BUSINESS AND REGULATORY NEWS

Roche's *Taq* patent invalid

A US federal judge has ruled that a key patent for an enzyme used in a DNA analysis technique is invalid and was obtained by fraud. The patent at issue—the '818 Taq patent—covers the native and recombinant forms of *Taq* DNA polymerase, a thermostable enzyme critical in polymerase chain reaction and gene sequencing owned by Hoffmann-La Roche (Nutley, NJ). Judge Vaughn Walker, who presides over the Northern District of California (San Francisco), upheld a challenge by Promega Corp (Madison, WI), which argued that scientists were originally awarded the patent after misrepresenting their experiments and falsely claiming advances over previous discoveries. Those scientists worked for the now defunct Cetus Corp, which sold the rights to the patent and a DNA replication process to Roche in 1991 for $300 million. Roche sued Promega in 1992 for breach of contract over a licensing agreement and the resulting dispute led to a four-week trial in February 1999.

"Roche remains convinced that our scientists conducted themselves with the utmost integrity and professionalism," Melinda Griffith, general counsel of Roche subsidiary Roche Molecular Systems said in a statement. However Judge Walker found that in eight separate instances the original patent holders at Cetus (who moved to Roche after 1991) intentionally withheld information and distorted facts; the judge's decision renders the primary *Taq* patent unenforceable.

The global market for sales of the enzyme is an estimated $200 million, and Roche and its licensing partner, Perkin-Elmer, rely on sales of licensed *Taq* to obtain PCR royalties. Unless overturned on appeal, the judge's ruling means that anyone can use the enzyme without paying Roche. La Roche officials say they plan to appeal the judge's decision.

"There's a GMO panic moving in from the west."

Business and regulatory news briefs written by Emma Dorey, Alan Dove, Jeff Fox, John Hodgson, and Eric Niiler.

Two patent disputes settled

November marked the settlement of two major biotechnology patent disputes. In one, Genentech (South San Francisco, CA) agreed to provide the University of California (Berkeley, CA) with $200 million to settle a patent infringement lawsuit involving a recombinant version of human growth hormone (hGH). At issue was whether researchers at Genentech benefited from unauthorized use of recombinant material encoding hGH that had been prepared by UCSF scientists (*Nature Biotechnol.* **17**, 634). The settlement ends a $2.8 billion lawsuit that originated ten years ago, had been heard earlier in federal court, but was pending retrial in January. A quarter of the settlement will go towards building a new research facility at the University of California San Francisco.

Meanwhile, Monsanto (St. Louis, MO) along with its DEKALB Genetics subsidiary (DeKalb, IL) settled several lawsuits with Novartis (Basel, Switzerland) covering several varieties of genetically engineered corn being marketed by all three companies. The corn varieties are engineered with genes encoding insecticidal proteins derived from *Bacillus thuringiensis* (*Bt*). As part of the agreement, Novartis was granted a license for *Bt* and Roundup-Ready corn, while Monsanto paid Novartis a fee based on past sales of a Novartis brand of genetically engineered corn.

Megamergers continue

In November, the UK's biggest biotechnology company CelltechChiroscience (Slough, UK) announced it will merge with pharmaceutical group Medeva (Leatherhead, UK) in a deal worth £563 million ($900 million). The resulting integrated lifescience company, Celltech Group, has a current market value of $2.1 billion, 56% being held by CelltechChiroscience shareholders, 44% by Medeva's. Through the acquisition, Celltech boosts its product pipeline with three phase III compounds (for hepatitis B, scleroderma, and attention deficit disorder) and one phase I drug (for cystic fibrosis). More importantly, Celltech will have access to a European sales and marketing network, through which it might be able to launch its own unpartnered products, CDP-571 for Crohn's disease and CDP-870 for rheumatoid arthritis, both currently in phase II. Celltech chair John Jackson and Medeva chair John Baker will become Celltech Group chair and deputy chair, respectively. CelltechChiroscience itself was only formed last summer (*Nature Biotechnol*, **17**, 741).

GMO roundup

- Baptist pro-biotech demonstrators at the US Food and Drug Administration in Washington in December carried placards reading "Biotech saves children's lives" and "Biotech equals jobs." Their lunch and ride to the demonstration were paid for by Monsanto's public relations company, Burson-Marsteller. Burson-Marstellar says that the demonstrators believed in the cause and that the payments the company had made merely facilitated the expression of existing sentiments.
- The latest pronouncements of professional environmental grouch, Jeremy Rifkin of the Foundation on Economic Trends (Washington, DC), indicate that he is with the birds and the bees rather than humans when it comes to GM crops for the third world. Commenting on the announcement by Monsanto of a vitamin A-enriched oilseed rape that might prevent blindness in hundreds of thousands of children in developing countries, Rifkin wondered only, "What are the repercussion for foraging birds, insects, and other animals when they digest plants that are acting as pharmaceutical factories? We just don't know."
- Simpleton eco-warriors revealed the depth of their knowledge of biology and plant breeding when they destroyed 90% of an experimental crop of raspberry bush es at a Washington State University. They had confused the raspberry bushes with hybrid poplar trees, which they wanted to destroy because they thought (if that is an appropriate word) "hybrid" implied "genetically engineered."
- The pope's advisors on life science matters, the Vatican Pontifical Academy for Life, has decided that it is not against the will of the catholic God to alter the genetic make-up of plants and animals. However, VPAL reasserted the Vatican's opposition to human cloning and in vitro fertilization. The vice president of VPAL, Elio Sgreccia, said "We are increasingly encouraged that the advantages of genetic engineering of plants and animals are greater than the risks." Perhaps straying somewhat from his theological brief, however, Sgreccia also urged continuing case-by-case risk assessment and called for proper labeling on GM products.