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PATENT LAW

Inadequate Descriptions

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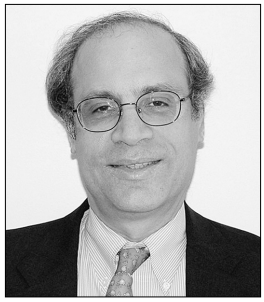

IN A CASE THAT pits university researchers against a major drug company, the U.S. Court of Appeals for the Federal Circuit on Feb. 13 affirmed dismissal of the University of Rochester's patent infringement suit against Pfizer Inc. over Pfizer's blockbuster arthritis drug Celebrex. *Univ. of Rochester v. G.D. Searle & Co. Inc.*, 358 F.3d 916 (Fed. Cir. 2004). In this significant decision for the biotech industry, the Federal Circuit panel strongly reaffirmed the court's commitment to enforcing the "written description" requirement of § 112 of the Patent Act.

The technology at issue in the 'Rochester' case

For more than 100 years, doctors have been prescribing aspirin—a member of a group of medications called nonsteroidal anti-inflammatory drugs (NSAIDs)—to relieve the pain and inflammation of arthritis. But aspirin and other NSAIDs also can produce stomach irritation and cause ulcers and gastrointestinal bleeding. In the early 1990s, scientists at the University of Rochester found out why. It had been known for 20 years that NSAIDs worked by inhibiting the activity of an enzyme known as cyclooxygenase. The Rochester researchers discovered that there actually were two cyclooxygenase enzymes, called Cox-1 and Cox-2. Inhibiting Cox-2 reduces inflammation, while inhibiting Cox-1 can cause stomach upset; typical NSAIDs inhibited both.

The Rochester group realized that a drug that targeted Cox-2—while not affecting Cox-1—would reduce inflammation without the potentially toxic side effects. They obtained a method patent (No. 6,048,850, known as the '850 patent) covering that discovery and a second patent on a screening assay for determining whether a drug inhibited Cox-1 but not Cox-2. But they did not find or claim a drug that actually showed such activity. For example, Claim 1 of the '850 patent covers: "A method for selectively inhibiting [Cox-2] activity in a human host, comprising administering a nonsteroidal compound that selectively inhibits activity of the [Cox-2] gene product to a human host in need of such treatment." Nothing in the 1992 patent application describes the structure of a compound that shows such activity.

In 1992, researchers at Searle (a drug company later bought by Pfizer Inc.) began efforts to identify such a drug. Eight months later, after screening more than 600 compounds, they identified a number of promising candidates. That work led to Celebrex, introduced in 1999. In 2003, Celebrex generated more than $2 billion of revenue for Pfizer.

The day the '850 patent was issued, Rochester sued Pfizer. In March 2003, that court dismissed the complaint on summary judgment, ruling that the '850 patent is invalid on two separate grounds: failing to satisfy both the written-description and the enablement requirements of § 112. 249 F. Supp. 2d 216 (W.D.N.Y. 2003). The court wrote: "[T]he real issue here is simply whether a written description of a claimed method of treatment is adequate where a compound that is necessary to practice that method is described only in terms of its function, and where the only means provided for finding such a compound is essentially a trial-and-error process." Id. at 221.

On enablement, the district court found that the patent required "undue experimentation," applying the well-known factors set out in *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). Those factors include the quantity of experimentation necessary, the amount of direction provided in the patent, the state of the prior art and the predictability or unpredictability of the art. The court noted that "considerable work and research was needed in order to turn the invention claimed by the '850 patent into reality, and the patent supplies very little guidance." 249 F. Supp. 2d at 235.

Rochester's appeal attracted motivated amici from academia. The University of California and two branches of the University of Texas argued that Federal Circuit case law subjected biotechnology inventions to a "heightened written description requirement" that "prejudices the rights of inventors engaged in basic research at universities" and "rewards industrial scientists who refine the universities'

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basic discoveries into specific pharmaceutical products." As an example, the amici pointed to the University of California's loss in *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), which invalidated a California patent covering human insulin on written-description grounds, and urged the court to examine en banc the doctrine as it applies to biotechnology.

As early as the Patent Act of 1793, patent statutes have required some "written description" of an invention. Until 1870, however, patent law did not expressly require that the application include specific claims. In the preclaims regime, therefore, the written-description requirement was considered necessary in part "to put the public in possession of what the party claims as his own invention." *Evans v. Eaton*, 20 U.S. 356, 434 (1822).

The requirement was carried over into the first paragraph of § 112 of the current Patent Act: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains...to make and use the same." That language conceivably can be read to mean that the written description serves only the purpose of "enablement," and that the claims now fulfill the notice function mentioned in *Evans*.

In *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991), the court recognized that "there appears to be some confusion in our decisions concerning the extent to which the 'written description' requirement is separate and distinct from the enablement requirement." Resolving that confusion, the court "reaffirmed" that the written-description requirement is distinct from enablement. To meet the requirement, the specification "must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." Id. at 1563 (citation omitted). The requirement "ensure[s] that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000).

On appeal, Rochester attempted to tap into the controversy over the existence and meaning of written description, arguing that the requirement should be liberalized, if not eliminated. Both sides argued that a victory for the other would chill innovation by denying just rewards.

The Federal Circuit had vigorously debated the issue of the written-description requirement in 2002 in *Enzo Biochem Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002), and again in *Moba B.V. v. Diamond Automation Inc.*, 325 F. 3d 1306 (Fed. Cir. 2003). Each decision upheld application of the requirement. In *Moba*, Judge Randall Rader wrote that the majority's application of the requirement "compounds the confusion, increases the chances for error, and augments the expense of the trial process." Id. at 1323.

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The *Rochester* panel declined to revisit these issues (each member of the panel had been on the prevailing side in either *Enzo* or *Moba*). Writing for the court, Judge Alan Lourie reaffirmed that the requirement is distinct from enablement, and rejected the view that it became "redundant" with the advent of claims in 1870, noting that the role of the claims is to give public notice, while the role of the specification is to teach both what the invention is, and how to use it. 358 F.3d at 922, n.5. The panel also rejected the fallback argument that the requirement should only apply in cases where priority is an issue, and not to original claims not the subject of an interference. Under this view, the purpose of the requirement is to "police priority"—preventing amended claims that would get the benefit of the priority date. The panel found that "the basic requirement of a written description of an invention exists whether a question of priority has arisen or not." Id. at 924.

Circuit affirms necessity of a written description

Although one can argue that there is no need for the specification to include a written description of an invention set out in the claims where priority is not in question, there is nothing in the statutory language to support that view. See *Moba*, 325 F.3d at 1327 (Bryson, J., concurring). Moreover, § 132(a) of the patent act provides that an amendment may not introduce "new matter into the disclosure of the invention." The written-description requirement would be largely redundant if limited to priority questions.

Against this background, the panel easily found that the '850 patent was invalid for lack of an adequate written description of the claimed invention. The patent did not "disclose any compounds that can be used in its claimed methods" (358 F.3d at 927) or disclose "any method for making" such a compound (id. at 928). The court rejected Rochester's argument that when the application was filed, researchers could have identified the drug by screening compounds known to bind to the target enzyme or contained in compound "libraries" maintained by pharmaceutical companies. That link was too tenuous. Rochester, the court found, failed to "present any evidence that the ordinarily skilled artisan would be able to identify any compound based on [the] vague functional description" in the patent. Id. at 928. Affirming on written description, the court did not reach enablement. Though the Rochester inventors made, as the district court noted, "significant discoveries in this field," they did not take "the last critical step" of isolating the necessary compound, or "developing a process through which one skilled in the art would be directly led" to it. Absent a reversal en banc, those efforts will not be compensated under the patent laws. NLJ