POLYMERASE CHAIN REACTION

Promega Wins Round in Fight Over Taq

A high-stakes battle over patent rights to Taq polymerase—the enzyme used in molecular biology labs around the world for the popular technique known as the polymerase chain reaction (PCR)—took a new turn in a San Francisco courtroom last week. A judge handed down a pretrial ruling that appears to strengthen the hand of Promega, a Madison, Wisconsin, biotech company that is trying to invalidate a patent on Taq held by the Swiss pharmaceutical giant Hoffmann-La Roche.

The judge concluded that the now-defunct Cetus Corp., from which Roche bought the PCR patents in 1991, did not adequately specify the purity of the enzyme in its patent application and withheld information from the U.S. patent office. Both findings could strengthen Promega's argument that earlier publications anticipated Cetus's 1990 patent, say some legal observers. The final result of the case, which could go to trial this fall, could affect the $80 million to $85 million worldwide market for Taq, because Promega sells the enzyme for less than its competitors.

Ironically, although Roche is now on the defensive, it started the fight. It sued Promega in 1992 for infringing Roche's PCR patents. Promega had a license to sell Taq for non-PCR uses such as DNA sequencing, but Roche charged that Promega had packaged the enzyme in a way that invited researchers to use it for PCR. Promega responded with a multipronged attack on the Taq patent itself.

In last week's ruling, the judge found that Cetus's patent claim to "purified" Taq polymerase could be interpreted broadly to mean any Taq preparation from which some contaminants had been removed. That leaves the patent vulnerable to being declared invalid in the trial if Promega can prove that either of two prior publications of a similar enzyme described less pure forms of Taq, says patent attorney Larry Stults, of the Atlanta law firm of Jones & Askew.

The judge also found that Cetus had concealed from the patent examiner data suggesting that the enzyme previously purified and reported by two other research groups had the same molecular weight—and therefore may have been the same enzyme—as the Taq polymerase discovered at Cetus. The judge said he could not decide whether the omissions stemmed from mere negligence or from intent to deceive the patent office, and set a hearing for 13 September to schedule a trial on that issue. If intentional deception is found, that would invalidate the patent.

Promega Vice President Randall Dimond says that the decision provides "a major advantage" to Promega, and Stults, who has no direct involvement in the case, agrees, saying that the two findings seem to give Promega "a gun with two live bullets in the chambers." Tom White, vice president of research and development at Roche Molecular Systems, says he is confident that Roche will "win with no trouble." But he adds that even if Promega's bullets were to find their mark, Roche holds other Taq patents that are not in question, and those would still keep Promega from selling Taq for use in PCR. The potential for further litigation may be endless.

–Marcia Barinaga

RUSSIAN SCIENCE

Fortov Named to New Post; Saltykov Out

MOSCOW—A postelection Cabinet reshuffle has eliminated the ministry of science and technology and created a new, lower level structure for overseeing Russia's R&D efforts: the State Committee for Science and Technologies. Boris Saltykov, a reformer who had held the post of science minister since 1991, was ousted in the move, and Vladimir Fortov, a high-temperature physicist, was named to head the new committee and also given the title of deputy chair for science and technology.

The changes, announced last week, are expected to bring an end to the bitter battle between the ministry and the Russian Academy of Sciences (RAS) for control over state policy and funding mechanisms (*Science*, 12 January, p. 139; 18 November 1994, p. 1153). The 50-year-old Fortov, who has headed the Russian Foundation for Basic Research (RFBR)—an independent body initiated by the ministry—since 1993, is expected to defend such programs. But as an academician and former head of the academy's Institute of High Temperatures, he is also seen as someone who can work with RAS officials, who openly feuded with Saltykov and who backed Fortov's appointment.

"He is a talented and successful researcher," says Mikhail Glubokovsky, deputy chair of the Duma (the lower house of the Russian parliament) Committee on Science and Education. "At the same time, he is a good diplomat who knows how to avoid unnecessary quarreling and conflicts." Andrey Fonotov, a former deputy science minister, sees Fortov's appointment as an acceptable solution to the problem. "If Saltykov had to go, Fortov is the best [replacement]," he says. "Being Saltykov's choice to head the RFBR, he was always supported by the ministry."

The science ministry was the only one dissolved in the new Cabinet following last month's reelection of Boris Yeltsin as president. There had been speculation that the science ministry would be merged with the Ministry of Education and the State Committee for Higher Education in a new state committee, or downgraded as a department within the Ministry of Industry. Although last week's announcement at least maintains science and technology's own bureaucratic niche, it does little to clarify the government's long-term plans for science.

"No matter what the level of the body is, what really matters is the people who work there, the professionals," says Sergey Kapitsa, president of the Russian Physical Society. "If they stay, everything will be all right."

The odd man out in the reshuffling is Saltykov, who holds no position in the new Cabinet. "It's a pity Saltykov was dismissed," says Kapitsa. "I think his policy of reforms was right, and I hope Fortov will continue them." Last month Saltykov, who could not be reached for comment, told *Science* that it is important for Russia to maintain a science ministry, with Cabinet status, because of the country's "highly centralized" system. Countries in which industry is the major R&D player can operate with a more decentralized government structure, he said.

One contentious issue left up in the air by the reorganization is the fate of the state research centers, created by Saltykov and controlled by the ministry as a counterweight to the academy's vast network of institutes. Although the centers have not received any of the promised financial concessions, many reformers believe the concept has merit. "The program had died long before Saltykov's dismissal," says Glubokovsky. "It should be renewed on another basis." Kapitsa gives Saltykov more credit, saying that "he did the maximum to support them when every institute was starved for funds."

What is clear, however, is that Fortov has for now become the most powerful person in Russian science. He still heads the RFBR and is said to have no intention of leaving that position. The combination of jobs could give him great influence over all state funding for science. But Glubokovsky doesn't see Fortov's ascendancy as a permanent change in how the government sets science policy. "This configuration of positions was related to Fortov personally," he says. "If [Fortov] goes for some reason, the structure will be changed again."

–Andrey Allakhverdov and Vladimir Pokrovsky

Allakhverdov and Pokrovsky are writers in Moscow.