

BioSpectrum

the business of life sciences

Vol 6 | Issue 16 | August 2011

ASIA EDITION

SPECIAL
ISSUE

INDUSTRY LEADER INSIGHTS



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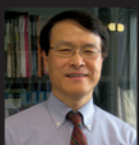
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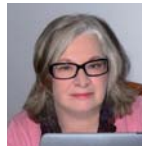
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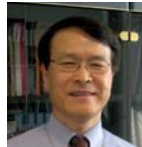
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Regulatory challenges: Indo-China case study



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Technological innovation is essential to the future well being of every nation. The ability of a nation to sustain economic growth, increase its standard of living, and improve human health and surrounding environment, directly depends upon the successful development and commercialization of new products, processes and services.

Generally, the terms invention, innovation and commercialization are applied in a number of overlapping ways to the process of developing new technology and incorporating it into new products, processes and services. However, confusion often results from the close ties between these three terms, and hence a clear definition of these terms becomes necessary to understand their dynamics and their intersection with each other.

sale or use of the novel process, product, or service.

However, as it is well known, innovation is a very complicated process in which economies of different jurisdictions often stimulate development of new technologies, and such development subsequently stimulates development of scientific and technical research. Additionally, commercial success is influenced by many factors, such as nature and composition of markets, competition from older technologies, choice of design and implementation, availability of financing and the ability to link with strategic partners among others.

The commercialization of innovations in the biotechnology industry has emerged as a vital and dynamic source of new technologies for the pharmaceutical, agricultural and chemical industries. Traditionally, the biotechnology industry has moved beyond the overstated promise for early and widespread commercial success in the 1970s, and biotechnology is now associated with a sustained flow of innovations and tools, offering dramatic improvements in human health and a compelling value proposition for health care and agricultural consumers.



India and China adopted policies in the areas of market access, IP protection, and regulatory review that have both fostered as well as discouraged innovation in biotech seeds

Invention refers to the act of devising or fabricating a novel process, product, or service, including initial conception, but not the act of putting it to use. Inventions are protected by patents, which may be licensed or assigned, and may further be commercialized.

On the other hand, innovation refers to the application and development of the novel process, product, or service, and includes, technical, scientific and market research; and marketing and manufacturing to the extent that it supports the application of the novel process, product, or service, whereas commercialization refers to the efforts to make profits from the

Indo-China perspective of biotech seed innovation

India and China have achieved remarkable economic growth over the last decade, although growth in the agricultural sector has lagged behind growth in the general economy. In both countries, the agricultural sector faces the tremendous challenge of producing more with fewer resources. It is well known that both India and China exclude plants and seeds from patent protection but provide some patent protection for microor-

ganisms and for non-biological and microbiological processes used to produce plants. However, global seed firms have expressed concern about the actual scope of the coverage given to biotechnology products and processes in both countries. Global firms also have expressed concern about the requirement in both countries that patent applications identify the source and geographic origin of biological materials that are used to make an invention, stating that it is ambiguous and burdensome.

Also, patent law provisions in both countries that permit compulsory licensing under a wide variety of circumstances also give rise to significant industry concerns. Though India and China have granted some agricultural biotechnology patents, it may be seen from the online records of the Indian Patent Office that Monsanto holds the largest number of recently granted patents for seed technologies. For example, it has obtained a patent for “Cotton Event Mon15985” the genetics underlying the second generation of its biotech cotton seed product, as well as patents for biotechnology processes used in producing plants with herbicide tolerance, improved germination rates, and other valuable traits. Similarly, biotechnology patents for improved traits for rice, cotton, corn, and other crops, as well as biotechnology-based seed coatings and treatments, have been issued to Bayer and Syngenta. At the same time, global seed firms also have a substantial number of biotechnology patent applications pending. In stark contrast, most large Indian seed companies, such as Rasi Seeds and Nuziveedu, do not hold patents or pending applications for seed-related technologies. However, one exception is Mahyco, which has a number of seed biotech applications pending. Additionally, public sector research

institutions, such as ICAR and the Council for Scientific and Industrial Research (CSIR), also hold few seed biotech patents or applications at the Indian patent office.

Whereas, in China, there is substantial patenting of seed biotechnologies by foreign firms, and Monsanto has the largest number of granted patents and pending applications. For example, it has obtained patents related to its insect-resistant cotton and for genetic sequences in corn and soybeans that confer tolerance to herbicides, improved trait qualities, and other benefits. Other global seed firms have only a handful of granted patents in China and a larger number of applications are still pending, which are in the areas of climatic

ogy Research Institute (BRI), all hold multiple patents or applications for Bt-related technologies, as do Huazhong Agricultural University and Central-China Agricultural University.

On the other hand, few domestic Chinese firms hold patents or applications in the BT technology area. China and India are thus similar in limited patenting activities by domestic companies compared with strong patenting by global firms. However, they differ in that Chinese research institutions and universities do engage in substantial patenting.

Conclusion

Both countries have determined that biotech is an important tool for responding to substantial challenges in their agricultural sectors, and have put in place institutions and funding mechanisms to support R&D in agricultural biotechnology. India and China also adopted policies in the areas of market access, IP protection, and regulatory review that have both fostered as well as discouraged innovation in biotech seeds. While judging by the strong market position of domestic varieties of Bt cotton, it may be concluded that China's strategy of public sector dominance of biotech seeds has been successful. However, the fact that no other biotech products have been widely commercialized even after more than a decade since the approval of Bt cotton suggests weaknesses in China's approach.

By contrast, India has opened its seed sector to foreign participation on terms equal to those of domestic firms. The enforcement of IP protections and regulatory requirements also remains a significant problem in India. Significant delays, and decisions that focus on factors other than bio-safety, undermine confidence in India's regulatory system. **BS**



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Strict price controls at the state level have undermined India's liberal investment environment and the innovative efforts of both foreign and domestic firms

stress tolerance, yield improvement, herbicide tolerance, insect and virus resistance, and other valuable traits.

One can also see that unlike India, China's government-supported research institutions and universities are also important players in biotech seed patents. For example, a review of patents and applications related to Bt cotton shows substantial activity by Chinese research institutes and universities. The research institutes of CAAS, including the Biotechnol-