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From the Director's Desk

K.T. Chacko

The past several decades are witness to a path-breaking revolution in biotechnology, which is bound to have multifaceted and far-reaching impacts on human life, in particular, and the environment, in general. The biotechnology revolution refers to the emergence of new technologies that allow life to be manipulated at its most basic level – genes. While biotechnology is a multi-dimensional concept touching upon a range of scientific disciplines, some of the issues pertaining to this discourse have turned out to be rather controversial; generating heated public debates the world over. These include genetically modified organisms (GMOs), human-cloning, and so on.

Given that the methods of biotechnology can be applied to study virtually any biological phenomenon, its far-fetched implications for biodiversity are rather obvious. Many of these implications, however, are far from clear till date. Take for instance, the case of GMOs in agriculture. While proponents of GMOs vouch for the immense potential ingrained in this technology to increase agricultural productivity manifold, the jury is still out on its possible impact on biodiversity. Several studies, however, have indicated that application of genetic engineering in agriculture may result in significant loss of biodiversity.

Another contentious issue in the context of the biotech revolution is that of bio-piracy – misappropriation of the genetic resources and related traditional knowledge (TK), predominantly of the Southern countries. Importantly, in recognition of the rights of the sovereign states over their biodiversity, the UN Convention on Biological Diversity (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 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 (Trade-related Aspects of Intellectual Property Rights) Agreement of the WTO 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 a view to rectifying such lacunae and ensuring implementation of both TRIPS and CBD in a mutually supportive manner, developing countries have been insisting on an amendment to TRIPS for the past several years.

A group of 100-plus developing countries, with India as a front-runner, are currently taking keen interest in bringing the issue of the relationship between TRIPS and CBD to the forefront of the ongoing Doha Round of WTO negotiations. They insist that amendment to TRIPS merits immediate attention of the WTO to check the problem of biopiracy and misappropriation of TK. The proposal, however, faces stiff opposition from developed countries, who emphasize that disclosure is not the most effective way of addressing biopiracy. However, a breakthrough on the disclosure issue as part of the Doha deal assumes enormous significance for developing countries to effectively address the biopiracy problem sooner than later. Hence, developing countries including India must make a full-throated attempt towards this end, once the stalled Doha talks resume, no matter when!

Growth in Biotechnology Products and Global Trade Regime

Emerging Trade Policy Concerns for Developing Countries

Sachin Chaturvedi*

The issue of biotechnology has become a contentious issue. Its proliferation has justified that in the wake of a severe impending food crisis, world hunger will be mitigated to a large extent through 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 everyone 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. This paper analyzes the issue in detail.

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The views expressed in this paper are personal.

I. Introduction

THE increasing role of knowledge in agricultural production and its assimilation, particularly through bio-technology, in the existing policy frameworks has emerged as one of the most important pressing issues before the developing countries. In the context of trade regime, the question is further complicated due to globalization and enhanced interaction at the levels of commodity exchanges and agricultural exports. This trend suggests that it has become increasingly important to bring dynamism in the functioning of the science & technology system at the national level so as to tune with the existing physical infrastructure. The development of an effective S&T system, to address trade requirements, depends crucially on institutional set-up that supports this system and the cohesion between the overall developmental objectives and the R&D endeavours in different streams. In fact, these factors play a far more significant role in frontier technologies, biotechnology, in particular than in case of any other technology. The potential of plant biotechnology for agriculture includes a diverse range of techniques, which appear to offer scope to help solve some of the problems of developing countries, particularly since they provide potential tools to solve agronomic problems. In fact, many developing countries, including India, launched a series of programmes to take advantage of this opportunity.[1]

With the growing trade in biotechnology products the issues related to trade policy span over several WTO agreements. They include agreements like SPS, TBT, Agreement on Agriculture (AOA) and Intellectual Property (TRIPs). However, at WTO committees like the Trade and Environment Committee (CTE), have also been discussing the GMOs from environmental perspectives. Although member governments have notified a large number of regulations related to GMOs to the SPS Committee, most of the discussion on the subject has been in the TBT Committee with the focus on labeling regulations. In the current agriculture negotiations, some members have called for clarity in the WTO rules as applied to products of new technologies. In this section we take up two important agreements in light of GMOs, viz. SPS/TBT and TRIPs for further discussion. As debate on labeling has emerged as a major policy

challenge, we discuss SPS measures in light of the experience of developing countries.

The rapid expansion in biotechnology is further complicating the policy issues related to trade. Pharming, is a new branch of biotechnology that utilizes transgenic plants or animals as living factories to produce pharmaceuticals for the use in humans and animals. The term "pharming" is based on a merger of the words "farming" and "pharmaceuticals" which illustrates the combination between the two highly different industries.[2] The trade related questions become further complicated when one considers plausibility of a scenario of food chain contamination as was first documented in 2002 in the US.[3] There, 13,000 tonnes of vaccine contaminated soybeans had been discovered. Also recent cases in Europe of contaminations of rice, with a genetically modified rice strain (LL RICE 601) that was never approved for commercial use, demonstrates impressively that neither confinement strategies nor import regulations have been efficient so far. In addition, it remains to be investigated whether confinement strategies are suitable for restricting consequences of pharming for nearby flora, fauna and soil microbiology.

In this paper, we have tried to address some of these issues. Section II covers definition and classification of various biotechnology products. Section III looks into standard related debate in the context of biotechnology products. The last section draws the conclusion.

II. Definition and Classification of Goods

Adoption of biotechnology in industrial and other activities is a relatively recent phenomenon even in many developed countries. It is expected that the statistics would provide clarity about the governance of biotechnology. It is, therefore, important to outline a statistical framework that allows the measurement of these industrial and developmental activities so that the policy-makers may evolve adequate responses. Moreover, there have been intense discussions on the impact assessment of this technology measurement. In several developing countries biotechnology products such as GM crops have created further confusion on the intricate issues related to the measurement of the impact of the technology. These discussions have important implications for both developed and developing countries. Several initiatives are taking place in various institutional settings which may influence eventual policy debates in the ambit of trade, inter-national regulatory arrangements like the Cartagena Protocol on biosafety (CPB) and within the multilateral, regional and national standards and regulation agencies responsible for the release, safety assessment and food use of biotechnology products.

In this context, the Working Party of National Experts on Science and Technology Indicators (NESTI) of Committee for Science and Technology Policy of OECD has initiated an exercise of data collection in biotechnology for member countries.[4] In its various meetings NESTI decided to initiate the exercise after finalizing the definition of biotechnology for statistical purposes. An inventory of policy issues and related indicators has also been prepared. Different working groups have come out with guidelines for the compilation of these indicators along with model questions and surveys. These working groups are also identifying links with other existing manuals like Oslo manual and *Frescati manual.* Some of the member countries have already launched data collection exercise, which we discuss briefly herewith. In order to collect policy relevant statistics, it is utmost important to have a precise definition of biotechnology. OECD, over the years, too has come out with a broad definition which says, "The application of science and technology to living organisms as well as parts, products, models thereof, to alter living or non-living materials for the production of knowledge, goods and services." Although the single definition defines the purpose of biotechnology, the list based definition is essential for identifying modern biotechnology. In the OECD report (*Biotechnology Statistics 2006*) includes data for a few countries that used a different definition of biotechnology, as long as the definition was limited to 'modern' biotechnology. This option will still be available in 2008, although we encourage countries to adopt the OECD definition.

In the context of trade, biotechnology products, being based on process based criteria are

an alien element for foreign trade classification.[5] In trade the HS classification is primarily preferred as an instrument for customs departments for invoking different tax regimes and it is for this purpose clear distinction of goods according to their usage and production becomes important. In this classification, an effort is made to describe various categories in such a way that customs officials can understand and implement the tax regime. However, the US Bureau of Census (USBOC) has made an effort to identify import and export statistics related to biotechnology. The definition that they have used relates to biologics consisting of therapeutics products derived from living organisms, such as vaccines, human blood and plasma proteins and monoclonal antibodies. Some of them are identified in Table 1.

In case of biotechnology products, there is also a need to address environmental goods as a priority in the Doha Round from the point of streamlining the related tariff regime.[6] Though tariffs on biodiesel are already quite low, but are still high for ethanol. For instance, the US tariff is 54 Cent per gallon. The constraint is that ethanol is covered currently by the WTO Agreement on Agriculture and thus is not taken in the environmental goods negotiations.[7] It is eligible according to the Doha Ministerial Conference, but OECD countries stonewalled it. It is also suggested that the subsidies to biofuel crops may be placed in the 'green box' in the agricultural negotiations, which would make them exempted from cuts to payments that distort production and trade.[8] However, apart from trade, it is also the question of increasing cross investments in the sector as seen in the case of Brazil where there are several foreign companies that have acquired sugarcane farms and processing units to produce bioethanol for their home markets.

TABLE 1

HS CLASSIFICATION FOR EXPORT AND IMPORT OF BIOTECHNOLOGY PRODUCTS

HS Code	*Biotechnology Products as Adopted by US Bureau of Census*
2933.24.4500	Drugs, excluding aromatic or modified aromatic, containing an unfused imidazole ring in the structure.
2937.10.0000	Pituitary (anterior) or similar hormones and their derivatives.
2937.92.0000	Estrogens and progestins.
2937.92.1010	Estrogens of animal or vegetable origin.
2937.92.1050	Other progestins of animal or vegetable origin.
2937.92.5010	Estrogens not derived from animal or vegetable materials.
2937.92.5020	Progestrerone not derived from animal or vegetable materials.
2937.92.5050	Other progestins not of animal or vegetable origin.
2937.99.9550	Other hormones and derivatives, other steroids, etc.
2940.00.2000	Other sugars, not elsewhere specified or not elsewhere included, excluding D-Arabinose.
3002.10.0040	Foetal bovine serum.
3002.10.0060	Other blood fractions not elsewhere specified or included.
3002.20.0000	Vaccines for human medicine.
3002.30.0000	Vaccines for veterinary medicine.
3002.90.5020	Antiallergenic preparations, and
3002.90.5050	Toxins, cultures of micro-organisms and similar products.

Source: Devlin (2002).

III. Standard Related Issues

Generally, the trade impacts of SPS measures can be grouped into three: *First*, they can prohibit trade by imposing trade ban on the product or on the inputs used for its production. *Second*, they can divert trade from one trading partner to another by laying down regulations that discriminate across potential supplies. *Third*, they can reduce overall trade flows by increasing costs or raising barriers for all potential suppliers.[9]

As the liberalization of tariffs and quantitative restrictions on trade in agricultural and food products has progressed, attention has focused on technical measures such as food safety regulation, labeling requirement and quality standards. The Agreement on SPS measures seeks to protect consumers by providing rules for food safety and animal & plant health. However, the SPS Agreement does not permit non-science concerns such as consumer preferences to be considered in the determination of whether an SPS measure is acceptable. In certain cases, stricter SPS measures are applied to imports than domestic supplies. Given the nature and depth of existing regulatory structures in case of SPS in developed countries, developing countries often find it difficult to comply with such standards. At times, it seems that,

SPS measures may impede trade in agricultural and food products since in many instances they are incompatible with prevailing systems of production and marketing. The developing countries often lack appropriate scientific and technical expertise to deal with such standards. Moreover, the multiplicity of standards in the developed country markets has further compounded the problems being faced by developing country exporters.

It was agreed at the WTO Ministerial Conference at Doha that negotiations on issues relating to SPS measures would be addressed on priority basis in the next ministerial conference. In this regard, the CTE was also instructed to give particular attention to this effect. This had become relevant in light of the fact that the past decade had seen a global proliferation of environment and health related standards along with a rise in the trade in environmentally sensitive goods.[10]

Since the inception of WTO, some 2300 notifications have been received and almost 11 per cent of them are related to environment. The SPS Committee, meeting on 31st October and 1st November 2001, for the first time discussed genetically modified organisms. While considering notifications at the SPS Committee, the US and Canada enquired about the EU's restrictions on genetically modified organisms (GMOs). They complained that the EU had failed to notify its latest directives on traceability and labeling under SPS, even though these indicate that health protection is one of the objectives. The EU delegate said that any comments on this notification should be sent to its authority handling technical barriers to trade issues. Under "other business", the US also complained about the lack of scientific justification for the EU's continued de facto moratorium on approval of GMO products, and Canada said the latest EC measures discriminate against products produced by GM technology, even where no trace remains in the final products.

The new agreements on TBT and SPS measures were added to the WTO, with an idea that no country should be prevented from taking measures - necessary to ensure the quality of exports, or for the protection of human, animal or plant life, or health of the environment, or for the prevention of deceptive practices, at the level, it considers appropriate. However, barriers in the name of technical regulations line the boundaries of internationally trading nations. It has been demonstrated that developing countries find it difficult to trade with the developed countries due to the differences in the quality requirements, which to some extent may reflect on the prevailing consumer concerns or the nature of government regulation.

Maskus and Wilson (2000) have evolved a framework to analyze the quantification of such trade barriers in terms of their impact. The paper also outlines the strengths and weaknesses in Mutual Recognition Agreements (MRAs). This is a model of regulatory harmonization first developed as part of an internal market reform in the European Community in the late 1980s. Some application on this line has come from Otsuki *et al.* (2000), who have used gravity equation model to estimate the impact of changes in food related EU standards on African exports. They did a survey of trade and regulatory data for 15 European countries and 9 African countries between 1989-1998. The results suggest that the implementation of the new aflatoxin standards in the EU will have a negative impact on African exports. The EU standards, which would reduce health risk to some extent, will decrease these African exports by 64 per cent or US$ 670 million. Apart from this very few studies have made an effort to quantify the impact of SPS measures on trade of developing countries. Cato (1998) attempts to quantify the costs of compliance with SPS measures by developing countries. This study assesses the costs of upgrading sanitary conditions in the Bangladesh frozen shrimp industry to satisfy EU and US hygiene requirements. It is estimated that $17.6 million was spent to upgrade plants over 1997-98. This gives an average expenditure per plant of $283,000. The total industry cost required to maintain HACCP is estimated to be $2.2 million per annum. Finger and Schuler (1999) examined the costs of SPS requirements in the developing countries. They found that the cost of achieving disease and pest free status to enable Argentina to export meat, fruit, and vegetables is reported to have been $82.7 million over the period 1991-1996. Mutasa and Nyamandi (1998) assess the degree to which SPS requirements impede exports of agricultural and food products from African countries. Of the African countries, 57 per cent

indicated that exported products had been rejected within the previous two years. The main reason was microbiological contamination.

Some standards evolved in the developed countries, as voluntary benchmarks for importing goods have become mandatory standards for the developing countries. Eco-labeling is one of them. It has generated many concerns in developing countries. They argue that the voluntary Eco-labeling programmes are of discriminatory nature and are thus inconsistent with free trade principles of the WTO (Tieje, 1995). Since they are designed to differentiate products on the basis of their environmental features, they can have a major influence on conditions of competition in a market. Adverse trade effects may arise, first of all, from lack of transparency in product selection, criteria development and threshold-setting processes.

Robertson, D. and Kellow, A. (2000) explore the aspects of risk with special reference to the WTO, where national instruments to reduce risks may conflict with international trade rules. Quarantine regulations, technical/ product standards and environmental legislation in some circumstances may conflict with trade rules and principles, and result in trade disputes. WTO treatment of risk is also important in the context of agreements on SPS and TBT. The authors conclude that the WTO has no role in assessing scientific risk, especially when environment is involved.

At the Committee on Agriculture this issue came up again in the same context. In July, special session of the Committee on Agriculture, the European Union tabled a controversial paper on food safety, proposing criteria for the application of precaution under the Agreement on SPS that would serve as a guideline for panelists in future disputes. According to the EU, the issue needs to be addressed to avoid the public perception that the WTO requires members to force consumers to accept unsafe food. The EU, other European countries, Japan and Korea argued that Article 5.7 of the SPS Agreement should be clarified through an Understanding that would send the right signals to consumers. Article 5.7 allows members to take provisional health measures when relevant scientific evidence is insufficient, and the substance of the discussions revolved around whether the Article was clear enough to maintain the balance between the need for consumer protection on the one hand and the need to avoid disguised protectionism on the other.

As the trade in the agricultural energy products derived from biotechnology would expand, the issues related to the sanitary and phyto-sanitary measures (SPS) and technical barriers to trade (TBT) assume importance. Since the European Union, the Republic of Korea and Japan have been viewing the development in the biotechnology sector with caution, the issues may act as a deterrent to the countries taking a policy decision in this context. These countries have been exercising their options as per Article 5.7 of SPS providing scope for members to take provisional health measures when relevant scientific evidence is insufficient. The EU has asked for the inclusion of precautionary principle in the ambit of the SPS agreement. In this context, the recently announced WTO ruling on the import ban by the EU of GM products becomes relevant. It is important to note that the United States, Canada and Argentina raised this dispute as per Article 5.2 of the SPS and not as violation of Article 5.7 of SPS.[11] This may have major implications for those countries, which are contemplating to explore options within this line of argument. As Para 7.428 of the interim report on the dispute clearly states that the dispute comes under SPS and not under any other agreement like TBT.

SPS is one agreement which is very narrowly defined hence provides very little manoeuvring space for the defending parties. Moreover, the view that Article 5.7 of SPS, under which precautionary principle is justified, is actually an exception to Articles 2.2 and 5.1 which expect members to base and maintain SPS measures on sufficient scientific evidence.[12] Moreover, biofuels are a highly processed product not intended for human or animal consumption. According to the SPS provisions of WTO, trading partners cannot discriminate against products based on their process and production methods (PPMs).[13] Under these rules, it is unlikely that a ban on biofuels because of the use of biotechnology would be found compliant to WTO. In this context, the international agencies would have to launch initiatives to establish the standards so that

the non-tariff barriers are not imposed. The developing countries should be assisted in reviewing and updating existing standards also to develop and notify standards for new and renewable systems/devices for which standards have not yet been laid down at par with international levels. With the growing urge among the developing countries to emerge as key exporters of several of these products, there is a need to set guidelines for product specification and performance parameters which should be developed and institutionalized in larger interest. As of now, there are three major producers, which have already come out with programmes related to standards. They are the United States, Germany and Austria.[14] The ASEAN has also launched a regional discussion forum based on such a framework.

IV. Concluding Remarks

With the expansion of biotechnology industry and introduction of new products through various branches like pharming have thrown up new challenges related to classification of goods. The new advances in biotechnology have led to greater convergence of biotechnology with other frontier technologies like information and communication technology, new material sciences and nano technology. The products emanating from this convergence has led to completely new value chains across the manufacturing sector. In some cases, it involves traditional production lines while in many cases it completely bypasses the existing production structures. This requires not only a new definition for classification of goods but also regulatory and standards regime to be geared up for meeting new policy challenges. Those countries which are keen to adopt restrictive biotechnology policies for various reasons are adopting policies such as OECD's unique code number scheme so as to be well aware of nature of imports. However, developing countries, due to lack of preparedness find it difficult to put in place such a regime. In this context, resource constraints faced by developing countries also play an important role.

As discussed in the text of this paper, very few developing countries have adopted a comprehensive biotech policy to capture various developments in the realm of this technology. Though, OECD countries have adopted a one line definition and an elaborated definition but multilateral institutions and developing countries have yet to respond to this development. In this context, the World Customs Organization (WCO) should work more closely with developing countries and other relevant multilateral institutions to evolve a wider consensus on trade classification which may eventually be adopted for various international trade databases generated through different UN agencies like UNCTAD, UNIDO, etc.

As EU still works towards the full implementation of WTO directive, in light of trans-Atlantic GM dispute, the focus on GM trade policies is largely hovering around other possible interpretations of Article 5.7. To create predictability for members and to prevent Article 5.7 from being abused for protectionist purposes, the EU proposed that precaution be applied according to the following five criteria: (i) the measure should not be discriminatory; (ii) it should be aimed at achieving consistency in the level of protection that the Member has chosen; (iii) the adopted measure should presuppose an examination of the benefits and costs of action and lack of action; (iv) it should be reviewed if new scientific information is obtained; and (v) the measure must be based on scientific evidence provided by qualified and respected sources, but not necessarily by the majority of the scientific community. The US and many developing countries strongly opposed this effort to bring food safety onto the agriculture negotiating agenda. They argued that the EU's version of the precautionary principle was based on political rather than scientific considerations. In this context, it would be in the interest of developing countries to work closely with WTO for removing any kind of ambiguity concerning the application of precautionary principle particularly, in the context of agricultural products. The GM products should be assessed within the ambit of food safety and, therefore, on the fora of SPS and the TBT committees rather than pushing them on the committees related to AoA.

ENDNOTES

[1] However, at the outset, it is important to clarify that biotechnology is something beyond the developments of Genetically Modified Organisms (GMOs). Sahai (1999)

[2] Engelhard (2007).

[3] *ibid*

[4] Some non-member countries like India and Israel have also been involved recently.

[5] Devlin (2002).

[6] Steenblik, Ron (2006).

[7] *ibid*

[8] Shapiro, Ira (2004).

[9] See Chaturvedi and Nagpal (2003).

[10] However, nothing of this could happen at Cancun.

[11] CIEL (2006).

[12] CIEL (2006).

[13] Loppacher (2004).

[14] ASTM International (2003); Koerbitz (2004).

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NEWS
(NATIONAL/INTERNATIONAL)

Biotech Sector Revenues Cross Rs 10,000 cr

THE domestic biotech industry has grown further to post revenues of Rs 10,273 crore ($2.56 bn) in 2007-08. Based on current trends aided by the new biotech policy, the 2015 revenue forecast is Rs 64,400 crore ($13-16 bn). In 2006-07, the industry posted revenues totalling Rs 8,541 crore ($2.01 billion). These are the findings of the sixth yearly BioSpectrum-ABLE Biotech Industry Survey, according to a release by the nodal Association of Biotech Led Enterprises (ABLE).

According to N. Suresh, Group Editor, *BioSpectrum,* "After five straight years of over 30 per cent growth, India's fledgling biotech industry has slowed down. The appreciation of the rupee for most of 2007-08 stole the high growth momentum from an industry that records two-thirds of its revenues from exports," which was Rs 5,733.7 crore in 2007-08. Investments touched Rs 2,750 crore, or up 21 per cent. During the surveyed year that ended on 31 March 2008, 56 per cent of the revenue came from exports, the release said.

ABLE's President, Dr K.K. Narayanan, was quoted as saying, "The inability to sustain the growth momentum can be attributed to several factors; the primary one being that the revenues from Indian-made innovative biotech products that can be sold globally are yet to kick in".

"The biopharma industry in India is coming of age now and the next five years will be a very interesting period for the Indian biotechnology industry. While bioservices will continue to attract significant interest, and biogenerics exports to the regulated markets are likely to produce a quantum leap in company earnings, there is a growing club of companies in India that are developing novel biotechnology-based pharmaceutical products.

"We expect biotechnology to begin to contribute significantly to other areas such as biofuels," commented Shrikumar Suryanarayan, Director-General, ABLE.

Bt Cotton

The bio-agri sector which took off in 2005-06 slowed down as Bt cotton seeds marketed by about two dozen companies faced pricing pressures in major markets. However, the transgenic cottonseed saw a significant increase in cropping area. The bio-agri revenues touched Rs 1,200 crore.

Serum Institute on Top

For the third consecutive year, the Pune-based Serum Institute emerged as the top biotech company with revenues of Rs 987 crore. Biocon (Rs 912 crore), Panacea Biotech (Rs 677 crore) and bio-agri company Nuziveedu Seeds (Rs 303 crore) follow. The top three - Serum, Biocon and Panacea - are in the biopharma space and retain their 2007 positions. They account for 25 per cent of the total revenue. The top 20 companies registered $1.25 billion in revenues and contributed to almost 50 per cent of the total biotech business. Only three companies, all of them biopharma companies had revenues of Rs 500 crore in 2007-08. Seven companies have revenues of Rs 200 crore and above; 85 per cent of top 20 companies have revenues in excess of Rs 100 crore.

(*The Hindu Business Line*, 17 July 2008)

Biofuel Rethink Necessary

BIOFUELS based on ethanol, vegetable oil and other renewable sources are increasingly popular with government and environmentalists as a way to reduce fossil fuel dependence and limit greenhouse gas emissions.

But new research led by a biologist at the University of Washington, Bothell, shows that some of the most popular current biofuel stocks might have exactly the opposite impacts than intended. The authors of a paper published in the June issue of the journal *Conservation Biology* offer a dozen policy recommendations to promote sustainability and biodiversity in biofuel production.

The study looked at factors such as the energy needed to produce a renewable fuel source compared with how much energy is produced, the impact on soil fertility and effects on food supply when fuels based on crops such as corn and soybeans are mixed with fossil fuels. Based on those factors, the authors determined that corn-based ethanol is the worst alternative overall.

"It's foolish to say we should be developing a particular biofuel when that could mean that we're just replacing one problem with another," said lead author Martha Groom of the UW Bothell. Co-authors are Elizabeth Gray of The Nature Conservancy and Patricia Townsend of the UW Seattle.

The authors argue that precise calculations are needed to determine the ecological footprints of large-scale cultivation of various crops used for biofuels. They note, for example, that because such large amounts of energy are required to grow corn and convert it to ethanol, the net energy gain of the resulting fuel is modest. Using a crop such as switchgrass, common forage for cattle, would require much less energy to produce the fuel, and using algae would require even less. Changing direction to biofuels based on switchgrass or algae would require significant policy changes, since the technologies to produce such fuels are not fully developed.

These concerns are becoming more acute with the rapid rise of both food and fuel prices, she said. The issue is especially touchy for farmers who might for the first time be realizing significant profits on their crops, but it also is a serious concern for motorists.

"I've heard about people getting their gas tanks siphoned, and I hadn't heard of that since the 1970s," she said.

A difficulty, Ms. Groom said, is that while escalating prices add pressure to find less costly fuel sources, acting too hastily could create a host of other problems. For example, farmers who plant only corn because it is suddenly profitable, and don't rotate with crops such as soybeans, are likely to greatly deplete their soil, which could limit crop growth and promote soil erosion.

Also, some plants are better than others for absorbing carbon dioxide from the atmosphere, while others perhaps need more cultivation, which requires more fossil fuel for farm equipment. In addition, fertilization, watering and harvesting all require energy.

The study took about a year to conduct and is a synthesis of peer-reviewed research published in various journals. The scientists examined the literature looking for indicators of biofuels that are more sustainable and carry a smaller ecological footprint, then used that information to derive the policy recommendations.

(www.scientistlilne.com/lab/?/biotechnology)

Biotech Regulator Needs Engineering

IT is good news that the government is expediting the process of setting up the national biotechnology regulatory authority, which is envisaged as a dexterous, one-stop facility. Even after a fair degree of streamlining of the regulation of modern biotech products—medicinal and agricultural— in recent years, the regulators tend to overreach their jurisdictions, causing a lot of hardship to applicants. At the same time, regulatory laxity and incompetence are posing a serious enough threat to nature including the humans therein.

The regulators in this domain are many. The Genetic Engineering Approval Committee (GEAC) attached to the Environment Ministry has the mandate to assess the compatibility with the natural environment of the genetically re-engineered product for which manufacturing/marketing approval is sought.

The Review Committee on Genetic Manipulations (RCGM) in the Department of Biotechnology which is part of the Ministry of Science and Technology is empowered to ask the applicant to produce the bio-safety data related to the genetically modified organisms and products derived therefrom, besides overseeing the process of creating the data.

The Drugs Controller General of India (DCGI) is entitled to give/deny approval for indigenous manufacture/import as well as marketing of therapeutic proteins and vaccines involving generic re-engineering such as recombinant DNA technology. DCGI also ensures that clinical trials (on humans) of these substances in three phases are done and the data produced is validated before the approval for manufacture/marketing is given.

DCGI, along with GEAC, is also responsible for maintaining post-marketing surveillance on these products as hazards could show up when the exposure to the nature/human body is widespread and prolonged.

The complexity of regulatory regime does not end there. There is the lower tier of Institutional Bio-safety Committees (IBSCs), which do the job of assessing the risk profile of these substances at the level of the researcher/potential commercial operator and recommend what kind of regulatory scrutiny the substance and the process of making it should be subjected to.

The IBSCs also oversee the conduct and examine the results of the animal toxicity studies prior to clinical trials, in coordination with another regulator, the institutional animal ethics committee. That the approval-giving mechanism is quite cumbersome is evident from the very fact the applicants need to produce clinical trials data, one of the many requirements for getting the approval, before three regulators – GEAC, DCGI and RCGM.

It is common that GEAC which gives the go-ahead for release of the substance to the environment, implements more exacting standards than other regulators, causing the applicant to stumble at a fairly advanced stage. It is not uncommon for GEAC to ask the applicant to do clinical trials afresh as per a changed protocol, after DCGI approval is given.

Since the regulators perform under different Acts of Parliament — GEAC under the Environment Protection Act, DCGI under the Drugs and Cosmetics Act and Institutional Animal Ethics Committees under the Prevention of Cruelty to Animals Act – the problem is exacerbated.

India is an emerging force in the area of biotech research. Many of its publicly funded institutions as well as a few private companies have made headway in this area. We have at least few recombinant DNA biotech products developed predominantly indigenously (if not totally) like human interferons (used for cancer cure), streptokinase (a clot-dissolving substance), erythropoitein (for blood regeneration) and a few vaccines. Competent and reasonable regulation is a prerequisite for the industry to grow. International trade in this area also holds tremendous growth potential, as endorsed by several studies by professional agencies.

Another area that will need to come under the regulatory gaze of the proposed national biotechnology regulatory authority is stem cell research. Currently, over a dozen institutions are publicly undertaking some activity or the other in the field of stem cells in India while scores of others are believed to be doing the same secretly. Yet, there is no formal regulation of the sector with necessary legal sanction and diligence.

The existing set-up comprising the Indian Council of Medical Research's National Guidelines for Stem Cell Research and Therapy, 2006, and a draft stem cell policy published by the Department of Biotechnology is devoid of proper legal backing. Also, DCGI, which is required to approve clinical trials of stem cell therapy, obviously need to harness expertise in the area.

Stem cell research which comprises creation of cell lines from multiple sources, including human embryo, adult cells and umbilical cord blood and therapy is therefore undertaken in the country in the absence of competent monitoring and this is obnoxious. It is evident that the regulatory agencies involved don't even coordinate properly.

Even while giving policy support to stem cell research, a promising area because of its potential to find cure for diseases caused by degeneration of cells, developed countries bar or restrict morally hazardous activities such as creation of human embryonic stem cell lines (derived from blastocysts, which, in turn, are sourced from surplus embryos in IVF clinics).

Regulators across the globe see the prospect of trade (even international) in human embryos, given the demand from stem cell researchers. The proposed national regulatory authority should therefore have an all-encompassing mandate in this area with necessary resources, technical and legal.

For biotechnology research and business to flourish in India (which offer immense benefits to patients, the farming community and consumers in general), mature regulation is a must.

(*The Economic Times*, 3 July 2008)

Developed Nations Thwart TRIPs Talks

DEVELOPED countries, including Japan, Korea, the US, Australia and New Zealand, are continuing to oppose India's attempts to start negotiations on amending the TRIPs Agreement to make stricter provisions for checking bio-piracy and usurping of traditional knowledge. In a recent meeting of the TRIPs Council, the countries said that amending the TRIPs Agreement will not solve the problem of bio-piracy and erroneous patenting.

According to a source in the WTO, India, Brazil, Peru and other developing countries kept pressing for WTO members to agree as part of the "horizontal modalities package" that their proposal to amend the TRIPs Agreement will be negotiated.

The "horizontal modalities package" is a reference to members' plans to try to strike a deal simultaneously in the coming month or so on blueprints for the final outcome on several subjects currently being negotiated, particularly agriculture and non-agricultural market access.

WTO members are trying to strike a deal on modalities for further opening up of the areas being negotiated under the ongoing Doha round in the next couple of months. The idea is to have the structure of the deal in place before the US temporarily opts out of the negotiations due to the forthcoming presidential elections in the country.

If members agree to negotiate amending the agreement, India, Brazil and their allies want the amendment to oblige countries to write into their laws a requirement for patent applicants to disclose the origins of biological materials and traditional knowledge used in their inventions, sources said. The countries also want evidence to be provided showing the applicants had received consent to research the materials and that the benefits of the inventions would be shared with the relevant local communities or authorities. Most developed countries, however, are not ready yet to accept the proposal and consider for negotiating and amendment to the TRIPs Agreement.

Developing countries like India have been victims of bio-piracy with entities from developed countries attempting to patent properties of items known to the people in developing countries and least developed countries for generations.

The group pressing for an amendment in the TRIPs Agreement argues that since disclosure was part of the convention on biodiversity (CBD) agreement and the mandate for the ongoing Doha round of negotiations at the WTO provided for a correlation between TRIPs and CBD, there was a strong case for amending TRIPs.

(*The Economic Times*, 27 March 2008)

India Wants WTO to Talk Beyond Farm and NAMA

INDIA is determined to have a say in the agenda for the mini-Ministerial meeting of the World Trade Organization (WTO) scheduled on July 21. It has decided to oppose the move of a few developed countries, backed by the WTO secretariat, to include just agriculture and NAMA issues in the Ministerial talks. India wants to ensure that issues of importance to developing countries such as concessions in the area of fishery subsidies and checking bio-piracy by amending the TRIPs Agreement are also included in the agenda.

The government sources pointed out that the agenda for the Ministerial meeting should be ideally decided by the entire trade negotiations committee (TNC) which has representation from the entire membership and is chaired by the WTO Director General. "We don't want the Director General to decide the agenda on his own," a source said.

There is a need to discuss in greater details the flexibilities to be given to developing countries in the area of fishery subsidies to protect the livelihood of poor fishermen. India, China and Indonesia have submitted a joint paper to the WTO on removing the stringent conditions mentioned in the draft proposal for allowing fishermen in developing countries to have access to government subsidies. The issue of amending TRIPs to incorporate disclosure norms, wherein a patent applicants has to disclose

the origin of the product and also share benefits with the country of origin, is also being pushed by India. "There are as many as 100 members of the WTO saying that this issue should be included in the discussions. If the issues are not put on the table now, they will be sidelined," the source said.

A mini-Ministerial is a formal meeting of a handful of trade ministers who represent various groups. If progress is reported in the mini-Ministerial, the areas of convergence are discussed by the entire membership to get everybody's endorsement.

It is hoped that the mini-Ministerial will result in a breakthrough in tricky issues holding up the Doha round of talks such as the flexibilities to be given to the developing countries in both agriculture and NAMA negotiations and the reduction in trade distorting subsidies in agriculture given by developed countries, especially the United States.

(*The Economic Times*, 27 June 2008)

India asks Lamy for Clarity on IPR, Subsidy Provisions

INDIA told WTO Chief Pascal Lamy that New Delhi would not remain silent if issues such as disclosure of provisions for genetic material, fishery subsidies and services were not resolved satisfactorily.

Mr. Lamy will convene a ministerial meeting on 21 July to finalize the modalities in Doha agriculture and market opening for industrials. The modalities in agriculture and non-agricultural market access (NAMA) would suggest the tariff and subsidy reductions for farm products and the tariff cuts for industrial products that members would have to undertake as part of the Doha agreement.

At a closed-door meeting of trade envoys from about 30 countries, Mr. Lamy said he was going to convene the July 21 meeting on the assumption that there is "better than 50 per cent progress" in agriculture and NAMA agenda.

He suggested that between now and 19 July when ministers are required to congregate in Geneva, members can bring about 90 per cent progress. "If we don't do it now, it would not happen," he said.

But there is widespread scepticism as many members say there is not even 50 per cent progress to warrant a ministerial meeting on 21 July.

"It is wrong to say that there is more than 50 per cent progress in agriculture and NAMA, and if anything, it is well below that figure," Argentina's senior trade negotiator, Nestor Edgardo Stancanelli, said. "There should not be a ministerial meeting if it has to result in a failure," he said.

India's trade envoy, Ambassador Ujal Singh Bhatia, challenged the Director-General to clarify the process and substantive issues, cautioning that within agriculture and NAMA there are umpteen unresolved issues such as the number and treatment of special products, the thresholds for special safeguard mechanism, and overall trade-distorting domestic support.

But more than agriculture and NAMA, Shri Bhatia said, there were issues such as fishery subsidies, TRIPs (Trade Related Aspects of Intellectual Property Rights), CBD (disclosure requirements for genetic material), and services which are vital for India in the Doha Round but not properly addressed till now.

"I can't be taking sides on TRIPs and CBD," Mr. Lamy told India, suggesting that the country must sort out the issues on its own with key members.

In a sharp response, Shri Bhatia said the Director-General could not turn a blind eye when 100 members demanded an immediate decision to launch negotiations on TRIPs, CBD and Geographical Indicators.

India then challenged the Director-General on the issue of fishery subsidies and rules that include a controversial provision to allow zeroing methodology, which inflates dumping margins.

(*Business Standard*, 26 June 2008)

New Tech Under Way to Fight Cotton Bollworms

SCIENTISTS are finding new ways to fight bollworms, the greatest threat to cotton crop across the globe. Genetic modification through Bt (bascillus thuringiensis) technology had been able to control it to a great extent and help increase the cotton crop, especially in India. Latest reports had shown that bollworms were developing resistance to Bt.

But good news is on its way to hapless cotton growers from Australia.

Scientists from Australia's Commonwealth Scientific and Industrial Research Organization (CSIRO), University of Melbourne and Baylor College of Medicine in the US are one step closer to deciphering the cotton bollworm genome. Insights from the bollworm genome will facilitate the development of new and more sustainable ways of controlling one of the world's worst agricultural pests.

The cotton bollworm, also known as the corn earworm or tomato grub, ranks as one of the most polyphagous and cosmopolitan pests, causing an annual damage of $5 billion globally. It is resistant to nearly every class of chemical pesticide and threatens the long-term effectivity of transgenic crops, which are reliant on Bt proteins.

The complete genome sequence will help scientists develop strategies to prevent the moth from developing resistance to Bt crops. It may also shed light on the biology of its American cousin, the cotton earworm. The team is expected to sequence the moth's genome in about four months.

The Australian Minister for Innovation, Industry, Science and Research, Senator Kim Carr, said at the recently concluded "BIO 2008 International Convention" in San Diego, California that the team was expected to sequence the moth's genome in about four months.

"This will allow the collaborating scientists and a worldwide consortium of specialists to work on new ways of controlling this pest," Senator Carr said.

According to CSIRO's group executive for agribusiness, Joanne Daly, these include: the molecular basis of resistance to chemical and Bt insecticides and population genetics related to the refuge strategies in place to help prevent helicoverpa from developing resistance to Bt transgenic cottons.

"This moth is resistant to nearly every class of chemical pesticide and threatens the long-term viability of transgenic crops, which are reliant on the biological pesticide Bt," Daly said.

(*The Financial Express*, 24 June 2008)

Total Review of Experience with Bt Cotton Sought

FRESH troubles are brewing for the Genetic Engineering Approval Committee (GEAC), which is slated to meet on June 25, to take a decision on the approval of several Bt cotton hybrids for commercial cultivation in this season. The Supreme Court's appointed invitee to the committee, Pushpa M Bhargava has not only called for a three or four years total moratorium on GM crops but has also called for "a total review of India's experience with Bt cotton".

Greenpeace India has brought to the fore cases of illegal imports of GM food, which is also the agenda for discussion.

Shri Bhargava, who is the founder director of the Hyderabad-based Centre for Cellular and Microbiology, has alleged, "there is substantial evidence which calls for a total review of the approval of Bt cotton in India."

He said that the GEAC relied on biosafety studies by the developer which included that on pollen flow, seed germination, soil microbial activity, toxicity and allergenicity. "Any study done by the developer is of no value. The GEAC has no mechanism to verify with the experimental and control groups nor the data is confirmed by a third party," he said.

According to Bhargava, chronic toxicity studies should be conducted, particularly in reference to aflatoxin. For soil microbial studies it was not enough to have total number of organisms determined as the bacterial profile and the effect on soil micro-nutrient were far more important. All toxicity studies should be done on the protein in the GMOs. Toxicity studies done with the surrogate protein made, for example, in E.coli should not be accepted.

He said that no GM crop should be released without appropriate and reliable DN finger printing, proteomics analysis and studies on reproductive interferences in at least 3 mammalian species by a reputed, accredited and independent laboratory.

(*The Financial Express*, 24 June 2008)

India Not Ready for a 'TRIP' on Bio-Piracy Issues

INDIA'S fight for tightening the TRIPs Agreement to check bio-piracy is slowly gaining support from more World Trade Organization (WTO) member countries.

While initially India's call for mandatory provisions for patent applicants to disclose the origin of genetic material or traditional knowledge used in their inventions (by amending the TRIPs Agreement) had the support of just eight members, there are as many as 100 WTO members now pushing for speedy negotiations on the issues of disclosure and extension of Geographical Indications (GIs) as part of the Doha negotiations. India, however, cannot afford to relax as there are heavyweights like the US and Australia opposing the move.

The 100 members favouring discussions on TRIPs including India, EU, Brazil, China and African countries, among others, want that the issue of disclosure and GIs to be a part of the horizontal process, i.e., the next phase in the negotiations when members move away from discussing each subject separately and aim for a balance across a range of subjects including agriculture, industrial products, to some extent services and possibly other subjects. The countries are seeking negotiations based on texts or draft agreements on the subjects.

According to sources in the WTO, the members against the move say that more technical discussion and more empirical evidence is needed before moving to "text-based" negotiations. These countries include the US, Japan, Singapore, Korea, New Zealand, Canada, Australia and Argentina.

Individuals and companies from developed countries, especially the US, have made several efforts to patent the properties of biological products like neem and turmeric which Indians have been using for centuries. The US government revoked patents on certain uses of neem and turmeric when India challenged the decision. Despite the small victories, the developed countries have been extensively using products growing in the developing world in their patented products without paying royalty.

Apart from disclosure of origin, India and other developing countries have also demanded that proper benefit sharing by the patent applicant with the country of origin should be in-built in the patents agreement. India is working on a digital directory of the country's traditional knowledge which it wants to share with the US so that US citizens seeking to patent India's knowledge could be identified easily. However, multilateral rules to deal with bio-piracy any day beats bilateral arrangements.

While all 100 members pressing for inclusion of the issues of disclosure, GI extension and GI register, are not in complete agreement with each other, all agree that the three issues need to be urgently sorted out at the multilateral level. While countries like India, China and Brazil have directed their efforts in pushing for disclosure norms, the EU is eager to see more products under GI apart from wines and spirits and the setting up of a GI register.

The WTO source said that the attempt to put three TRIPs issues into the mix of subjects to be discussed horizontally (known as parallelism) along with "modalities" (blueprints of final agreements) in agriculture and industrial products turned out to be the most discussed topic in the brief TRIPs Council.

Countries which spoke for both disclosure and parallelism and claimed that over 100 countries or around two-thirds of the membership support including all three subjects even if positions differ on the detail, included India, Indonesia, the least developed countries (Uganda speaking), Brazil, Ecuador, China, Switzerland (which favours disclosure but not necessarily through TRIPs), Mauritius (as a member of the African Group and African-Caribbean-Pacific Group), Peru, Colombia, Thailand, Nepal, the EU (which favours disclosure but outside patent law), Norway, Venezuela and Turkey. Philippines and South Africa spoke for disclosure but against parallelism.

Speaking against both, on the grounds that "disclosure" is not the most effective way of dealing with misappropriation, and in most cases that including these three with other subjects would jeopardize the negotiations in agriculture and industrial products were US, Japan, Singapore,

Korea, New Zealand, Canada, Australia and Argentina.

The on-going Doha round of negotiations include a number of areas like agriculture, industrial goods, services, rules and implementation issues flowing from the earlier Uruguay round.

(*The Economic Times*, 19 June 2008)

Lamy Backs India's Stand on Bio-Piracy

IN a major boost to India's fight against bio-piracy at the multilateral level, WTO Director General Pascal Lamy, in his report on "GI Extension and Bio-diversity Consultations", has said that there is an important common ground on the need to implement TRIPs and the convention on bio-diversity (CBD) in a mutually supportive way. However, the DG also said that there is no agreement on whether the issue is part of the on-going Doha negotiations.

While the recognition that TRIPs and CBD have to be implemented in a mutually supportive way would mean that the important issue of disclosure of origin of a biological product and benefit sharing, which is a part of CBD, could also become a part of the TRIPs Agreement, it could all come to naught if the issue is removed from the Doha negotiations. "The issue is very much a part of the Doha agenda and we will not allow it to be taken off," a government source said.

Disclosure of origin and benefit sharing would result in a mandatory requirement for patent applicants for disclosing origin of the biological resource being patented and sharing the benefits being generated by the patent with the country where the resource originates from. India, which is leading a group of nine countries including Brazil, China, Pakistan and Cuba, has been pushing for an amendment to the TRIPs Agreement to bring about the stated changes.

The amendment is very important for developing countries as it would give them ammunition to fight against patenting of natural resources originating on their turf by companies or individuals in the developed world. A group of about 100 countries, including India, have recently submitted a non-paper to WTO stating that the issues related to bio-diversity consultations and extension of geographical indications (another issue related to TRIPs) be made part of the '"horizontal process" in which senior officials and trade ministers from key countries would meet to agree on the modality texts for liberalizing trade in agriculture, industrial goods and other issues. The process is expected to expedite the negotiations of the Doha round and move it closer to a conclusion.

However, another group of countries, including the US and Australia, has insisted that the TRIPs issue be kept out of the negotiating process as it would make it too complicated. The DG report adds that a common ground has been reached on the avoidance of erroneous patents for inventions that involve the use of genetic resources and related traditional knowledge and securing compliance with national access and benefit-sharing regimes.

On the negative side, the report points out that the work continues to be characterized by different approaches to meet these objectives, including whether TRIPs Agreement needs to be amended and whether it was agreed at Doha that this issue is part of the negotiations and of the Single Undertaking. There are also different views on whether this matter should be addressed in the context of the modalities decision.

(*The Economic Times*, 12 June 2008)

India's Suggestion on Bio-Piracy Ignored

INDIA'S long-standing demand for mandatory disclosure for genetic resources to stop bio-piracy was given a short shrift when WTO Chief Pascal Lamy indicated that there were sharp differences among members over starting negotiations on this issue at this juncture.

New Delhi had insisted that the disclosure for genetic resources must be part of the so-called horizontal negotiations to discuss trade-offs between Doha agriculture and market-opening for industrials commitments.

But the US, along with some other industrialized countries, vehemently opposed India's proposal, which was backed by a number

of developing countries on the ground that it "would substantially set back efforts to arrive at a viable way forward for the Doha negotiations."

In his report on the extension of the protection of geographical indications to items other than wines and spirits and those related to the relationship between the TRIPs Agreement and the Convention on Biological Diversity, Mr. Lamy said, "Different views have been expressed about linkages between the issues of GI extension and TRIPs/CBD and also between these issues and work elsewhere."

Though the WTO Director General did not pronounce a judgment on what would happen to these two issues, the report, for all practical purposes, has poured cold water on India's demand to start negotiations to hammer out the disclosure provisions in the TRIPs agreement due to fierce opposition from the US and other members.

India attached more importance to amending the TRIPs Agreement for including the disclosure provisions for genetic resources. It has also evinced interest in extending the GI protection to items other than wines and spirits because of the problems faced on the basmati rice when an American company sought the trademark for Texmati rice.

Mr. Lamy said while a large number of members – the European Union, India, Brazil, among others, who are proponents of GI extension and a new TRIPs disclosure requirement – have proposed that these issues, together with that of the GI register for wines and spirits pressed for modality texts to reflect the key parameters for negotiating these two issues.

(*Business Standard*, 10 June 2008)

India Seeks TRIPs to Bio-Piracy

INDIA has insisted that the issue of amending the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement to check bio-piracy should be made part of the upcoming horizontal process at the World Trade Organization (WTO).

The horizontal process is a jargon for negotiations among a few WTO members to discuss modalities in agriculture and industrial tariff together with other issues such as services and TRIPs alongside it. The process would start with senior officials and then extend to trade ministers of the select countries. The remaining countries would be included in the discussions later.

A group of about 100 countries has submitted a non-paper to the trade negotiations committee on the WTO proposing that three intellectual property issues, including amendment of TRIPs Agreement related to biodiversity, extension of the higher level of protection for geographical indications (GIs) currently only required for wines and spirits, and the issue of creating a multilateral register for GIs of wines and spirits, should be part of the horizontal process.

The non-paper was produced by India, Brazil, EU and Switzerland. India and Brazil rooted for inclusion of the bio-piracy issue, while the EU and Switzerland supported the issue of GIs.

The indicators identify a good as originating from a particular place with which its reputation gets associated. At present, the WTO extends enhanced GI protection to only wines and spirits. Some countries, including the EU and Switzerland, are pushing for enhancement of the list of GIs accorded protection by the WTO.

According to sources, a group of countries including the US, Australia, Mexico, Canada and New Zealand, have spoken against the inclusion of the intellectual property issues. These countries argue that the controversy surrounding these would jeopardize the chances of success in the negotiations.

India insists the issues are part of the Doha negotiations as the consultations on extending the enhanced protection for GIs and on proposals related to biodiversity are part of the "implementation-related" issues in the Doha Development Agenda.

The TRIPs amendment, discussed in relation to the Convention on Biological Diversity (CBD), would require patent applicants to disclose the origin of genetic material and traditional knowledge used in the invention, to show that they have received permission to use the materials and knowledge and to show they are sharing the benefits with the original owners.

India and other supporting countries are of the view that the amendment is of importance as it would check the blatant bio-piracy being carried out by developed countries where individuals attempt to patent properties of items known to the people in developing countries and least developed countries for generations.

(*The Economic* Times, 9 June 2008)

India Upset over New WTO Proposals

INDIA has expressed disappointment with the revised drafts on agriculture and non-agriculture market access (NAMA) circulated at the WTO recently.

In agriculture, dilution of the special safeguard mechanism (SSM) protecting the livelihood concerns of poor farmers is unacceptable to the country, officials said. India also rejected introduction of three different tariff reduction coefficients for developing countries, the linkage established between reduction commitments undertaken and flexibilities and the various carve-outs given to individual developing countries. New Delhi feels this is an attempt to divide developing country members who are negotiating as one through the NAMA-11 group.

"If our core national interests are not protected in both agriculture and NAMA, there will be no deal," Commerce Secretary G.K. Pillai said at a press conference.

While lauding the Committee on Agriculture (CoA) chairman Crawford Falconer for managing to come up with a text with just 30 square brackets, which indicate areas yet to be negotiated, India said that the NAMA Chairman Don Stephenson appears totally confused as he has introduced 97 brackets as opposed to 17 brackets in the earlier text.

Speaking to the media, Commerce Secretary G.K. Pillai said, it was impossible to hold a ministerial meeting with a draft text which has so many unresolved areas. "While some revisions have to be made in the agri text, the NAMA text has to be completely re-done," Shri Pillai said.

The WTO secretariat is trying to hold a ministerial meet by the end of June in which it wants to finalize the modalities for liberalization of both agriculture and NAMA. The following months would be utilized for scheduling of the commitments undertaken by each member and taking forward the negotiations in other areas which are part of the Doha round including services and rules. The broad idea is to have the Doha agreement in place by end of the year, following which each country would have to individually ratify it domestically.

In agriculture, India is unhappy with the text suggesting a price trigger of 30 per cent dip below existing prices for introducing SSMs which involves increasing import tariffs. "We can't wait for domestic prices to drop by 30 per cent before introducing safeguard measures. We will insist on the trigger to be the three-year average of price for a particular product," officials said. India will also insist on the volume trigger to be a 5 per cent increase in imports rather than 30 per cent suggested by developed countries.

Moreover, the condition of applying SSMs on 3 to 8 products is also unrealistic for a country with 23 agro-climatic zones, officials added. "During the Uruguay Round, developed countries had SSMs for 40 products. Why should we settle for less?" an official wondered.

In NAMA, India said that the reduction coefficient of 7-9 for developed countries and the three bands of 19-21, 21-23 and 23-26 for developing countries, translated into greater percentage cuts for the latter. Moreover, linking flexibilities for developing countries to the reduction coefficients they undertake is outside the mandate of the negotiations. India will also oppose the various carve-outs given to developing countries such as Venezuela and South Africa. "We are not against the concessions as long as we also get them," officials said.

The Indian industry, too, has lashed out against the NAMA text. According to FICCI, flexibilities have to be treated on stand-alone basis and there is no "trade-off" between flexibilities and tariff reduction coefficients. CII said the trade-off between the coefficients and flexibilities as proposed in the new text go against the development dimension of the Doha declaration. It said the proposed set of coefficients 23-26 without any flexibilities goes against the accepted development principles in the round.

(*The Economic Times*, 21 May 2008)

Biotech Sector Posts 30 per cent Growth in 2007-08

THE domestic biotechnology industry is now a $3-billion (around Rs 12,000 crore) sector, registering 30 per cent growth in 2007-08 over the previous year. Half of the 24 companies that came up were in Bangalore, that accounts for 60 per cent of the $1.5-billion exports, the Karnataka IT and Biotech Secretary, Shri Ashok Kumar Manoli, said citing an industry survey.

The top five companies by revenue contributed a third of the $3-billion turnover of the industry. Research services touched $500 million and bio IT (bioinformatics) was $250 million.

The State Chief Secretary, Shri Sudhakar Rao, said Bangalore's biotech companies had maintained 35 per cent growth rate with investment of $250 million in 2007-08. Bangalore's bio-cluster alone has 200 diverse companies, he said.

The city's growing strength in the sector was reflected in the growth of the annual bio conference this year: 150 exhibitors from 120 last year; 650 delegates from 500 last year; 15 countries and 50,000 visitors.

Phase 1 of the biotech park Bangalore Helix was nearing completion and the $1-million phase 2 would be ready in two years.

(*The Hindu Business Line*, 25 April 2008)

Biotech May See Boom Time; Turning into a Rs 11,000 cr Segment

THE time, the fund, the trend, linkages and policy support for the domestic biotechnology industry — all seems to be falling in place as it matures into a Rs 11,000 crore segment.

Dr. M.K. Bhan, Secretary, Department of Biotechnology, said he saw a second biotech wave as new investments poured in. Project funds alone of $100 million flowed in from overseas in one year. The Department has submitted the biotech regulator plan to the Union Cabinet and is crafting a mega scheme to bring expat scientists and technocrats back.

"We hope to see 2,000-3,000 scientists who went abroad come back to India in the next seven to eight years," Dr. Bhan said at the eighth annual Bangalore Bio event.

Dr. Bhan said, "We have taken the help of Welcome Trust to launch a mega programme to attract Indian scientists and technocrats working abroad back to India. This is a very attractive re-entry package for young Indians. There are a series of initiatives that should mature over a couple of years."

Biotechnology itself has got a Rs 6,500 crore outlay for the Eleventh Plan. The biotech policy focussed on creating human resources and this was backed by the big budgetary allocation for higher education.

The overseas funds were coming not just from old sources – the US and the UK; they came in from new geographies Australia and New Zealand, Denmark, Holland and Sweden. The long-awaited biotechnology regulatory authority on the USFDA lines should be in place in two years' time. This would be a professional body with solid training and members drawn from the industry, Dr. Bhan said.

About a dozen research institutions were coming up across the country over the next two to three years. In all these moves, Dr. Bhan said, "We are looking at the long term, for the next couple of decades."

Ms Kiran Mazumdar Shaw, Biocon Chief Managing Director and Chairperson of the Karnataka Vision Group on Biotechnology, said, "We are all seeking partnerships in a variety of ways — between countries, companies, labs and academia. The need is to provide affordable and accessible food and medicine and partnering makes it possible." India, she said, offered the lowest production cost of generic drugs, vaccines and now, biosimilars.

(*The Hindu Business Line*, 25 April 2008)

Genetically Modified Crops: Potential Benefits to Australian Agriculture

ACCORDING to a report prepared by ABARE, GM oilseed and wheat crops, if adopted, could provide significant benefits to Australian agriculture. The uptake of GM oilseeds and wheat could lead to a

gain of AU$912 million in the Australian economy by 2018. The economic benefit of GM crops is estimated under the assumptions that imports of GM crops are not restricted in foreign markets and the emerging economies of Argentina, Brazil, India and China will fully adopt these GM crops by 2018.

Argentina, Brazil, India and China in aggregate, account for around 39 per cent of the world's total GM crop plantings and this share is expected to increase as they continue to introduce GM crops at a faster pace than other countries. The increase in GM crop adoption has increased on-farm productivity, farm incomes and reduced input-use in these emerging economies.

Under an alternative scenario where it is assumed that the European Union bans the importation of GM crops from GM adopting countries, the estimated gain to the Australian economy of adopting GM oilseeds and wheat would reduce to AU$732 million by 2018, compared with what would otherwise be the case.

(*Agri Export Advantage*, 31 March 2008)

'Biotechnology Can be more Transformative than Infotech'

THE Vice-President, Shri Hamid Ansari, said biotechnology could be more transformative in its impact than information technology (IT). Its impact is more immediate and humane as it seeks to find solutions to the problems of human suffering. It is also more inclusive in its impact than IT, as its beneficiaries include farmers, the poor needing public health interventions, etc., he said.

Inaugurating the three-day 5th BioAsia 2008 conference at HICC here, Shri Ansari said biotechnology also brought together entrepreneurship, innovation, business and industry, State support, private and venture capital funding – an excellent example of public-private partnership.

The biotechnology industry grew at 40 per cent during the last five years and the turnover in 2005-06 was over $1.5 billion. It is estimated that the annual turnover would be over $10 billion by 2010, he said.

While addressing a large gathering of biotech professionals, foreign delegates and students present, Shri Ansari said that India was among the very few developing nations to have recognized the importance of biotechnology in agricultural and industrial growth. In the Sixth Five-Year Plan (1980-85), the first document to cover biotechnology development in the country was presented.

The Vice-President also laid the foundation stone for the Centre for Stem Cell Sciences, which would attract an investment of Rs 150 crore for developing a hospital, R&D Centre, cord blood bank to undertake frontline stem cell research. He unveiled a plaque of the Biotechnology Incubation Centre in the Genome Valley, being set up with an investment of Rs 30 crore.

The Nobel Laureate for Medicine, 2007 — Prof Martin J. Evans was conferred the Genome Valley Excellence Award by the Vice-President. The Australian High Commissioner to India, Mr. John McCarthy, said Australia wants to do a lot more in science and technology with India. India's Science and Technology Minister, Shri Kapil Sibal, is in Australia getting a feel of our capabilities now, he added.

The Andhra Pradesh Chief Minister, Dr. Y.S. Rajasekhara Reddy, in his presidential address assured full support to the growth of the biotech industry in the State, while his Industries Minister, Ms J. Geeta Reddy stated that Hyderabad's Genome Valley had emerged as the top destination for life sciences and biotech companies.

(*The Hindu Business Line*, 8 February 2008)

"BT will Overtake IT in Market Capitalization"

BIOTECHNOLOGY (BT) is an area with tremendous potential for growth in India like the IT sector, says Prof M. Radhakrishna Pillai, Director, Rajiv Gandhi Centre for Biotechnology (RGCB), one of the few nationally reputed establishments under the Central Department of Biotechnology (DBT). Excerpts of an interview:

What is the status of biotechnology in India at present *vis-a-vis* information technology (IT)?

Biotechnology (BT) is the new magic word in India, after the highly successful information technology or IT. BT got a late start in India because

the earlier corporate attempts by Monsanto and Cargill to usher in biotech in agriculture were stonewalled by farmers' movements on the apprehension that the companies were attempting to fossilize and hold back the inevitable technology.

The current thrust is to apply IT to BT, plant genomes, transgenic crops, food security, crop protection, and induced resistance to plant diseases. The McKinsey report states that by 2020, the market capitalization of only two major BT companies will equal the combined market capitalization of all the present listed IT companies.

That is real big business indeed! Biotech entry points are in the creation of databases and contract research organizations (CROs). The global trend to outsource R&D to areas of lower-cost capabilities in biotechnology is increasing.

How and where could BT contribute significantly to the Indian economy?

India could have aggressive and leading roles in production of vaccines, reagents for research and diagnostics, bioactive therapeutic proteins, seeds (hybrids, GM), bio-pesticides, bio-fertilizers, amino acid production, speciality bio-chemicals and plastics.

The Indian pharmaceutical market is growing exponentially. Bio-therapeutics and diagnostics of which recombinant Hep B dominate medical biotech segment vaccine is the major product. Others include GCSF, EPO & Interferon Alpha 2b, Human Insulin, Streptokinase, other vaccines and diagnostics.

Production of proteins and antibodies and fabrication of diagnostic protein chips would be a promising area for investment. With the liberal attitude India has adopted towards stem cell research, cell engineering and cell based therapeutics could be another area where India could cash in its expertise.

What does the future look like?

Because of the rising costs of R&D abroad, companies in the US and Europe are looking for contract research in India. India also offers a suitable population for clinical trials because of its diverse gene pools covering a large number of diseases. The IT skill of Indian manpower also offers services in bioinformatics and data mining.

(*The Hindu Business Line*, 14 January 2008)

Govt. Will Set Up Biotech Regulator

THE Government has decided to set up a National Biotechnology Regulatory Authority, which would provide a single window mechanism for biosafety clearance of all genetically modified products and processes.

"The Department of Biotechnology (DBT) has been entrusted with the responsibility of setting up the authority and funding it," the Science and Technology Minister, Shri Kapil Sibal, said while launching the National Biotechnology Development Strategy.

The Government has finalized the document after a two-year discussion with stakeholders. "The authority would be set up through a legislation, which should be ready in three months," Shri Sibal said.

The biotechnology development strategy, aiming to help the Indian biotechnology industry generate at least $7 billion annual revenue by 2010 against the present level of $2.3 billion, also lines up various schemes to promote specialized educational institutions.

In order to promote the biotech industry, the Government has decided to invest up to 30 per cent of DBT's budget in public-private partnership schemes by the end of Eleventh Plan.

The investments would promote innovation, pre-proof-of-concept research, accelerated technology and product development in biotechnologies related to agriculture, human health, animal productivity, bio-manufacturing and environment.

To promote advanced technologies with long gestation periods where the private sector might be unwilling to invest, the Government has also decided to fund 30-50 per cent of project costs and let the private party retain the intellectual property – provided it pays a certain level of royalty to the contributing public sector scientists. During the Eleventh Plan period, DBT is likely to be allocated Rs 6,500 crore against Rs 1,450 crore during the Tenth Plan period.

(*The Hindu Business Line*, 14 November 2007)

Bt Seed Market to Top Rs 1,000 Cr

IN 2006, an estimated 38 lakh hectares (lh) were covered under Bt cotton – out of the country's total cotton area of 91.30 lh, including some 63 lh under hybrids and the rest under various *desi* and American varieties.

According to the Union Agriculture Ministry, cotton acreage this year has touched 87.45 lh as on August 17, of which Bt hybrids account for 53.32 lh. "It looks we will see Bt coverage crossing 55 lh in 2007. And, I expect the share of hybrids in total area at 75 per cent, against last year's 70 per cent," says Shri Bhagirath Choudhary of the International Service for the Acquisition of Agri-Biotech Applications (ISAAA).

At 2.47 acres to a hectare, 55 lh translates into almost 136 lakh acres. Since farmers plant one packet (containing 450 grams of seed) for every acre and assuming an average rate of Rs 750, the size of the domestic Bt seed market would be roughly Rs 1,020 crore. Not bad for a technology that was commercialized first here in 2002, when it covered a mere 50,000 hectares.

(*The Hindu Business Line*, 22 August 2007)

GEAC Clears Large-Scale Trial of Bt Brinjal

THE Genetic Engineering Approval Committee (GEAC) has approved large-scale trials of what could be the country's first-ever transgenic food crop — Bt brinjal developed by the Maharashtra Hybrid Seed Company (Mahyco).

"We have allowed large-scale trials of Mahyco's Bt brinjal, which are to be conducted at the farms of the Indian Institute of Vegetable Research, Varanasi (IIVR) and its affiliate centres," a GEAC official said. The approval followed a GEAC meeting on August 8 to look into the report of an Expert Committee on Bt brinjal and related issues.

Additional Safeguards

The Expert Committee, headed by the Vice-Chancellor of Delhi University, Dr Deepak Pental, had gone into the bio-safety data generated by Mahyco, besides suggesting detailed protocols and additional safeguards to be observed during the large scale trials. "We have given the go-ahead for the trials based on what the Expert Committee has recommended," the official added.

Mahyco had sought permission for large scale trials of seven genetically modified (GM) brinjal hybrids: MHB-4, 9, 10, 80, 99, 11 and 39. These hybrids contain a foreign gene cry1Acisolated from a soil bacterium, Bacillus thuringiensis (Bt).

The gene synthesizes proteins toxic to the fruit and shoot borer (Leucinodes orbonalis). The cry1Ac gene's incorporation into brinjal is said to confer "in-built" resistance to the dreaded insect pest, thereby reducing reliance on pesticides.

Commercial Cultivation

Brinjal is a 150-180 days crop that starts giving fruit after 60 days and yields 15 pickings over the entire cycle. Farmers often spray 2-3 times before each picking, adding up to around 50 sprays. The crop is cultivated on about 5.1 lakh hectares across the country, with annual production estimated at 80-85 lakh tonnes.

The large scale trials are likely to take place over two seasons, which means consumers will not get to see the GM brinjal on their plates before 2009. So far, cotton is the only GM crop that has been approved for commercial cultivation since 2002.

Mahyco had sourced the original cry1Ac gene construct from Monsanto, the US-based life sciences major that also has a 26 per cent stake in the former. The transformation process or "event" – fitting the gene construct in the right place of the brinjal genome – was achieved at Mahyco's research centre at Jalna, Maharashtra.

(*The Hindu Business Line*, 17 August 2007)

"India, A Hothouse for Biotech R&D"

ASIAN countries provide certain distinct advantages for biotech companies of the developed countries, which are aiming to consolidate through partnerships, acquisitions and mergers in the next two years.

Cost advantage, quality standards would play a key role in consolidation and rapid growth of large and medium-sized international companies,

which was the theme at the three-day Bangalore Bio 2007 meet.

The meet also highlighted India's pre-eminent position among the emerging "biotech powers" for its own consolidation after its remarkable growth in the last two years.

"Tremendous Activities"

Shri Alok Gupta, Country Head, Life Sciences & Technology, Yes Bank Ltd., said, "There have been tremendous activities in the life science sector over the past few months. Lots of acquisitions, outsourcing deals, R&D, increasing cross border discussions on IPR licensing, etc. — all reinforcing the message of India's and Asia's growing importance in the sector."

Mr. Crispin Kirkman, Managing Director, Emerging Technologies Network Agency, UK, while underlining the ability of Asian pharmaceutical companies in retaining their cost advantage and matching the quality standards of the West, said that India was an increasingly attractive destination for R&D activities in the pharmaceutical and biotechnology industry.

"Western companies are looking to partner with Asian companies especially Indian companies because of low cost, flexibility, increasing number of FDA and other key international approvals, high proficiency in health care and science, access to Asian market and excellent talent pool."

Planning is Key

Mr. Mark Ravera, Principal, Strategic Pharma Consulting Group, LLC USA, stressed on planning as a key strategy. He said, "Before entering a new market, a proper planning, clear focus and flexibility are key to success. Knowledge of target market needs to be incorporated in the drug development efforts — the earlier, the better. Focus on the therapeutic area is needed to build depth of expertise for sustained success while flexibility is needed due to imminent changes in market."

Drug discovery may be feasible, but just like US-based small biotechnology companies, Asian companies will have to look for partners to help bring any thriving innovation to market.

"Early stage funding remains one of the biggest challenges, which the industry is facing in spite of various developments happening in biotechnology sector. Investors are not willing to take risk, which is involved while investing in the incubation stage of the company. They are more in favour of mid- to late-stage investments," concluded Shri Gupta.

(*The Hindu Business Line*, 11 June 2007)

Bioinformatics Pie Worth $60 bn

THE bioinformatics pie is worth $60 billion and big players such as TCS, Infosys, Wipro, Cognizant and HCL are scaling up for a share of this sector, according to speakers at the Bangalore Bio.

Bioinformatics is the tool for accelerated drug discovery. With intellectual property its main driver, companies are involved in clinical informatics, corporate IT, clinical development IT and scale IT.

According to Shri Sandeep Raju, Head of Delivery Operations, Life Sciences, Infosys, "The tremendous growth is reflected in package implementing, supporting and financing. Opportunities are enormous for software companies. One would in the near future see companies investing in building and owning IP in bioinformatics to fuel growth and revenues."

(*The Hindu Business Line*, 9 June 2007)

Biotech Industry Lauds Budget Measures on Drug Trials, R&D

THE biotechnology industry gets a breather and a boon. For one, the suspense has ended on the incentive on R&D spend, which was closing this financial year. It gets a five-year extension on 150 per cent weighted average tax deduction on R&D expenditure.

What are the tax benefits in the Budget?: View Special

For the other, the exemption from 12.24 per cent service tax should add to the country's edge in outsourced clinical trials for new drugs. According to Dr. K.K. Narayanan, President, Association for Biotech-Led Enterprises (ABLE), this was a major

demand of the industry, along with exemptions for drug development research.

However, ABLE said there is a serious persisting anomaly about customs and excise duties levied on imported and indigenous life saving drugs and diagnostics. Indigenous manufacturers of these products are charged the duties on raw materials and components; imported products are duty free.

The service tax levy was making clinical services uncompetitive in the global market, he said. "We were not as competitive as China or Thailand though we have much more potential and diversity."

Shri R. Basil, Managing Director and CEO of Manipal Health Systems, said, "The (move) will help our clinical trial initiatives attract more foreign and domestic partners."

India already figures in the top five destinations for clinical trials. An estimated 85 CROs (clinical research organizations) - among them Quintiles, Biocon's entity Clinigene International, Manipal Acunova, Lotus Labs - are said to be operating across the country, conducting 100 trials worth $300-500 million currently for both international and domestic drug companies.

This is expected to grow to $1billion by 2010 - or 10 per cent of the global clinical research market, according to Shri Sudhir Pai, Commercial Director of Lotus Labs, a leading CRO. "We expect to sign 5-8 trials worth Rs 25-30 crore this year and this gives us a huge advantage. There will be more business flowing in," Shri Pai said.

While domestic players could get a rebate on the service tax, it will now make a huge difference for foreign projects and give India - already a low-cost player - an added edge over European or US CROs, according to Shri Pai.

About the rebate on R&D spend, Ms Kiran Mazumdar-Shaw, CMD of Biocon Ltd., said, "The industry has been pursuing this single point for five years. Biocon, for instance, spends at least Rs 100 crore on R&D.

"The Finance Minister has announced incentives for innovation and research, development and growth and manufacturing. By passing on tax benefits to VCs investing in biotech, he has created a positive entrepreneurial environment."

The $1.5-billion domestic biotech industry is growing towards $5 billion by 2010 and $25 billion by 2015. "The extension of the weighted average tax exemption on R&D investment, service tax exemption for technology business incubators and pass-on direct tax benefits to VCs investing in biotech and related technology sectors will provide the much needed support to innovation," Dr Narayanan said.

Dr. Narayanan said though there has been much VCF (venture capital fund – with estimated investments of $300 million in 2006) interest in biotechnology, they were hesitant about start-ups. The announcement of benefits signals that the Government acknowledges this industry as a key sector.

(*The Hindu Business* Line, 3 March 2007)

Biotech Seeks STPI-Like Prop to Boost Growth

THE biotechnology industry, which looks up to the infotech sector for inspiration, has sought a Software Technology Parks of India-like single-window prop for its growth and extension of these benefits up to 2020.

> *'We must make the pitch for weaning back talent to India, by creating the environment for biotech professionals... ' Sector should look at boosting agriculture:*
>
> *–Shri P. Chidambaram*

Also needed are biotech "IITs" to churn out the much-needed bio-manpower, said Ms Kiran Mazumdar-Shaw, CEO of Biocon Ltd., at the inauguration of the seventh annual Bangalore Bio event.

Speaking in the presence of the Finance Minister, Shri P. Chidambaram, she said the biotech sector, which touched $2 billion turnover (nearly Rs 9,000 crore) in 2006-07, needed the same kind of support and incentives as the STPI scheme gave the IT industry.

STPI Model

The industry is at a critical stage and "we are looking at the STPI model that the IT industry benefited so much from. We also have to look at models and special institutes like IITs. ABLE (the Association of Biotechnology-led Enterprises) has suggested Indian institutes of biotechnology" for the country's next emerging knowledge sector, Ms Mazumdar-Shaw said.

Shri Chidambaram said the biotech sector should look at boosting agriculture – currently limited to cotton – and averting foodgrain imports. Productivity in wheat, paddy, pulses and oilseeds had fallen and needed a boost. "What was done with [Bt] cotton should be done in wheat." While experts should address concerns over genetic engineering, the Government would address early stage funding where necessary, he said, without elaborating.

"We must make the pitch for weaning back talent to India," by creating the environment for biotech professionals, Shri Chidambaram said.

New Courses

Apart from an industry-backed biotech finishing school for life sciences graduates, the Karnataka Government, jointly with Australia's Deakin University, is starting a post-graduate and PhD centre in biotechnology.

The Karnataka Chief Minister, Shri H.D. Kumaraswamy, suggested that a percentage of IT export revenue should be set apart as "IT and BT infrastructure fund". He handed over the work order for phases 2 and 3 of the biotech park, Bangalore Helix, to the consortium of Alexandria Real Estate Equities of the US and TCG Group.

(*The Hindu Business Line*, 8 June 2007)

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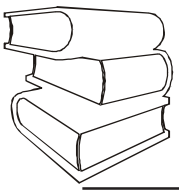

BOOKS/ARTICLES NOTES

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

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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DOCUMENTS

Dr. Ashwani Kumar Calls for Greater Indo-french Cooperation in Technology, Pharma & Biotechnology

Dr. Ashwani Kumar, Minister of State for Industry, Government of India, has called for greater Indo-French cooperation in several areas including technology, pharmaceutical and biotechnology. During his meeting with Mr. Francois Loos, Minister of Industry, Government of France in Paris yesterday, Dr. Kumar reiterated India's commitment to further strengthen Indo-French bilateral relations. He said that there was great scope for cooperation between India and France, especially in Competitive Clusters in advanced and newer technologies and sought the support of France in these specific sectors. The meeting was in keeping with the regular high-level and Ministerial interactions, which have been taking place between the two countries to strengthen the multifaceted relations between India and France.

Dr. Ashwani Kumar also mentioned that India attaches great importance to the Strategic Partnership between the two countries. The Minister conveyed India's appreciation for the support given by France with regard to civilian nuclear cooperation in order to meet India's growing energy requirements. He also acknowledged the support given by France for facilitating India as a participant Member State of ITER.

The two Ministers also reiterated their commitment to strengthen cooperation in regard to various aspects of Intellectual Property Rights, and highlighted the fact that India has a TRIPS compliant regime. Mr. Francois Loos referred to the effective enforcement of Intellectual Property Rights in India and the potential for manufacture of innovative products, especially in the pharmaceuticals sector.

Mr. Francois Loos conveyed that he looked forward to his visit to India to participate in The Partnership Summit 2007 – Emergent India: New Roles and Responsibilities being held in Bangalore, India from 17-19 January 2007. Dr. Ashwani Kumar also said that the forthcoming visit to India by Mr. Francois Loos to India would provide another forum for exchange of views between India and France on potential areas of bilateral/multilateral cooperation.

(PIB, Ministry of Commerce & Industry, Government of India, 7 December 2006)

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