## *UNIVERSITY OF ROCHESTER V. G.D. SEARLE & CO.*

*358 F.3d 916 (Fed. Cir.), reh'g en banc denied, 375 F.3d 1303, cert. denied, 160 L. Ed. 2d 484 (2004)*

The Federal Circuit ruled that a pharmaceutical patent was invalid for lack of written description under 35 U.S.C. § 112 where the patent claimed a method of administering a compound in a human to achieve a therapeutic effect but failed to disclose any such compound, suggest how to make it, or proffer any evidence that the inventors knew of the compound when the patent application was filed.

University of Rochester ("Rochester") owned U.S. Patent No. 6,048,850 ("the '850 patent"), claiming a method for selectively inhibiting cyclooxygenase-2 (COX-2) activity in a human host through administering a non-steroidal compound. Traditional anti-inflammatory drugs function by inhibiting not only COX-2, which is responsible for inflammation, but also COX-1, which protects the stomach lining. Rochester sued G.D. Searle & Co., Monsanto Co., Pharmacia Corp., and Pfizer Inc. (collectively "Pfizer"), alleging that Pfizer infringed the '850 patent by selling its COX-2 inhibitors Celebrex and Bextra for treatment of inflammation. The district court granted Pfizer's motion for summary judgment, invalidating the '850 patent for failure to comply with the written description and enablement requirements. Rochester appealed.

The Federal Circuit affirmed the district court's ruling on the written description ground. Writing for the three-judge panel, Judge Lourie first rejected Rochester's argument that the written description requirement does not exist independent of the enablement requirement. The court stated that despite their significant overlap, the written description, enablement, and best mode requirements are independent of each other. Thus, an invention may be enabled without being sufficiently described, and vice versa. The court noted that the Federal Circuit's precedent "clearly recognizes a separate written description requirement," and cited the rule articulated in recent cases such as *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), and *Enzo Biochem, Inc. v. Gen-Prob Inc.*, 323 F.3d 965, 968 (Fed. Cir. 2002): A patentee must disclose an invention in enough detail so that one skilled in the art may "visualize or recognize" the identity of the invention. Extending the written description standard developed in *Lilly* for DNA inventions to chemical inventions, the court stated that the written description requirement involves a "precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed . . . invention."

The court also rejected Rochester's arguments that the written description requirement only applies in the priority context. The court reasoned that the statute does not limit the written description requirement to cases with priority issues. Furthermore, while the '850 patent is directed to a method, rather than a composition of matter as in precedent cases, the court considered this difference a mere semantic distinction. Regardless of whether it claims a compound or a method that requires its use, the patent must contain an adequate description of the compound in question.

The court found that the '850 patent failed to adequately describe the claimed invention. Because the claimed method depends on a compound that selectively inhibits COX-2 activity and yet the patent discloses no such compound, the court concluded that one

skilled in the art could not practice the claimed invention on the patent's specification. Thus, the court upheld the district court's decision invalidating the '850 patent.