where opposition to GMOs is most vocal).

In Western Europe where food supplies are abundant and incomes are high, people can afford to be critical about the introduction of new agricultural biotechnologies and production processes about which they are unsure. In developing economies, by contrast, the benefit/cost ratio is very different. Many food-insecure people in developing countries live in rural areas, earn a significant share of their income from agriculture, and meet a substantial share of their food needs from their own production. For them, increasing agricultural productivity and thereby real income is a big priority. And for the urban poor in those countries, anything that lowers the effective price of basic foods and/or boosts the nutritional value of those foods is highly desirable. Given the large value shares of agriculture and textiles in production and food in consumption in developing economies, GMO technologies for such crops as rice and cotton have the potential to generate significant economywide benefits that may well dwarf any costs as perceived in those countries in terms of environmental and food safety risks. The same

is true for GM maize and soybean from which, along with Bt cotton, rich-country adopters (most notably the United States) appear to be already benefiting, judging by the rapid rate of adoption.

Environmental, food safety and ethical concerns with the production and use of GM crops have been voiced so effectively as to lead to the recent negotiation of a Biosafety Protocol (UNEP 2000) with its endorsement of the use of the precautionary principle. However, if that Protocol were to encourage discriminatory trade barriers or import bans, or even just long delays in approving the use of imported GM seeds, it may be at odds with countries' obligations under the World Trade Organization. The first part of this paper provides a brief overview of the trade policy issues at stake here. It concludes that these issues have the potential to lead to complex and wasteful trade disputes. The extent to which that potential is realized depends on the economic stakes involved. They can only be determined by quantitative economic modelling, using – pending more reliable knowledge assumptions about the sizes of any shifts in the crop supply (or demand) curves. The second part of the paper illustrates one way in which this can be done. We use a well-received empirical model of the global economy (GTAP) to quantify the effects on production, prices, trade patterns and national economic welfare of certain countries' farmers adopting GM maize and soybean crops without and then with trade policy or consumer responses in Western Europe (where opposition to GMOs is most vocal). The results suggest such policy or consumer responses can alter significantly the potential size of the global GMO dividend and its distribution.

The potential economic welfare gains from adopting GMO technology in even just a subset of producing countries for these crops is non-trivial. Developing countries would receive a sizeable share of those gains, and more so the more of them that are capable of introducing the new GM technology. The paper states in its conclusions that these gains, especially for developing countries, are sufficiently large that policy-makers should not ignore them when considering policy responses to appease opponents of GMOs.

The paper further says the most extreme use of trade provisions, such as an import ban on GM crops by Western Europe, would be very costly in terms of economic welfare for the region itself. Imposing a ban prevents European consumers and intermediate demanders from gaining from lower import prices. It also means domestic production of corn and soybean would be forced to rise at the expense of other farm production, and hence overall resource allocative efficiency in the region would be worsened.

Many consumers in Western Europe are concerned about GMOs, the results of the market-based partial preference shift experiment suggest in this Paper that letting consumers express that preference through the market reduces the welfare gains from the new technology much less for both Europe and the GM adopters than if a GMO import ban is imposed in Europe. The results also suggest, however, that developing countries that do not gain access to GM technology may be slightly worse off in terms of economic welfare if they cannot guarantee that their exports entering the Western European markets are GMO-free.

Authors say in this Paper that the estimated welfare gains from the adoption of GM technology are, they are dwarfed by the welfare gains that could result from liberalizing global markets for farm products and textiles & clothing (recently estimated at around $180 billion per year *even after* the Uruguay Round) is fully implemented in 2005, almost one-third of which would accrue to developing countries. Should opposition to GMOs lead to the erection of further barriers to farm trade, that would simply add to the welfare cost of restrictive trade policies. Authors further say that four caveats need to be kept in mind: that estimate refers to only two of many products that the new biotechnology may impact; the next generation of GM foods may be quality enhanced as well; a ban on imports will dampen investment and so reduce future growth in GDP; and developing countries in particular would enjoy less technological spillovers as a result, and for the poor in those countries especially the welfare foregone would be a far higher percentage of their income than is the case in Europe.

A Primer on Intellectual Property Rights and Agricultural Biotechnology by Philip G. Pardey, Brian D. Wright and Carol Nottenburg, Annual Report 2000-2001, Biotechnology (http//www.ifpri.org/pubs)

INTELLECTUAL property refers to products of the mind. Inventions, computer programs, publications, videotapes, and music are all examples of intellectual property. Intellectual property rights afford a time-limited legal protection to artistic, scientific, technological, or economic products. Copyrights, trademarks, design patents, utility patents, plant patents, plant breeders' rights, and trade secret laws are some of the ways of protecting intellectual property rights. The type of intellectual property to be protected and the legal and administrative system of the country where the right is being sought affect the extent of rights, such as the scope of the protection and the geographical limits to and duration of the rights.

In plant breeding, patents and plant breeders' rights have generally been the most important forms of intellectual property protection. As the biotechnological revolution unfolds, however, copyrights are becoming more important because the databases that hold information about plant genes can often be copyrighted. Such copyrights do not, however, affect trade in products developed using the protected information. US state trade secret laws have been used to protect in-house breeding materials such as the inbred lines of maize used as parents of hybrids, but these laws do not protect against independent discovery or reverse engineering of products by their purchasers. Hence, patents afford stronger protection than trade secret law for innovation embodied in products. Trademarks are used for the protection of brand names of biotechnologies, such as Monsanto's Roundup ReadyJ technology or Aventis's Liberty7 and LibertyLink7 technologies. Trademarks only protect the names and other symbols denoting products or technologies, not the technologies themselves.

Plant breeders' rights (PBRs), or plant variety protection, are a form of intellectual property protection for plants offered in most developed countries and a growing number of developing countries. While countries differ in how they implement PBRs, the laws usually grant protection to varieties that are novel, distinct, uniform, and stable. Thus, the variety must not have been previously sold, be clearly distinguishable from previous varieties, be uniform, and breed true to type. The holder of a plant breeder's right has a legal monopoly over commercialization of that variety for a prescribed length of time, allowing the recovery of the cost of breeding commercially valuable new plant varieties. Although the details of protection vary from country to country, in general, the sale, reproduction, import, and export of new varieties of plants are encompassed. Exceptions may be made, however, for research, breeding of new varieties, and use of seed saved by a farmer for replanting. Moreover, in some countries, if a protected variety is used as the basis for a transgenic plant, the latter is covered by the plant breeder's right if it constitutes a variety "essentially derived" from the protected variety.

Contractual and Technological Proprietary Tools

In addition to the legal protection afforded by patents and plant breeders' rights, contractual provisions may be used to extend or establish intellectual property rights. Such contracts include

- material transfer agreements between technology developers and third parties, which limit the transfer and use of materials such as vectors, genes, and plants developed by the transferor;
- bag label contracts between the manufacturer and the buyer of seed, for example, which limit further uses of purchased material that would otherwise be allowable;
- technology use agreements between technology suppliers and farmers, which typically control the right to plant a given seed on a specific area of land for a certain period of time; and
- licenses between patent or property holder and licensee, which are negotiated grants of some or all of the holder's rights, such as allowing the use and sale of the technology.

There are also a number of genetic technologies that impose technical limits on farmers' use of seeds from their harvest to replant or to sell for replanting. The most common is production of hybrid crops that generally have a lower yield through loss of "hybrid vigour" if replanted. Modern alternatives include genetic use restriction

technologies that confer sterility on replanted seeds "popularly dubbed terminator technologies" and others that allow reproduction but prevent expression of proprietary traits until the plant is treated with a specific chemical activator.

Benefiting from Biotechnology: Pro-Poor Intellectual Property Rights and Public–Private Partnerships by Baris Karapinar and Michelangelo Temmerman, *Biotechnology Law Report* 189, Number 3, June 2008, World Trade Institute, Switzerland

THE agricultural sector in developing countries comprises around 500 million small farms, with the labour force working at low levels of productivity. According to the database of the Food and Agriculture Organization (FAO), 85 per cent of these farms are small-scale, operating on less than 2 hectares. Hence, there is an urgent need to boost the competitiveness of small-farm agriculture and its contribution to poverty alleviation through science and technology. In this context, new biotechnology, including genetic engineering, may have a historic role to play. Some advanced developing countries have already made significant progress in fostering technological innovation and knowledge transfer. For those lagging behind, designing an institutional framework to promote small-scale agriculture is essential.

An effective IPRs regime can play an important role in such an institutional design – as the accessibility of any existing technology to farmers is as important as its technical availability. However, there are concerns that small-scale farmers in poor countries are by and large being excluded from the benefits of new biotechnology. This is of particular importance because the biotechnology companies leading in research and innovation have substantial market dominance in the field. Hence, there is a situation whereby a highly sophisticated private industry investing heavily in research and innovation in agriculture does not seem to be addressing the technological needs of the majority of farmers in developing countries. From the legal and institutional perspectives, this Paper addresses some of the reasons smallholders in developing countries, particularly in the least developed countries (LDCs), seem to have been left out of the process of technological development. It also evaluates the importance of public private partnerships (PPPs) in offering new possibilities for making biotechnology available to small farms.

This leads to an analysis of the WTO's TRIPs, which obliges members to implement a patent system. The paper assesses the extent to which the protection requirement is flexible enough in its essence and content to leave some room for members to develop their own IPR regimes. We argue that the institutional challenge for developing countries is to design an efficient framework that is compatible with multilateral (and in some cases regional and bilateral) IPR regimes, but, more importantly, is capable of offering incentives specifically favouring small-scale biotechnology research and innovation in agriculture. Given the wide heterogeneity of farming systems and variations in domestic institutional capacities, countries should design their own IPR frameworks promoting both home-grown innovation and technology transfer. In this context, authors attempt to assess the possibility of designing a special IPRs regime for public-private partnerships aimed at developing pro-poor biotechnology tools and products in developing countries.

This Paper is organized as follows. It begins with an analysis of some of the opportunities that new biotechnological applications offer to small-scale farmers in developing countries. Second, it provides an overview of the physical, technical, and institutional factors affecting the accessibility of biotechnology.

The Biofuels Landscape: Is There A Role for the WTO? by Motaal, Doaa Abdel, *Journal of World Trade*, February 2008.

THIS article seeks to draw attention to the multiple policy objectives that are driving governments to promote biofuels, and to how "trade policy" is largely being put to the service of the specific goals to which governments are attaching priority. It argues that a coherent vision at the international level of the role that biofuels should play in energy, economic and environmental policy has yet to emerge, but that despite this situation it is key that this sector develops on a "level trade policy playing field" for its long-term efficiency. Such a leveling would, in particular, unleash the full comparative advantage of tropical developing country

producers of ethanol. The article highlights that – even in the absence of a concerted decision by governments on how to handle these fuels at the WTO – certain restrictions to biofuel trade would in any event be reduced through the current Doha Round of trade negotiations. But for the Doha Round to bear full fruit, it would be important for governments not to fully shelter either biofuels, or their production feedstock, through existing "flexibilities" in the negotiations.

Intellectual Property Rights in Plant Biotechnology: A Contribution to Crop Biosecurity by Kauser Abdulla Malik and Yusuf Zafar, *Asian Biotechnology and Development Review*, Vol. 8 No. 1.

THIS article reviews different forms and scope of IPRs relevant to crop biosecurity; the genetic assets and commitments made by developing countries under the TRIPs Agreement and the alternatives open to them.

The impact on developing countries of strengthening the IPRs as a result of the Uruguay Round TRIPs Agreement on genetic resources is a sensitive issue at the centre of a polarized debate. Loss of biodiversity is the major global threat to the planet; other threats being climate change and agrochemical pollution. Fears have been expressed that genetic resources originating in developing countries will be used for the development of new agricultural biotechnology based techniques and products by the industrialized countries, and to which biotechniques and bioproducts access would subsequently be restricted by IPRs.

The potential positive and negative consequences of introducing and strengthening IPRs for the transfer of technology and innovation in developing countries with special reference to crop biosecurity is highlighted.

It is argued that strengthened IPRs would increase the flow of "plants and animals other than micro-organisms". It does require that countries provide for the protection of plant varieties either by patents or by an effective *sui generis* system (i.e. PVP) or both. The TRIPs Agreement permits countries some flexibility in the precise form and the extent of protection and promotes the fundamental idea of extending IPRs to agricultural genetic resources. The general objectives of the TRIPs Agreement are the protection and enforcement of IPRs, the promotion of technological innovation, and the transfer and dissemination of technology. A WTO member country must be non-discriminatory and extend the same treatment to all other members that it affords to one member. Most developing countries are opposed to the use of patent systems in agriculture.

Contributions of TRIPs Agreement towards Crop Biosecurity

The article states that the TRIPs Agreement under Article 27.3(b) imposes on all Member States the introduction of plant variety protection either through patents or an alternative *sui generis* system. However, there has been:

- The modification of protection regimes to accommodate new technologies (particularly, biotechnology and information technology).
- A new emphasis on the protection of new knowledge and technologies produced in the public sector.
- The focus on the relationship between IP protection and traditional knowledge, folklore and genetic resources.
- The geographical extension of minimum standards for IP protection through the TRIPs Areement and of higher standards through bilateral and regional trade and investment agreements; and
- The widening of exclusive rights, extension of the duration of protection, and strengthening of enforcement mechanisms.

Furthermore, relevant viewpoints to the debate on access and benefit-sharing of the global plant genetic resources, genetic erosion and biopiracy that are of significance for crop biosecurity are provided in this article. Consequently, governments should consider formulating internationally compatible laws, standards and practices regarding plant materials and data such as crop protection and biosecurity as well as the ethical handling of biological materials and data from plants can be guaranteed.

WTO Ministerial Must Address Biopiracy Concerns by Kasturi Das, *The Economic Times*, 14 July 2008.

COME 21 July, ministers from the member countries of the WTO will gather in Geneva in a crucial meeting with the aim of achieving a breakthrough in the Doha Round of trade talks. While agriculture and non-agricultural market access (NAMA) would form the core of any decision that the trade ministers may agree to, speculation is rife as to which other issues included in the negotiating mandate of the current round would form part of the decisions.

Making some observations at the outset of the Ministerial meeting, the article states that the relationship between the WTO TRIPs Agreement and the UN Convention on Biological Diversity (CBD) is high on the agenda of India, along with a host of other developing countries. Underlying the negotiations is an attempt by developing countries, with India as a front-runner, and resisted in varying degrees by developed countries, to address the problem of biopiracy and misappropriation of traditional knowledge.

Developing countries have consistently been pointing out that implementation of the two key elements of the CBD, viz. the sovereign rights that the states have over their biodiversity and protection of traditional knowledge have been undermined by the TRIPs Agreement. In recognition of the rights of the sovereign states over their biodiversity, Kasturi Das mentions that the CBD provides that the users of biological material must seek prior informed consent (PIC) from the designated authority identified by each member state of the convention.

Furthermore, the author explains in this article that the users are expected to enter into fair and equitable benefit sharing arrangements arising out of the utilization of genetic resources. Developing countries have argued that while the patent regime introduced by the TRIPs Agreement affords protection to technologies that have been developed using biological material, the rights of countries providing the material, as recognized by the CBD, are completely ignored.

With the aim of rectifying the aforesaid lacuna of TRIPs and ensuring implementation of both TRIPs and CBD in a mutually supportive manner, India and other like-minded developing countries (e.g. Brazil, Pakistan, Thailand and Peru) have been vouching for an amendment of TRIPs over the past several years.

The proposal calls for an amendment establishing an obligation for WTO members to require patent applicants to meet the following conditions: (i) disclose the origin of biological resources and/or associated traditional knowledge; (ii) provide evidence of PIC; and (iii) provide evidence of benefit sharing. The proposal further suggests that in cases where insufficient, wrongful or lack of disclosure would be discovered after the grant of a patent, the legal regime would include provisions for revocation of the patent in question.

However, strong opposition has been posed by developed countries, she mentions, including the US, Canada, Australia, Korea, and Japan. This group has argued that disclosure is not the most effective way to address biopiracy, which can be done through alternative routes, such as establishment of improved databases on traditional knowledge under the aegis of the World Intellectual Property Organization (WIPO) and contractual arrangements under national access and benefit sharing (ABS) laws.

They have also argued that the additional conditions imposed on the patent applicant would introduce significant administrative burden on the patent offices.

In recent months, support for the proposal to amend the TRIPs Agreement has increased considerably with the Africa-Caribbean-Pacific (ACP) group and least developed country (LDC) group joining the league. This 100 members-plus camp is now keen to include this issue in the forthcoming "horizontal" process of the Doha Round. In WTO parlance, "horizontal" is the term used to describe the upcoming stage of the negotiations when a range of negotiating issues would be taken up together in order to strike a balance across them.

Commenting on India's official submission of 27 May 2008 on behalf of the proponents of the disclosure requirement to the WTO in this regard, she maintains in this article that further facts-oriented discussions are necessary on the issue, opponents of the disclosure requirement, however, have vehemently opposed the idea of including the issue in the "horizontal" process, ostensibly on the

apprehension that it might jeopardize efforts to arrive at a viable way forward for Doha negotiations. Hence, uncertainties continue to loom large as to whether the crucial issue would form part of the upcoming mini ministerial meeting. Even the recent report on the issue, by the WTO Director General Pascal Lamy (June 2008), has refrained from throwing any light on the matter, restricting itself to the current status of the negotiations, instead.

It may be noted at this juncture that negotiations are under way in CBD, since 2005, to develop an international regime on ABS. In that forum also, she states that India and other developing countries are vouching for a legally binding system, again amidst strong opposition from developed countries. In a significant development in the recently concluded ninth meeting of the Conference of Parties at Bonn, Germany, parties to the CBD have agreed upon a broad road map, which outlines the next steps to be undertaken to complete the negotiations on an international regime on ABS by 2010.

From the authoress viewpoint, the need for a breakthrough on disclosure requirement under TRIPs before conclusion of the Doha Round assumes further significance in view of the 2010 deadline being set by the CBD. Hence, it is time for India and allies to make a full-throated attempt at the WTO to ensure inclusion of the contentious issue in the upcoming ministerial. Time is running out!

Does India Need Bt Brinjal? by K. Prabhakaran, *The Hindu Business Line*, 28 September 2007.

IN this article the author raises some current issues on Bt Brinjal in response to contentious issue of genetically modified (GM) crops in reference to an ordinance passed in a case in the Supreme Court.

On 22 September 2006, in response to a public interest litigation (PIL), the Supreme Court passed an order that the entire question of field-testing and approval of GM crops should be handled by competent, and committed bodies/scientists. The question before the court was with regard to Bt brinjal, which an MNC, through its Indian subsidiary, was promoting.

Accordingly, an independent committee was constituted by the Centre for Sustainable Agriculture in Hyderabad, which had some of the leading toxicologists, plant physiologists, entomologists, agronomists and economists of the country, supported by field activists, with this author as its Chairman to look into various aspects of Bt brinjal.

The committee submitted its report, examining the field data provided by the Indian subsidiary of the MNC from all aspects – bio-safety protocols to marketing of the end-product – to the Supreme Court in October.

Since then, the Union of India has been seeking modification of the order passed by the Supreme Court on 22 September wherein the court had directed the Genetic Engineering Approval Committee (GEAC) to withhold approvals till further instructions to be issued by the court on hearing all concerned. In the 8 May 2007 hearing that followed, the Additional Solicitor-General submitted that in view of the order passed by the Supreme Court, the GEAC was not in a position to grant approval to various applications pending with the authority, for field trials on various plant varieties. The GEAC, between May and September 2006, had granted approval for 24 items, including Bt cotton, Bt cauliflower, Bt brinjal, Bt rice, transgenic rice, Bt castor, Bt groundnut, transgenic tomato and potato. The field trials are going on in respect of these items.

The 8 May Supreme Court order specifically states that:

The GEAC shall take sufficient precautions to see that these trials do not cause any contamination to neighbouring fields.

There should be at least 200 metre distance between trial fields and the neighbouring ones, where the same type of crop is being grown.

In all the trials, the name of the scientist and other details of the person responsible should be reported to the GEAC and there should be regular supervision.

Prior to bringing out the GM material from the green house to the field, for open field trials, the approved institution should submit a validated, specific test protocol at an LoD (Level of Detection) of at least 0.01 per cent (that is at 99.99 confidence level in statistical parlance) to detect and confirm that there has been no contamination.

The Reality on the Field

The independent expert committee cited instances of scientific inaccuracy in data reporting, breach of scientific protocols and improper reporting of allerginicity and toxicity in the field data provided by the Indian subsidiary of the MNC on Bt brinjal.

The manner in which these field trials are being conducted leaves much to be desired. Farmers are being tricked into accepting GM material for field testing without being made aware of the possible adverse consequences.

Experience in "Cotton Bowl"

A few months ago, Shri Balasaheb Thorat, the Maharashtra Minister for Agriculture, went on record that Bt cotton was a failure in the Vidarbha district, the cotton "bowl" of India and, yet, why is the Government of India pushing so many new strains of the crop?

The MNC that introduced the first Bt cotton in India three years ago was selling a 450-gm packet for Rs 1,950, while the same MNC was selling it for under $2 (less than Rs 90 at the time) in China. Can there be a worse instance of fleecing poor farmers?

Breach of Scientific Protocol

The independent expert committee noted the following breach of scientific protocols in collecting field data on Bt brinjal by the Indian subsidiary of the MNC:

The allerginicity of the protein extract from the Bt brinjal was apparently carried out on brown Norway rats and not on male rabbits as prescribed by the Department of Biotechnology (DBT).

DBT guidelines prescribe *in vivo* immunological assays for the detection of reactogenic antibodies in the test sera. These were allegedly not carried out.

Though the Cry 1Ac gene was earlier considered innocuous, recent published evidence indicates that the specific protein from *Bacillus thurengiensis* (Bt) is a potent systemic and mucosal adjuvant that enhances mostly serum and intestinal IgG antibody responses.

There is apparently conclusive evidence to show that root exudates of GM crops alter the soil microflora profile, negatively impacting soil productivity.

The field data was not statistically analyzed for precise scientific interpretation, and, as such, the conclusions are invalid. No cost-benefit ratio for the farmer was calculated to examine whether or not the new technology is economically viable.

Circumventing SC Order

In response to public outcry against clandestine cultivation of GM crops – farmers of Karnal in Haryana and Ramanathapuram village in Coimbatore district burnt Bt rice fields – the move by the GEAC to legitimize these field trials by requiring them to be conducted in institutional premises is most curious as this does not forestall the possibility of transgenic contamination.

Our farms and fields are not put to monoculture as in the US, the UK or Canada. Even in the UK, the recent reporting of super-weeds near GM rape-fields shows that the risks of pollen transfer leading to the breeding of unwanted plants cannot be wished away, as the protagonists of GM technology are doing.

Larger Picture

The introduction of Bt brinjal in India calls for a "holistic" approach, rather than a "reductionist" one, as brinjal is a favourite vegetable of India that figures on meal menus across regions and social classes.

India is the place of origin of this interesting vegetable, which finds its way into the popular *kathirikai poriyal* of Tamil Nadu, *vazhuthinanga thoran/ upperi* of Kerala, the *badnekai sambar* of Karnataka and the *baingan ka bharta* of North India — and has made its way to kitchens in the US, the UK, Canada and Europe.

The next time you polish off these delicacies, would you want to eat them with the fear of ingesting the Bt toxin as well?

Are we risking the health of millions of Indians when published scientific data, as of now, is ambiguous about the safety of GM food crops?

A small nation, such as Mexico, had the courage to say "No" to GM maize. Yet, India is issuing a "blank cheque" for any GM crop, be it brinjal, which originated here, or rice, in which India has a tremendous export stake.

Are we being pushed to do this, and if so, by whom? ●

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