BioSpectrum the business of Bio & Health Sciences

FBAE urges govt to lift the ban on Bt brinjal

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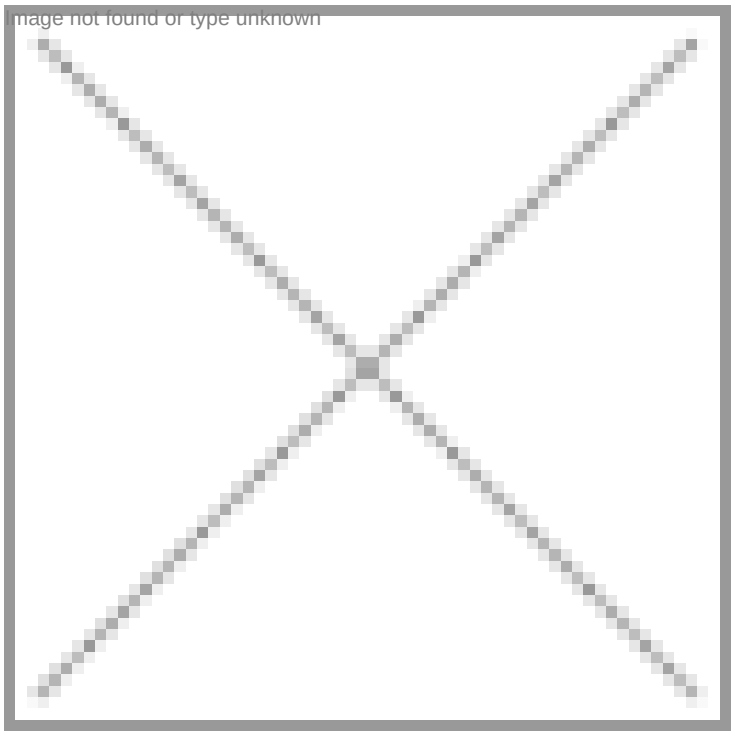

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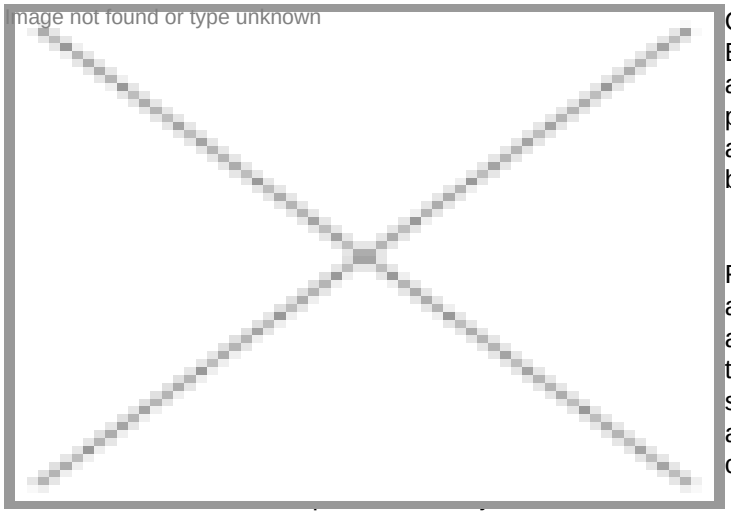


On the eve of the first anniversary of the moratorium on Bt Brinjal in India, the Foundation for Biotechnology Awareness and Education (FBAE), a non-profit organization formed to promote public awareness of scientific issues of biotechnology and to enhance levels of biotechnology education and training based in Bangalore has called for an immediate lift on the

Reiterating the concerns raised by over 40 Indian scientists at a workshop organized by the FBAE in July 2010 in New Delhi, and the memorandum submitted to the central government then, the FBAE cited recent important publications on the socio-economic benefits such as better living standards, health and education, and reduced tension, among the farming community and a healthier product to the consumer, that

Scientists opined that the moratorium on Bt brinjal was strongly influenced by those opposed to agricultural biotechnology. They also suggested that like the Philippines, India should also follow the credible, critical, and balanced scientific judgment of technologists and biosecurity experts for the approval of genetically modified crops such as Bt brinjal.

â€œThe government's decision of imposing a moratorium on Bt brinjal seriously affected research and developmentactivities in the country's agricultural biotechnology sector. The moratorium has created a regulatory uncertainty on the development of

all genetically engineered crops in the country. In a year, there has been no palpable, effective and time bound effort to lift the moratorium or to resolve the uncertainties caused by the moratorium,â€? said Prof C Kameswara Rao, executive secretary, Foundation for Biotechnology Awareness and Education (FBAE).

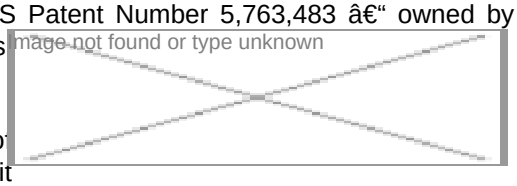
Dr TM Majunath, consultant - agricultural biotechnology, said, â€œConsidering that the product efficacy, biosafety and environmental safety of Bt brinjal was evaluated for over seven years, as per international standards, involving over 200 scientists and more than a dozen public and private sector research institutions, Bt brinjal should be commercially released without further delay.â€?

As per a recent publication from the National Center for Agricultural Economics and Policy Research, an ICAR institute, Bt brinjal adoption would add between 30,000 to 119,000 tons to the total production of brinjal, depending upon the extent of cultivation in different areas/ states. The absolute annual gain at the country level from Bt brinjal cultivation would be about $127.05 million (` 577 crore) at an adoption level of 15 percent, about $257 million at 30 percent and $526 million at 60 percent adoption levels.

Natco challenges Gilead's Tamiflu patent

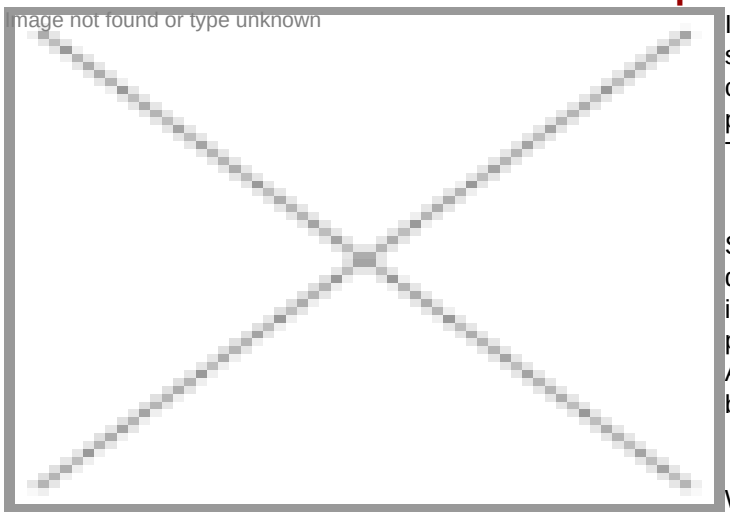
Gilead Sciences, a biopharmaceutical company headquartered in California with operations in North America, Europe and Australia, has announced receipt of a Paragraph IV Certification Notice Letter advising that Natco Pharma, an Indian enterprise, submitted an Abbreviated New Drug Application (ANDA) to the US Food and Drug Administration (FDA) requesting permission to manufacture and market a generic version of Tamiflu (oseltamivir phosphate) 75 mg capsules.

In the notice letter, Natco alleges that a patent associated with Tamiflu â€“ US Patent Number 5,763,483 â€“ owned by Gilead Sciences is invalid, unenforceable and/or will not be infringed by Natco's manufacture, use or sale of the product described in its ANDA submission.



Gilead is currently reviewing the Notice Letter and has 45 days from the date of receipt to commence a patent infringement lawsuit against Natco. Such a lawsuit would restrict the FDA from approving Tamiflu's ANDA for up to 30 months or until a district court decision that is adverse to Gilead, whichever occurs first. Tamiflu is protected by this patent, which is listed in the FDA's Approved Drug Products List, and the patent would need to be invalidated or not infringed upon before a generic version of Tamiflu could be marketed without liability for patent infringement. Tamiflu was invented by Gilead Sciences and licensed to F. Hoffmann-La Roche in 1996.

Tamil Nadu to announce new biotech policy



In a major step to boost the biotech industry in Tamil Nadu, the state government is revising its decade-old biotech policy and coming up with new measures, investments and expansion plans. Mr MK Stalin, deputy chief minister, Government of Tamil Nadu, announced that the state government is

Speaking at the inauguration of a roundtable on biotechnology development and its enabled services, organized by the industry association, CII in Chennai, he said that the state has plans to set up marine and medicinal plant biotech parks soon. Around 300 acres were identified to set up a marine biotechnology park, plans are also there to set up a marine

With the success of TICEL Biotechnology Park-I, which was established with the technical collaboration of Cornell University, US at a cost of $12 million (` 54.76 crore) and now fully occupied, the government is taking initiatives to drive the growth further. TICEL Biotechnology Park- II is expected to provide employment opportunities for 1,500 scientists. The park is expected to be completed in 2011 and will have a 'biotechnology core facility' to provide scientific and incubation support to the clients and biotech industries at the cost of $4.3 million (` 19.30 crore), and labs of BSL3 at a cost of $2million (` 7.37 crore).

Mr Stalin also stressed on the need to ensure that any development made in biotechnology does not erode the genetic pool and the rich diversity in flora and fauna. According to Mr PM Murali, convenor, Confederation of Indian Industry (CII) Tamil

Nadu Biotechnology Panel; Tamil Nadu has fallen behind other states such as Maharashtra, Karnataka, Andhra Pradesh, National Capital Region (NCR) and Gujarat, in spite of having several advantages in biotechnology. He proposed the need to form a separate department of biotechnology to enable 'single window clearance', which may attract a lot of MNCs in this field.

Mr Murali also added that the Indian biotech industry was worth $3 billion (~14,000 crore) last year according to the BioSpectrum ABLE Survey, and it will expand five-fold by 2015. Biogenerics worth $70 billion will come off-patent soon and it presents a great opportunity for Indian companies. It will also generate a lot of employment.

The conference discussed about the need for a new policy which is expected to address the needs of the industry like creating infrastructure, bio-incubator facilities, regulations, human resources and a common platform for the industry, academia and the government to communicate, according to a senior official from the government. It would also elaborate on the funding options and policies to support biotech research and manufacturing.

DHR frames health research policy

The Department of Health Research (DHR), Ministry of Health & Family Welfare, Government of India, has sought the public opinion on its National Health Research Policy survey report. One of the mandates of the DHR is to improve governance of health research. DHR has asked for feedbacks to improve the quality and contents of this draft policy.

As a first step, a National Health Research Policy was formulated with active participation and contributions made by several experts. The division of non-communicable diseases (NCDs) at Indian Council of Medical Research (ICMR) was identified as the nodal point for surveillance of NCDs and their risk factors by the WHO, and multi-site studies helped in developing a sound strategy for NCD risk factor surveys at the national level under Integrated Disease Surveillance Project (IDSP).The ICMR signed a memorandum of understanding with IDSP for the standardization and quality assurance of the NCD risk factor surveys under the World Bank-funded IDSP on behalf of Ministry of Health.

As per IDSP plan, these surveys were to be carried out in three phases so as to cover all states and union territories in India. In phase I, the state-based estimates of the risk factors in seven states were arrived at through the IDSP-identified seven State Survey Agencies, five Regional Research Centers and a National Nodal Agency under the overall guidance and supervision of ICMR headquarters through the National Technical Advisory Committee.