IN brief

Canada ends EU row over GM products

Canada is the first nation to settle a dispute with the EU over the importation of genetically modified (GM) products. In 2003, Canada, Argentina and the US complained to the World Trade Organization (WTO) about the EU's imposition of a six-year *de facto* moratorium on approving new GM crops and food. The WTO responded the following year by lifting the moratorium after finding that it violated global trade rules, and the parties entered discussions. Canadian International Trade Minister Stockwell Day says the settlement is positive news for the country's producers, as it will improve market access for all locally produced GM products, particularly canola seed. Under the agreement, EU officials will meet Canadian authorities twice a year to discuss issues affecting agbiotech, including GM product approvals and commercial outlook. Argentina and the US have yet to agree on a solution. Canada may have been first, according to Nathalie Moll, director of Green Biotechnology at EuropaBio, because it has no products awaiting EU approval, and thus no legal basis to continue the dispute. Meanwhile, 70 global crop biotech products await EU approval. Sharon Bomer Lauritsen, executive vice president of food and agriculture for the US Biotechnology Industry Organization, says, "Trade problems will continue to exist until Europe has a science-based, timely and predictable approval process, which could be achieved if the EU simply followed its own laws and regulations." *Emma Dorey*

Pakistan's first biotech plant

Pakistan has launched its first biopharma company BF Biosciences based in Lahore, to manufacture interferon-α for hepatitis treatment. BF Biosciences is a joint venture between Pakistan's largest pharmaceutical company, Ferozsons of Lahore, and Argentine pharma Bagó, with a total investment of 600 million rupees ($7.2 million). Hepatitis affects 7–10% of the Pakistani population, and this manufacturing plant will enable the country to become self-sufficient. At the same time, Pakistan's government has announced a 294 million rupees ($3.53 million) injection over the next five years to build up its biotech sector in agriculture and healthcare. The financial boost will focus on upgrading existing scientific facilities, and establishing research institutes for wheat and cotton. "The government has, for many years, identified biotechnology as a major national priority in science," says Anwar Nasim, president of the Federation of Asian Biotech Associations and chairman of Pakistan's National Commission on Biotechnology. "We are at the stage now in Pakistan where we have done enough research in the lab and we are now ready to scale up and commercialize." Nasim adds that government has put 2 billion rupees ($24 million) into biotech over the last year or so. Pakistan will also officially start cultivation of *Bacillus thuringiensis* cotton next year, following the lead of the world's other top cotton producers, the United States, India and China. *Susan Aldridge*

R&D, it will be considered adequate practice of the patent. Under the previous rules, patent holders were also obliged to practice their patents within three years, "so this is a normal continuation and intensification of the previous rules," says Shen. She adds that legislators are mainly concerned with Chinese academics applying for patents for career promotions rather than for use, as in many public institutions, patent numbers in addition to publications are a major criteria used in awarding professorship.

The compulsory licensing clauses are also not without precedent, according to a patent reviewer at SIPO, who wished to remain anonymous. The clauses were already in place, issued by the State Council, China's cabinet, and it is these rules that have been incorporated into the revised law. Ho agrees: "Huge foreign investments have poured into China, and the country is keen to absorb more, so that the government [is likely to] be highly cautious in using the licensing clause."

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But further problems loom with respect to generic drug production. The new law ushers in a subtle but crucial stipulation that places brand manufacturers in a weaker position. The amendments stipulate that a company manufacturing patented products with a view to obtaining regulatory approval does not infringe the patent. "It means pharmaceutical generics can be developed and registered while their patented counterparts are still under IP protection, and once the protection is over, the generics can be immediately sold," says Hongyan Tong, an agent at Beijing-based IP law firm AFD China.

The new rules have also retained a previous stipulation that allows the use of patent information for scientific research. This provides generics producers with an opportunity to study the original patented products in the name of research without it being considered as infringement.

On the domestic front, experts anticipate problems implementing the 'absolute novelty' aspect. The SIPO patent reviewer contacted who requested to remain anonymous for this article acknowledges it will be difficult to judge whether a product under review is absolutely new and whether or not it has been used abroad. The situation is particularly complicated for the biotech industry, as the patents often cover multiple technological aspects.

In addition, the push to encourage Chinese citizens to file for international patents could backfire, as local academics might take a more cautious stance towards patenting than they have shown so far. Foreign patents are expensive, and Chinese researchers are unlikely to opt for them if the chances of international development remain low, says Xiaodong Lin, director of the patent office of Peking University Health Science Center.

Overall, Yongzhang Luo, a professor of biochemistry at Tsinghua University, is optimistic about China's handling of IP protection. The series of revisions to China's patent laws reflect the improved expertise of local patent regulators. A surge in local IP knowledge means "It is more difficult for people to apply for trash [low-quality] patents," says Luo. However, until mid-August, the new regulations for implementing the patent law, which work like a guidebook for law enforcement officials, had yet to be released by the State Council.

Simons & Simons' consultant Ho has also noticed that the new patent law has reduced his clients' unease, encouraging them to increase their research base in China. This is what Tony Zhang, head of Eli Lilly's China R&D Center in Shanghai has experienced. "Actually, despite worries in the West, we felt that the IPR protection in China has been quite good in the field of research. The problems [of patent pirating] mainly exist in the production area," Zhang says. Eli Lilly R&D Center is one of the first such centers opened in China by big pharmas. The center has outsourced most of its research to contract research organizations (a) surrounding it. Without a good IPR environment, Chinese CROs would not experience this boom, Zhang adds.

As a further means of fostering home-grown innovation, Luo suggests when the government endows grants, awards or subsidies to high-tech firms or researchers in applied research fields, patent ownership should be taken into account. "Only then can consciously applying and using high-quality patents become a regular habit in China," he says.

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