Bio News

This section puts together news about the recent and key developments related to intellectual property rights.

Monsanto wins key patent dispute regarding Dicot plant transformation

Monsanto Company announced that it has won the key patent battle regarding biotech-gene technology for the transformation of dicot plants, such as cotton. The decision by the U.S. Patent and Trademark Office (USPTO) that Monsanto's scientists were the first to invent this important discovery ends a 12-year patent interference dispute with the Max Planck Institute and other parties. The decision, issued by U.S. Patent and Trademark Office, recounts the basis for finding that Monsanto was the first company to invent *agrobacterium* transformation in dicot plants, which eventually gave farmers the choice to use biotech crops on their farms. The *agrobacterium* is one of the ways to insert beneficial characteristics into plants. Monsanto's Bollgard insect-protected cotton was developed using agrobacterium transformation for the formation of dicot crops. Monsanto Company is a leading global provider of technology-based solutions and agricultural products that improve farm productivity and food quality.

New patent regime may pose challenges to Indian farm sector

The Indian Parliament approved the Third Patents (Amendment) Bill 2005. This will meet the country's obligation to usher in new product patent regime under Trade Related Intellectual Property Rights (TRIPs) agreement of the WTO. The third amendment is slated to provide product patent regime in pharmaceuticals, food and chemicals, including agro-chemicals. The granting of patent rights over

microorganisms, microbiological and non-biological processes for production of plants and animals are also covered under the third amendment.

All safeguards had been built in to the legislation to protect the interest of Indian pharmaceutical industry and prevent an inordinate rise in prices. The new legislation would not lead to an increase in the prices of essential drugs said the Indian Commerce Minister.

The Bill also stipulates that only a "new entity" involving "one or more inventive steps" will fit the criterion of patentable pharmaceutical substances. On compulsory licensing of life saving drugs and pre-grant opposition, the Bill has incorporated the necessary safeguards. Finally, the unnecessary restriction on the export of patented drugs manufactured generically in India under compulsory licence to less developed countries – such as the sale of African nations, at much lower prices, of antiretroviral to combat AIDS – have been removed. On the protection of traditional knowledge, plants were completely out of the purview of the legislation. Though India opted for *sui generis* system for protection of varieties and enacted a law for the purpose, it is likely that the transgenic seeds developed through human intervention may be covered under the new patent regime.

The Third Amendment to the Patent Act may, therefore, pose new challenges before the farm sector. In this context, the policy makers have a duty to ensure that several protections given to farmers like saving seeds for the next season under the Plant Varieties Protection & Farmers' Rights Act are not diluted. Similarly, the community rights ensured under the National Biodiversity Act should not be ignored. The challenge, therefore, before the government is to develop a holistic view of the entire intellectual property rights (IPR) regime in the country.

The TRIPs agreement has not defined microorganisms and microbiological processes. Here the question is whether the micro-organisms existing freely are patentable or their mere isolation in pure form are patentable or human intervention in establishing a level of novelty in the discovered micro-organism is needed for patenting. The United States Patent and Trademark Office (USPTO) verdict of the case *Diamond vs Chakraborty* in 1980 establishes that human intervention leading to a novelty in expression can be patented. It says: "respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not due to a hitherto unknown natural phenomenon, but to a non-

naturally occurring manufacture or composition of matter - a product of human ingenuity having a distinctive name, character and use... His discovery is not nature's handiwork, but his own..." The Government of India introduced many issues, including data protection and quality of patents, would need to be attended to even after the Third Patent (Amendment) Bill is passed by Parliament. There will be "immediate attention to data protection, particularly in the area of agrochemicals and agricultural biotechnology".

The farmer's bodies of India were opposed the recent patent ordinance, which seeks to introduce patent monopolies on seeds. With the proposed amendments to the Seeds Act, government policies attempt to modify the structure of regulated markets for agri produces. "The Patent Ordinance has proposed patent monopolies on seeds, genes and markers. This will lead to farmers' paying royalties to seed companies. Further, the proposed amendments to the Seeds Act, like compulsory registration, will prevent farmers from using farm-saved seeds", said the director of a Delhi based NGO.

The new Patents Act is going to change the global perception of India, which is now the preferred destination for pharmaceutical business and global opportunity. While the industry is set to undergo a major transformation with focus on discovery research, it could expect to gain revenue of at least $10 billion in the years to come, said Dr. William A. Haseltine, one of the leading experts in genomic and Chairman of the Scientific Advisory Board of Matrix Labs.

He also stated that Indian pharmaceutical market should not restrict its focus to regional markets and should aim at the global market by maintaining world-class standards. The contract research, contract manufacturing, venture capital and clinical trials are the areas in which the country can emerge as a major player in the global market. However, the country needs to take several measures to exploit these opportunities by strengthening the regulatory framework with respect to drug approvals and patents. At present, there are certain structural weaknesses in the Indian regulatory framework with regard to the drug approval process. The country also suffers from inadequate infrastructure in patent protection, said Dr. Haseltine.

Seed sowing and patent controversy

Monsanto sued Homan McFarling, a petitioner for saving seeds and replanting them. The seeds had been genetically modified by Monsanto

to resist Roundup (R) herbicide and were patented. (U.S. Patents 5,633,435 and 5,352,605). At the Federal Circuit, McFarling argued that the Sales Agreement from Monsanto involved an unlawful misuse of Monsanto's patents by restricting use of "god-made" second-generation seeds. The Appellate Court disagreed. Because the first-generation seeds (sold by Monsanto) were nearly identical copies to the second-generation seeds, the Court found that the patent scope includes both generations. Thus, the Court rejected McFarling's appeal and held that the Sales Agreement did not impermissibly extend Monsanto's right. The Supreme Court has asked the Solicitor General to brief in this case expressing the views of the United States. It is expected that the Bush Administration, through the Solicitor General, will support Monsanto's position.

TRIPs council considers public health, biodiversity

The public health and biodiversity-related concerns emerged as major issues at the 2004 final meeting of the WTO Council for Trade-related Aspects of Intellectual Property Rights (TRIPs) on 1-2 December. At the meeting, Nigeria submitted a proposal (IP/C/W/437) on behalf of the African Group, which includes all African WTO Members for converting the waiver provided for in the decision on pharmaceutical patents into a formal amendment of the TRIPs agreement. Many developed countries criticized the Nigeria-led proposal, arguing that it sought to re-open the debate on the substance of the decision and would only complicate current discussions. The supporters of the proposal countered that the suggested text was only an attempt to simplify the complex nature of the waiver. In the session on biodiversity, traditional knowledge (TK) and folklore an attempt was made to move the substantive debate forward on the relationship between the TRIPs Agreement, biodiversity issues and TK with a new proposal (IP/C/W/438) submitted by Bolivia, Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand and Venezuela.

Open-source biology evolves

The scientific knowledge can be used for good or ill for the industrial application and other related activities. Scientists need to draw from the best data and innovations in their field to push research further. Much of the work and discovery, however, is patented, leaving many academic and non-profit researchers constrained. But an Australian organization advocating an open-source approach to biology hopes to free up biological data without violating intellectual property rights.

The knowledge like open-source software, open-source biology users own the patents to their creations, but cannot delay others from using the original shared information to develop similar products. The battle lies between biotechnology companies like multinational Monsanto, who can grant or deny the legal use of biological information, and independent organizations like The Biological Innovation for Open Society (BIOS) and Science Commons.

BIOS will soon launch an open-source platform that promises to free up rights to patented DNA sequences and the methods needed to manipulate biological material. Users must only follow BIOS' "rules of engagement, which are similar to those used by the open-source software community. There are technologies which need to innovate and then there are the innovations themselves," said Richard Jefferso, founder and director of BIOS in Canberra, Australia. But those can only happen when there is fair access to the technologies. Any improvements of the shared methods of BIOS, the Science Commons or other open-source communities must be made public, as well as any health hazards that are discovered. While free access to biological information will benefit those doing research, companies who have invested millions in patents, on the other hand, won't perform expensive groundbreaking research without a guarantee that their intellectual property rights would be upheld. "Patents attract investors, providing the resources necessary to bring the product to market," said Brigid Quinn, deputy director of public affairs with the U.S. patent office.

Survey shows IP laws favors developed countries

The development in intellectual property (IP) has raised concerns about IP's implications in food production and animal health, especially throughout the developing world. These same developments, however, are made more in developed countries, and little attention is given to developing nations. This was raised and explored in "Plants and Intellectual Property, an article written by Dr. Bonwoo Koo and colleagues, published in the November1 19, 2004 issue of *Science*. With a survey conducted in national IP offices in 191 countries, researchers found that only 91 countries offered statutory IP protection, while another 29 countries had legislation under consideration. The majority of the 91 were high and upper middle-income countries; only 22 of 61 low-income countries had any statutory protection in place for plants. Surveys also showed that 31 per cent of the applications in high-income

countries, 65 per cent in upper middle-income countries, 25 per cent in lower middle-income countries, and 38 per cent in low-income countries were lodged by foreigners.

Patent rights to agrobacterium technology

The Syngenta International AG (Basel, Switzerland) and Monsanto Company (St. Louis, Missouri) announced an agreement in which the companies cross-licence proprietary *Agrobacterium*-mediated transformation technology. The agreement resolved a patent interference proceeding in the United States Patent and Trademark Office (USPTO) involving transgenic broad leaf crops. The Monsanto-Syngenta deal also resolved a lawsuit that had been pending in the U.S. District Court for the District of Delaware. Syngenta had filed the case in 2002, alleging that Monsanto and Delta and Pine Land infringed U.S. Patent No. 6,051,757, which covers methods of transferring genes into dicotyledonous plants using *Agrobacterium* based vectors. On the day that the companies announced their new agreement, the Delaware district court dismissed the patent infringement case. Monsanto have the *Agrobacterium*-related patent rights. As the Monsanto's scientists had intentioned Agrobacterium transformation methods.

Access to research tools in biotechnology

The biotechnology industry's shifting ideology and the increasingly proprietary nature of research tools are hampering research efforts. Access to key data and research tools to deal with new scientific initiatives like plant biotechnology has become limited. Hence, there is a need for reforms to the current patent system to deal effectively with these problems. According to David Faye, winner of Borden Ladner Geravais LLP award in constitutional law. Canada's "the proliferation of patent rights could impede or effectively preclude use of the research tools". As such, some studies have shown that researchers are forced to circumvent the patent system, with one-third of private and public firms indicating that they use patented research tools without a licence. Again it focuses on the experimental use exception in patent law in the United States and the United Kingdom as a possible means to solve the problem. "If recent trends to narrow policy initiatives can be reversed or, at the very least, halted, the potential may exist for public policy initiatives to permit use of the exception in a manner which would ultimately benefit the intended sectors," Faye said.

Genetic Diversity and Patent Regime

After the UN Convention on Biological Resources at Bangkok, the issue of the new patent regime and how to regulate access to genetic resources comes out. The world's biggest developing countries Brazil, India and China along with others, want a global convention that would regulate patents on inventions developed from genetic resources. The concern is that developing countries, and their indigenous communities, are not securing the benefits when lucrative inventions are marketed. The issues to prevent the hijacking of genetic resources and to establish contract arrangements. There will be payment agreement for accessing the resources and right to use them. The world's biggest drug companies are the targets. Martin Khor, head of the Penang-based non-governmental organization and a long-time campaigner for curbs on intellectual property rights, said, "Farmers and indigenous peoples are outraged that plants they have developed are being hijacked by companies."

India, Brazil and other so-called "mega-diverse" countries have proposed something much more complicated. They want an international convention that controls patents. Even after a patent has been granted for an invention using genetic material, the country from which the material was sourced would have the right to determine how products based on a patented invention from it would be used. This would certainly stop bio prospecting because it would stop pharmaceutical industries in any country that adopted such a law. The cost of developing new drugs is too great to handle without secure rights to use the genetic materials (provided by contract arrangements) and inventions developed from them (provided by patents). No country aspiring to develop biotech industries could succeed if it diminished intellectual property rights as proposed by the mega-diverse countries.

Southern African countries reject 'TRIPs-plus demand in FTA negotiation.

Southern African Countries have rejected the European Free Trade Association's (EFTA), comprised of Switzerland, Norway, Iceland and Liechtenstein), proposal on intellectual property rights (IPR) in the free trade agreement (FTA) negotiation between the two trading blocs. They criticized the European bloc's proposed 'TRIPs-plus' provisions on public health and agriculture. The organizations contended that EFTA's pressure on SACU (SACU; South Africa, Botswana, Namibia, Lesotho, and

Swaziland) states to introduce a five-to ten-year data protection period for clinical test data, as well as a provision to potentially allow five-year patent extensions to brand-name drugs, would "block and delay generic competition," thus hindering access to medicine. They also criticized EFTA for asking SACU states to grant patents to "biotechnological inventions" and accede to the 1991 version of the UPOV convention (International Convention for the Protection of New Varieties of Plants), arguing that these measures would threaten the rights of Southern African farmers to use farm-saved seeds, thus threatening both biodiversity and food security. The South Africa approach for trade negotiation is always to seek the benefit of the community with SACU in all area of negotiation. As the SACU and EFTA have not able to agree on IPR, SACU suspended the negotiation of TRIPs-Plus Agreement. The Southern African Customs Union had refused to accept EFTA's proposed IPR provisions that went beyond the requirement of the WTO Agreement on Trade–related Intellectual Property Rights (TRIPs), said South African Trade Minister Mandisi Mpahlwa and a South Africa-based grassroots public health group.

Canada to allow generic medicine exports.

The Canadian government announced the patent laws to allow generic pharmaceutical companies to produce and export patent-protected drugs to those countries which are unable to manufacture their own generic drugs. The government's announcement followed the WTO General Council on a mechanism for relaxing the restrictions in the TRIPs Agreement (Article 31) on using compulsory licensing to produce generic medicines in one country for export to another. This initiative spurred a strong response, with Canadian NGOs, international organizations such as UNICEF, and health activists outside Canada in both developed and developing countries welcoming it. In contrast, the International Federation of Pharmaceutical Manufacturers Association criticized the initiative, saying it was premature and unhelpful.

Since the announcement, Canadian civil society organizations have called on the government to ensure that its legislation will fully implement the flexibility reflected in the WTO decision, and therefore will not be limited to exporting generic drugs for only certain diseases for countries facing health emergencies. They note that statements by government ministers have only referred to pandemics such as HIV/

AIDS, tuberculosis and malaria, and to helping countries facing emergencies. In its only public statement, the brand-name pharmaceutical industry association has stated that the WTO decision "relates to the provision of generic medicines to treat HIV/AIDS and other life-threatening diseases such as tuberculosis and malaria".

Indian trademarks and geographical indications laws enter into force

The Indian laws on trademarks and geographical indications entered into force as part of the country's effort to bring its intellectual property laws in line with the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs). The Trademarks Act 1999, which consolidates and amends the Trade and Merchandising Marks Act 1958, introduces the new concepts of 'service marks', i.e. a trademark for services, 'collective marks', which will allow associations to get registration for their marks, and 'well known-trademarks', which under specified criteria will receive higher levels of protection (irrespective of whether they are registered or used in India). The new Geographical Indications of Goods (Registration & Protection) Act 1999 provides for the registration and legal protection of geographical indications relating to goods in India. The Geographical Indications Registry, to be established in Chennai, is charged with administering the legislation and Appellate Board. Meanwhile the TRIPs committee also discussed in the meeting of June 2004,which took place in the context of geographical indications (GIs), in particular regarding the usefulness of GIs as a tool for protecting traditional knowledge (TK).

TRIPs council split over role of intellectual property to prevent 'biopiracy'

The WTO Council for Trade-related Aspects of Intellectual Property Rights (TRIPs) remained divided over the need to harmonize the TRIPs Agreement and the Convention on Biological Diversity (CBD) as a means for preventing 'biopiracy'. The relationship between the TRIPs Agreement and the CBD, the TRIPs Council received a new submission from Brazil on behalf of a group of developing countries, including China, Cuba, the Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe. The submission (IP/C/W/356) stressed the need to modify the TRIPs Agreement, arguing

that the Agreement contained no provisions to prevent biopiracy acts or ensure prior informed consent and the fair and equitable sharing of benefits. To this end, the group of countries proposed several conditions for acquiring patent rights related to biological materials or TK, including requirements for patent applicants to disclose the source of origin of the biological resource and associated TK; and evidence of prior informed consent and benefit-sharing. The Brazil-led submission, however, stressed that the proposed requirements would only provide "defensive" protection of TK. Echoing similar proposals raised in related fora (i.e. the CBD, WIPO and preparations for the World Summit on Sustainable Development), the submission called on the TRIPs Council to also consider "positive" protection of TK, including, *inter alia*, an internationally agreed instrument that recognized national-level TK protection.

The trade delegates convened to continue their discussions on Article 27.3(b) (patentability of life forms), genetic resources, traditional knowledge and folklore in the WTO Council for Trade-related Aspects of Intellectual Property Rights (TRIPs). Despite continued efforts by developing countries to keep these issues on the table, the meeting made no real advances in the debate. The biodiversity-related discussions focused on the checklist of issues for further discussion that had been put forward by Bolivia, Brazil, Cuba, Ecuador, India, Peru, Thailand, Venezuela and Pakistan.

General Assembly bypassed in informal WIPO talks on patent harmonization.

The World Intellectual Property Organization (WIPO) member states met to discuss the continuation of the global patent harmonization process at Morocco. Many developing countries most of which were not invited were heavily critical of the meeting. They noted that Brazil was the only country among the 14 proponents of a 'WIPO Development Agenda' invited to the event, suggesting that this may have been an attempt to make support for the development agenda appear to be an isolated point of view. The other Southern representatives in attendance were from countries that have been passive in WIPO debates on the development agenda, or from states that are already committed by bilateral or regional trade agreements to intellectual property standards that go beyond those required by the WTO, such as Chile and Morocco. During the consultations, the approximately 20

countries and patent offices in attendance came up with an action plan for moving forward on patent harmonization, identifying six issues to be dealt with in an accelerated manner: prior art, grace period, novelty, inventive step, sufficiency of disclosure, and genetic resources. The meeting did make mention of the need to pursue a "robust, effective and actionable WIPO Development Agenda." Brazil was the only country to register opposition to the statement adopted at the end of the meeting.

Industrialized countries have recently been pushing the WIPO secretariat to move forward on patent harmonization. According to James Love, director of CPTech, an NGO focusing on IP issues, "the US, the EU and Japan are beating up on the WIPO Secretariat, insisting that it do what it can to get developing countries to do what they want on patent harmonization. They'll effectively take the Patent Cooperation Treaty out of WIPO by setting up a rival system..." The Patent Cooperation Treaty, which regulates the registration of global patents, is WIPO's main source of revenue

The parties participating in the Morocco meeting included: Brazil, Chile, China, France, Germany, India, Italy, Japan, Malaysia, Morocco, Russian Federation, Switzerland, the UK, the US, the African Regional Industrial Property Organization, Eurasian Patent Office, European Patent Office, African Intellectual Property Organization and the EU. Dr. R.A. Mashelkar, Director General of the Council of Scientific and Industrial Research and Secretary of the Department of Scientific and Industrial Research in India, chaired the meeting.

Patent regime not to affect prices of life-saving drugs

The Government of India has clarified that the new patent regime will not affect prices of the 350 essential (life-saving) drugs available in the market. As much as 97 per cent of the drugs available in the market are already off patent globally and are not likely to be patented in India. These drugs, therefore, would not experience any price increase, it claimed. According to a report, 3 per cent of the domestic pharmaceutical market were likely to get covered by patents in the coming months as the government took decision on mailbox applications. And, there are therapeutic alternatives for most of these drugs. The patentability criteria in the amended Act as it had 15 listed exclusions from patentability, including seeds and seed varieties. Once the Bill is introduced in Parliament changes would be incorporated in it. There are 9,000 patent

applications in the mailbox with majority of them being from US companies. Although the number appears huge, only 2,500 applicants have followed it up with examination requests.

Patent law must fully reflect public health concerns: WHO

The World Health Organization (WHO) has observed that patent law in India does not reflect the concerns about public health as expressed in the Doha Declaration on TRIPs Agreement. The observation of the WHO is significant as the country is slated to amend its patent laws by January 1, 2005 as part of its obligation to WTO. Already several experts have suggested to the government to take the advantage of the flexibilities in protecting public health interests. The WHO study further said: "The grounds to realize the role of domestic enterprises in the availability and affordability of medicines are weak and need to be strengthened." It also said that Chapter XVI on compulsory licence in the Patents (Second Amendment) Act 2002 should have provided the possibility of the grant of voluntary licence to domestic enterprises by the foreign patentee who may not like to set up its own infrastructure in the country to promote its product.

The compulsory licensing system should aim at preventing the abuse of patent rights by the patentee in various regions of the country as sub-licensing is essential to country like India. The WHO report also said that the licensing system should be devised in such a manner so as to aid domestic companies to get licence from patent holder for commercial activity on reasonable commercial terms and conditions. The other important aspect about the scope of patentability needs to be formulated on basis of specific recommendations of the pharmaceutical research committee headed by the director-general of the Council for Scientific & Industrial Research (CSIR), Dr R.A. Mashelkar.

Gene campaign challenges European soyabean patent

Some multinational companies, scientists and non-government organizations (NGOs) have challenged the broad patent right granted by European Patent Office (EPO) to Agracetus (located in Middleton and founded in 1981 as part of Monsanto for R&D facility) for its claimed innovative particle bombardment (biolistic) method of transforming soyabean. The Delhi-based NGO Gene Campaign is one of those who deposed before the EPO in Munich. Syngenta and

DeKalb are amongst the multinational companies, which have opposed the patent rights to Agracetus. Greenpeace Germany, ETC-Canada, German Farmers Organization and a member from the Chinese scientific community also deposed before the EPO vouching for withdrawal of the conferred rights. The patent right in question was a very broad spectrum patent awarded on all existing genetically modified (GM) soyabean varieties and for all other GM crops where the same particle bombardment (biolistic) method was used. Such a broad patent right on GM cotton granted to Agracetus was struck down by the United States Patent Office said convener of Gene Campaign.

Novartis' case may spark patent vs patient debate

Novartis, the first pharmaceutical company to get an exclusive marketing rights (EMR) in India for its cancer drug, Novartis has heard from Indian patent office on the implementation of the Madras High Court order on giving the drug free to patients who cannot afford it. The company had received the letter from the Patent Controller. The company had given the anti-cancer drug free to about 3306 patients and only 45 were actually paying for the medicine. "On an average, about 30-odd patients enroll for the free cancer drug per week". The Government has asked Novartis for market related data on the drug, the pricing and number of patients who need it. This could be laying the ground for government's intervention if the price is found to be high and if patients have been denied the drug, said an industry representative.

Ever since the EMR was granted to Novartis, the company had taken legal recourse to get Indian companies to stop marketing copies of the same drug. A year's course of the anti-cancer drug Glivec internationally costs about $2700 (about Rs 11,61,000), while local copies from India at $2700 (about 1,16,100). Indian companies, on their part, too contested the EMR and the case is in the apex court. According to representative of pharmaceutical industry, the EMR is being contested. The Government of India could take up Novartis's patent application for the cancer drug.

Regulation of multiple gene products

On April 14, 2005, the Confederation of Indian Industries (CII) organized a meeting on 'Regulation of Biotech Crops: Going Beyond

Single–Gene Products'. Multiple gene products or stacks have more than one trait present in the same plant. For example, cotton plants containing a combination of herbicide tolerance and insect protection. Combined trait products have several benefits, including the ability to use the formerly approved single traits as building blocks for new products and improving the growth efficiency of a product. The meeting took place at a period when a draft policy for developing biotechnology, prepared by the Department of Biotechnology, was open for public comments.

Currently, India regulates only single gene products. So far, the only GM crop permitted for commercial cultivation in India is the Bt cotton, which is resistant to the bollworm. Similarly, countries such as Australia, China, Canada, Colombia, New Zealand, Russia and Taiwan regulate products at the single trait level. In the U.S., it is not mandatory to produce additional safety information on multiple trait products developed by conventional breeding if a single trait product is already approved and the traits are unrelated. In contrast, the European Union considers every stacked trait product as novel or unique, regardless of the status of the parent trait. Till date, no stacked trait product has ever been approved in the European Union.

Dr M.K. Bhan, Secretary, Department of Biotechnology, who delivered the keynote address, stated that in the midst of much controversies surrounding agricultural biotechnology it is important to have clearly articulated information on biosafety prepared by a neutral source that steers clear of advocacy. "The GEAC can contribute to disseminating knowledge by producing a manual that is accessible to the public," said Bhan, adding that "in order to create a more proactive structure, regulators should be available for consultation." He also stressed that the role of the decision-making body should be clearly distinguishable from that of the policy makers and suggested that the Ministry of Environment and Forests form a permanent policy board to look into policy related matters.

Sharing his experiences with large scale trials, Dr C.D. Mayee, Chairman, Agricultural Scientist Recruitment Board, pointed out that 55 different trials on Bt cotton were carried out at 11 locations around the country prior to its approval in 2002. Mayee stated that, "Multi-locational Cry 1AC trials should be abolished since a lot of trials have already been conducted and since there is serious land shortage." Instead, he felt that the field trials should focus on new genes. He also stated the practical difficulties faced by the Monitoring and Evaluation

Committee in visiting and inspecting the field trials carried out at different locations in the country.

DD Verma, joint secretary, Ministry of Environment and Forests stated that India is among the world's 17 megadiverse countries. The conservation and sustainable management of such a rich genetic diversity, he maintained, consequently contributes to greater prospects in agricultural biotechnology.

Dr Philip J Eppard, Regulatory Affairs Lead, Monsanto elucidated the different country regulations on stacks or combined trait products. Eppard explained that stacks maximize the benefits of biotechnology, by helping the "growers realize the benefits of each trait without having to forego benefits of another trait." Eppard further added that the lack of a globally recognized food, feed and environmental safety assessment paradigms on stack products is one of the many challenges in its development. He further stressed the need for a scientific approach for the regulation of conventionally bred stacks.

Dr S.R. Rao, Ministry of Science and Technology, who presided over the second half of the meeting explained the need to focus beyond the confines of risk assessment, and echoed the concerns of Dr M.K. Bhan by stressing the need to address issues of biosafety to the public through information generation and dissemination. Dr Rao also added that scientists as well as professors have a responsibility in strengthening the current low level of public knowledge on biosafety.

Presenting the industry's point of view, M Prabhakar Rao, Managing Director, Nuzeevedu Seeds Pvt Ltd, expressed concern about the GEAC having to deal with applications concerning hybrids with approved gene as well as hybrids with new or unapproved genes under the same platform. "A sub-committee should be formed under the GEAC to test the release of new hybrids," asserted Dr Rao. He reiterated Mayee's statement that it is not necessary for a hybrid that is already approved to go through an approval procedure before the GEAC. Dr. Rao also suggested the formation of a sub-committee of stakeholders under the aegis of the Genetic Engineering Approval Committee or the Department of Biotechnology to deal with subject based issues.

One of the main subjects of discussion was whether biosafety risk assessment should be differentiated from agronomic performance. This ambiguity, according to several participants, is a dilemma that has contributed to the increasing workload of the GEAC and the RCGM where a lot of time is spent attempting to sort out problems related to

agronomic performance. In the process, less time is spent on 'real issues' such as biosafety and issues related to food and feed. The need for risk assessment to be based on scientific knowledge and rationale and not process oriented was also strongly articulated. One of the participants stated the importance of having a formal risk assessment document of approved products in place, simultaneously lamenting the lack of available scientific documents prepared by the government.

Dr K R Khetrapal, head, division of plant quarantine, National Bureau of Plant Genetic Resources, expressed concern over the absence of several mechanisms in India, including trade policies on genetically modified organisms (GMOs), that is significant in order to operationalise the Cartagena Protocol on Biosafety (CPB), to which India is a signatory. The CPB is an internationally binding legal agreement that regulates the transboundary movement of GMOs that may have adverse effect on the biological diversity and human health. These concerns, he felt, have strong implications since the recent WTO meetings have increasingly focused on the biosafety and trade interface.

Emphasis on stringent regulation on biotechnology is a futile exercise, particularly when illicit or unapproved Bt cotton is already cultivated in more than six lakh acres of land, a clear reflection of the government's failure to control its proliferation, stated a participant, who felt that the decision should be left to the farmer who is the best judge. At the same time, there were strong opinions regarding the need for regulation, particularly in the case of stacks, since there is a probability of environmental harm.

(Source RIS based on *Check Biotech*, October 5, 2004; *Hindu Business Line* February 18,2005; *Check Biotech* November 10, 2004; *Check Biotech* November 16,2004; *Check Biotech* November 18, 2004; *Crop Biotech Update* November 19,2004; *BRIDGES Weekly* November 24,2004; *BRIDGES Weekly* December 8, 2005;*Crop Biotech Update* January 7,2005; *Check Biotech* January 11,2005; *Check Biotech* January 18, 2005; *Check Biotech* January 21,2005; *Check Biotech* January 24,2005;*Deccan Herald* January 29,2005; *Check Biotech* February 7,2005;*Crop Biotech* February 2005; *Check Biotech* February 18, 2005; *BRIDGES Weekly* March 9,2005;*BRIDGES Weekly* October 15,2003; *BRIDGES Weekly* September 25,2003; *BRIDGES Trade BioRes* July 11,2002; *BRIDGES Trade BioRes* June 25,2004; *BRIDGES Weekly* February 23,2005.*Financial Express* January 6, 2005; *Financial Express* November 25,2004; *Financial* Express May 08, 2004; *Financial Express* June 23, 2004; *Hindu Business Line* February 18,2005; and Report by Lian Chawii).