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Ariad Pharmaceuticals *et al.* v. Eli Lilly & Co.: A Question of Possession



BY N. SCOTT PIERCE

In *Ariad Pharmaceuticals et al. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010), the U.S. Court of Appeals for the Federal Circuit held *en banc* that the first paragraph of 35 U.S.C. § 112 includes a written description requirement that is distinct from enablement to

Scott Pierce is a principal at Hamilton Brook Smith Reynolds PC in Concord, Mass., and adjunct professor at Suffolk University Law School teaching biotechnology patent law. He is the author of "University of Rochester v. G.D. Searle & Co.: Writing on the Wall," 4 J. Marshall Rev. Intell. Prop. L. 406 (2005). His most recent article is "Common Sense: Treating Statutory Non-Obviousness as a Novelty Issue," 25 Santa Clara Computer & High Tech. L.J. 539 (2009). He can be reached at (978) 341-0036 and scott.pierce@hbsr.com. The views expressed herein do not represent those of his firm, or any client or organization.

make and use an invention. Specifically, Judge Lourie, for the court, held that 35 U.S.C. § 112, first paragraph, contains a written description requirement separate from an enablement requirement, and that the scope and purpose of the written description requirement is to convey to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.

On June 2, 2009, Ariad Pharmaceuticals, *et al.* ("Ariad") filed a petition in the Federal Circuit for an *en banc* rehearing to decide whether the Federal Circuit erred by "engrafting . . . a separate written description requirement onto section 112, paragraph 1" and to determine the "proper test to satisfy the requirements in section 112, paragraph 1." Ariad's petition repeated the opinion of some commentators that the statutory standard for meeting the written description, as applied in *Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) ("Lilly") in 1997, was "tantamount to a 'super enablement' test." The petition also reiterated Judge Rader's opinion from his dissent in *Rochester* that a written description requirement, separate from enablement, did not exist prior to the decision by the U. S. Court of Customs and Patent Appeals in *In re Ruschig*, 379 F.2d 90 (C.C.P.A. 1967). Even then, according to Judge Rader in his dissent from denial of rehearing *en banc* in *Enzo Biochem, Inc. v. GeneProbe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002) ("Enzo"), the written description requirement has been applied only to "police priority" of claimed subject matter.

Judge Moore, writing for the majority prior to the Federal Circuit's *en banc* rehearing, stated that Ariad had not adequately disclosed any embodiments of the transcription factor NF-kB employed by the claimed method of U.S. Patent No. 6,410,516 for ameliorating the harmful extracellular influences that normally trigger NF-kB activations, and, therefore, failed to "demonstrate that the patentee was in possession of the inven-

tion that is claimed.” She also invoked Judge Rader by commenting that “the situation presented in this case should not often occur, because ‘in simple terms, the court would properly interpret the claims as limited.’” Judge Moore concluded that, “nonetheless, as it stands, Ariad chose to assert claims that are broad far beyond the scope of the disclosure provided in the specification of the ’516 Patent.”

Possession Standard Criticized. “Possession by the inventor,” as a standard for meeting the written description requirement, was first applied by the Court of Customs and Patent Appeals in *In re Wertheim*, 541 F.2d 257 (C.C.P.A. 1976), nine years after *Ruschig*, and has been employed with some frequency by the courts since that time. However, possession by the inventor also has been criticized as a threshold requirement of written description. For example, the Federal Circuit in *Enzo* stated that a “showing of ‘possession’ is ancillary to the statutory mandate that ‘the specification shall contain a written description of the invention,’ and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention.”

The Court of Customs and Patent Appeals in *Ruschig* did not explicitly partition written description and enablement requirements under 35 U.S.C. § 112. Rather, Judge Rich, who wrote the opinion in *Ruschig*, merely stated that a compound that is not described in a specification as filed can not later be claimed simply because it falls within a broader class of compounds that is supported by the specification. Judge Rich, in fact, stated that “we doubt that the rejection is truly based on 112, at least on the part relied on by appellants,” and that, the “issue here is in no wise a question of its compliance with § 112, it is a question of fact: *Is the compound of claim 13 described therein?*” Judge Rader’s later interpretation of *Ruschig* as putting forth a distinct written description requirement under Section 112, 1st paragraph, only as a “priority policeman,” is misplaced. Decisions since *Ruschig*, such as *In re Robins*, 429 F.2d 452 (C.C.P.A. 1970), clearly state that, “where no explicit description of a generic invention is to be found in the specification (which is not the case here) mention of representative compounds may provide an implicit description on which to base generic claim language . . . it has also been one way of teaching how to make and/or use the claimed invention, thus satisfying that aspect of § 112.” Therefore, despite the fact that written description and enablement were considered to be distinct requirements, the written description standard was applied in at least one case that post-dated *Ruschig* without reference to a priority claim.

Commentators Incorrect. Commentators have been incorrect in characterizing the written description requirement as a “super enablement” test. Judge Lourie, who wrote the opinion in *Lilly*, indicated that claims to

a genus “may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.” He further stated that support of a genus by means of recitation of a representative number of species “is analogous to enablement of the genus under § 112, ¶ 1, by showing the enablement of a representative number of species within the genus.” In the case of *Lilly*, Judge Lourie found that the written description requirement was not met for claims directed to “vertebrate insulin cDNA” or “mammalian insulin cDNA” where the only support for those claims was a constructive reduction to practice of a proposed method by which to obtain those cDNAs. The key to sufficiency of a “representative number,” for Lourie, was predictability in the art.

Although the written description requirement is distinct from that of enablement of how to make and use a claimed invention, there is an aspect of the written description requirement that parallels enablement in that the proper measurement of written description in the specification of a patent application is whether one skilled in the art can comprehend from the specification the scope of an applicant’s invention. Further, this requirement extends back to the earliest days of U.S. patent law as the question whether *the public* has been put in possession of the invention by the patent specification and predates patent claims, which were not required by statute until the Patent Act of 1870.

Enablement of one skilled in the art to comprehend the scope of an applicant’s invention has consistently been applied by courts until the Federal Circuit’s decision in *Rochester*. There, the court held that the written description requirement was not met because the applicants failed to identify a single embodiment of a “Cox 2 inhibitor” that fell within the scope of the claimed method for selectively inhibiting PGHS-2 activity in a human host. Had the court in *Rochester* simply applied an enablement standard for sufficiency of the written description, wherein the question simply would have been whether the specification, in the absence of any embodiments of suitable compounds to be employed in the claimed method, enabled one skilled in the art to practice the claimed use of Cox 2 inhibitors without undue experimentation, the outcome of that case would have been much more straightforward.

The correct test for written description in *Rochester* and in *Ariad*, where no compounds are identified that are suitable for use in the claimed methods, is not “possession by the inventor,” which is inherently meaningless. Rather, the issue is whether one skilled in the art is enabled by the specification as filed to comprehend the scope of the invention ultimately claimed and to practice that claimed invention without undue experimentation.