US Supreme Court applies strict limits to patents

In a keenly anticipated ruling, the US Supreme Court has not upheld a highly controversial Federal Circuit Appeals Court decision in the patent infringement case of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.* The Supreme Court's unanimous decision is good news for small biotech companies as it clearly sends a message to the inventing community that the court places a high value on intellectual property and the legitimate expectations of inventors in maintaining their property interests. However, patents must now be re-evaluated in light of a new rule implemented by the Supreme Court—a move that is expected to result in much costly litigation as biotech firms scramble to define the scope of their inventions.

At issue is the legal relationship between two critical components: the doctrine of equivalents, which extends the literal meaning of a single patent claim to include a wide range of equivalent inventions; and a prosecution history estoppel, a countermeasure that bars a patentee from arguing that an equivalent invention, that was initially described but subsequently discarded during the patent examination process in order to gain patent approval, is within the patented claim. Until the Court of Appeals decision, the doctrine could not be invoked for specific claims that were modified because they encompassed a previously disclosed or patented invention ("prior art").

In its November 2000 decision, the Court of Appeals ruled that if a patentee amended and narrowed its original claim—for any reason—to gain patent approval, then a prosecution history estoppel was invoked, completely blocking the subsequent use of the doctrine of equivalents when interpreting the amended claim. This "complete bar" meant that any equivalent invention whatsoever that fell outside the literal scope of the amended claims was not covered by the patent (*Nat. Biotechnol.* **19**, 394, 2001). That decision would have allowed "copyists" to evade liability for infringement simply by making insubstantial changes to a patent invention. Biotechnology companies with patented proteins, for instance, have invoked the doctrine to prevent competitors from marketing molecules that have slightly different amino acid sequences but perform the same biological function. For example, Celltech (Slough, UK) has asked a UK court to find that MedImmune's (Gaithersburg, MD) Synergin, an antibody for treating respiratory infections in premature babies, infringes Celltech's patent under the doctrine of equivalents; MedImmune's antibody differs from the patented Celltech molecule by one amino acid out of 1,320.

It is common practice in biotech patents that describe new technologies to broadly claim initially and then negotiate with the US Patent and Trademark Office (Washington, DC) to determine an acceptable set of amended patent claims. Thus the Court of Appeals decision, which was also retroactive, shook the biotech patent community, which could not have foreseen that the amendment process would limit both their invention and their ability to sue others who make identical or equivalent products. Several companies and research organizations filed briefs urging the Supreme Court to overturn the decision (*Nat. Biotechnol.* **20**, 103, 2002).

Now, in its May 28, 2002 decision, the Supreme Court has ruled that the "complete bar" was an impermissible new rule that unfairly diminished the scope of value of existing patents. Acknowledging that the nature of language makes it impossible to capture every nuance of an invention, the Supreme Court has ruled that holders of narrowed patents can, in some circumstances, argue the doctrine of equivalence when faced with copycat inventions. Justice Anthony Kennedy clearly pointed out that inventors who had previously amended their claims had no reason to believe that they were "relinquishing their right to equivalent inventions."

"The elimination of the retroactive nature of Festo is highly beneficial in the area of biotechnology, where the primary asset of a company is intellectual property," says Jeffrey Winkelman, patent counsel for the functional genomics company Elitra Pharmaceuticals (San Diego, CA). "The scope of many patented inventions would undoubtedly be narrowed if Festo were upheld because the claims in most, if not all, biotechnology patents were amended for one reason or another during patent prosecution."

However, the Supreme Court has not returned the law to its exact position before the Court of Appeals' decision. Instead, it has imposed a "flexible bar rule" whereby the doctrine of equivalence cannot be invoked for specific claims initially described in a patent application but subsequently amended for any reason related to patentability. (Before the Court of Appeals' decision, the doctrine could not be invoked for amendments relating to "prior art".) But inventors can still protect their patents from equivalencies that were unforeseeable (and therefore not described) at the time the claims were amended.

The legal community is unclear what impact this "flexible bar" will have on defining the scope of individual inventions. "Biotechnology patent holders must [now] re-evaluate their own claims and enforcement strategies in light of the Festo ruling," says Barry Wilson, patent attorney in the intellectual property group at Foley & Lardner (San Diego, CA). "This decision directly impacts the company's business strategy as it determines the scope of its commercial invention and its rights to enforce the patent."

Thus the Festo ruling may be especially costly for the biotechnology community by opening a floodgate of litigation, increasing legal fees and lost time. Moreover, the decision places on biotechnology companies and other patent owners the burden to prove that their invention includes a literal description and a range of known and unforeseeable equivalent inventions. The ruling "leaves a number of issues that will undoubtedly only be resolved via litigation," says Winkelman. "The Supreme Court decision appears to be a windfall for patent litigators."

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New SEC regulations could hinder biotech investment

With the aim of curbing biased behavior by research analysts, the US Securities and Exchange Commission (SEC; Washington, DC) laid down new rules in May requiring analysts covering companies to disclose potential conflicts of interest, such as whether they personally own stocks in, or whether their bank has led any financings for, the companies they are covering. The new rules also sever some of the direct links between banks and their research analysts. Although biotech industry representatives welcome such efforts to protect companies and investors, some are concerned that the new regulations, and ongoing SEC investigations, could inadvertently make it more diffi-