Syngenta scores in patent skirmish

On May 10, a federal judge cleared Syngenta from infringing on Monsanto's glyphosate-tolerance technology by using a transgenic corn crop acquired from Bayer CropScience in 2004. Basel-based Syngenta triggered one of two cases on May 12, 2004, by announcing that it had acquired from Bayer CropScience of Monheim am Rhein, Germany, the rights to GA21, a glyphosate-tolerance technology in corn. Monsanto of St Louis, Missouri, immediately sued Syngenta in the Delaware federal district court, alleging infringement of a claimed chimeric gene for introducing the glyphosate-tolerance trait. The court eventually consolidated this action with a lawsuit filed by Monsanto subsidiary, DeKalb Genetics, contending infringement of claims covering methods for producing glyphosate-tolerant corn. In May, this year, Judge Sue L. Robinson found the asserted chimeric gene patent claims invalid for lack of enablement. Syngenta had not infringed the asserted process patent claims, Robinson held, because these claims would have required Syngenta to bombard maize cells with DNA-coated microprojectiles, a step that DeKalb, not Syngenta, had performed. "Worldwide, glyphosate-resistance in crops represents the most widely adopted genetic modification technology," says Michael D.K. Owen, professor of agronomy at Iowa State University in Ames. "It appears that the seed companies will use resistance to glyphosate herbicide as the platform for all other genetically modified traits." The value of glyphosate tolerance correlates with the proliferation of patent litigation over the technology. Monsanto has announced plans to appeal. *PJ*

NYSE-Euronext merger to benefit biotech?

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Euronext President Jean Francois Theodore and NYSE Group President John Thain shake hands after the NYSE Group acquired Euronext NV for nearly $10 billion.

On June 1, 2006, the New York Stock Exchange Group (NYSE) and Euronext announced an agreement to combine the US and pan-European securities trading exchanges in a merger of equals, to be named NYSE Euronext. However, the two exchanges will continue to be run independently for now even if consolidation of trading operations is on the agenda. Biotech companies may have to wait some time to gain any benefits for the industry especially in Europe. "If it does enable there to be more focus on getting more analysis from the buy side of the industry then there should be a benefit [to biotech companies in Europe]," says William Powlett Smith, head of the UK biotech team for consultancy Ernst and Young, located in Reading, UK. "But I'm not sure that that is one of the benefits designed into the agreement," he continues, explaining that any benefit from more analysis of European biotech would probably come further down the road after the two companies consolidated trading operations. The agreement could also foreshadow more US capital for the European biotech markets depending on how the regulatory environment shapes up in Europe. Powlett Smith points out, however, that more liquidity in capital markets is a two-way street. "Capital flows could go both ways," into or out of Europe, he says, concluding that the less onerous investor regulation in Europe could eventually prove a boon to listed companies. "You need to see this as a defensive strategy from the NYSE in regards to Sarbanes-Oxley," he adds. Sarbanes-Oxley is a body of regulations in the US addressing the reporting requirements for public companies in light of some notable accounting irregularities by companies such as Enron and Worldcom (See article Lawrence p 731). Europe has no such regulations. "In that case, my guess is that higher volume companies, like big pharmaceuticals, would benefit before biotechnology." *JR*

Amgen big in Japan

Amgen announced on June 13 that it plans to triple its employee base in Japan by 2010 and build up a 150-person strong sales force to sell its products there directly rather than licensing them to Japanese companies. The announcement followed a US Food and Drug Administration decision to grant priority review status to ABX-EGF (panitumumab), Amgen's monoclonal antibody treatment for colorectal cancer. The biotech giant's move was expected, says Pino Modica, vice president of Plexus Ventures, a global pharma consultancy based in Maple Glen, Pennsylvania, and its timing with "something successful coming down the pipeline" makes sense. The US pharma presence in Japan has been historically based on joint ventures with local companies. Amgen's involvement with Japan began in 1984, when it struck a deal with Kirin Brewery to manufacture its first product, EPO (erythropoietin), there. But most US companies retain the rights for direct marketing, he notes, and with Japan now the second largest pharmaceutical market in the world, those who can are seeking to go solo. The trend is creating a paradoxical situation in which local companies are cramped in their own market. "Japanese companies are seeing their marketplace dominated by Western companies," says Modica. "In response, you see this mirror strategy" in which they are heading West. *AK*

US approval for Omnitrope

The US Food and Drug Administration (FDA) on May 31 approved Omnitrope, a recombinant human growth hormone and the country's first so-called biogeneric. The move came in response to a legal ruling in April calling on the FDA to resolve the status of the drug's application, which was filed by Sandoz (the generics arm of Swiss pharma giant Novartis of Basel) in 2003 (*Nat. Biotechnol.* **23**, 1327–1328, 2004). But the agency made clear that the okay for Omnitrope is no green light for future biogenerics approvals. Omnitrope was approved in April in the EU, after Sandoz filed a similar lawsuit, and after the European Medicines Agency issued regulatory guidelines for such approvals. But though promised by the FDA, such guidelines have not yet materialized in the US. With over $10-billion worth of biotech products due to come off patent in the next five years, industry has been resistant to the notion of cheaper copycat versions of biologics. Still, some experts say that even careful case-by-case approvals will push industry to embrace biogenerics as a means to create more affordable products. "Biogenerics is a paradigm shift, not just a generation of new products," says Alan Liss, senior director of biotech at Duramed Research in Pennsylvania. The idea that biotech products are based on complex science, accessible to only a few companies, will slowly be replaced by acceptance of the fact that biologics "can be made for the masses," he notes. *AK*

News in Brief written by K.S. Jayaraman, Philip Jones, Alla Katsnelson, John Ransom

Peer review coming to patents?

At a conference held on 12 May, the US Patent and Trademark Office (USPTO) discussed plans to build an online peer review system into the patent application process. The initiative, called Community Patent Review Project, will initially run as a one-year pilot for software-related patents—the area in which the USPTO has the biggest application backlog—with plans to extend to other areas such as biotech. "The aim long-term is to decrease litigation, increase licensing and help the [patent] examiner do his job faster and more efficiently" by creating a forum where experts can post relevant prior art, says Beth Noveck, director of the Institute for Information Law & Policy at New York Law School, who is spearheading the project. "In biotech there's more systematic prior art out there, but the question is, how to navigate it and apply it," she says. "We'd love to hear from industry experts" on the parameters that would be most useful to the field. Although Noveck concedes that there may be some secrecy concerns in industry, "there is a much wider community out there" who might participate, such as graduate students and other academics. According to Gregg Kyle, a licensing associate for healthcare inventions at Stanford University's office of technology licensing in California, having experts weigh in could be a positive step. "If the patent isn't really that valuable, we'd rather know sooner than later," he says. AK

Bt eggplant to be introduced in India

The Indian government has given 15 days for public feedback on its decision allowing Mahyco—the Jalna-based Indian partner of the US company Monsanto of St. Louis, Missouri—to produce and supply hybrid seeds of *Bacillus thuringiensis (Bt)* brinjal (eggplant), the country's first genetically modified food crop. The anti-GM lobby denounced what it said was haste in the approval process. They oppose the introduction of *Bt* brinjal claiming its effects have not been studied by the health ministry. Monsanto, whose *Bt* cotton was a commercial success in India, says the Cry1Ac gene in brinjal will protect it from shoot and fruit borer attack that damages nearly half of the crop. Monsanto has transferred its technology free to three Indian universities so that they, too, can develop and market their own *Bt* brinjal varieties. Industry sources say Monsanto's generosity is part of its commercial game plan: keep the monopoly of *Bt* technology on winners like *Bt* cotton with itself and give it away for commercially less important crops to create goodwill. Arvind Kapur, managing director of Nunhems India Pvt. of Gurgaon, near Delhi—the regional office of the Haalen Netherlands-based vegetable seeds company—says that though *Bt* brinjal may not rake in big money, the technology will benefit thousands of small vegetable farmers across the country. He says cauliflower and cabbage developed by private companies including his own will soon join the ranks of GM food crops in India while GM mustard could be the next. *KSJ*

Selected research collaborations

Partner 1	Partner 2	$ (millions)	Details
Xoma (Berkeley, California)	Schering-Plough (SP; Kenilworth, New Jersey)	25–75	A collaboration to develop and discover monoclonal antibody therapies for undisclosed indications. Xoma will use its phage display libraries to discover antibodies to targets provided by SP. SP will provide an upfront payment as well as R&D funding and milestone payments to Xoma. In addition, SP will pay royalties on any product sales resulting from the collaboration.
Pharmacopeia (PCOP; Princeton, New Jersey)	Cephalon (Frazer, Pennsylvania)	15	A deal to discover small-molecule drugs for a wide range of therapeutic areas. Cephalon will pay Pharmacopeia an upfront access fee. Pharmacopeia will conduct medicinal chemistry and primary biology on compounds identified by Cephalon. Cephalon will take the lead in development and commercialization of any clinical candidates, but Pharmacopeia also retains an option to develop candidates. Milestones and royalties will be paid by the developing and commercializing company to the other company.
CombinatoRx (Bethesda, Maryland)	Cystic Fibrosis Foundation (CFF; Cambridge, Massachusetts)	13.8	An agreement to discover novel therapeutics for cystic fibrosis built from synergistic drug combinations, using CombinatoRx's combination drug discovery platform. CFF will provide research expenses and up to 75% of clinical development expenses through Phase 2a. CombinatoRx will retain full commercial rights and receive milestone payments. CFF will be eligible for royalties on sales of any approved products.
Oxford Genome Sciences (Oxford, UK)	Medarex (Princeton, NJ)	*	A partnership to discover human antibody therapeutics for colorectal and other cancers. Oxford Genome Sciences will provide novel targets using its human protein databases, and Medarex will generate fully human monoclonal antibodies. Development and commercialization will be evenly split between the two partners.

*Financial details not disclosed. *AK*