

HIGH COURT SHOULD RESOLVE DISPUTE OVER KEY PATENT LAW REQUIREMENT

by

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The U.S. Court of Appeals for the Federal Circuit recently declined an opportunity to clarify, *en banc*, the requirements of Section 112, paragraph 1, of the United States Patent Act, Title 35.¹ In *University of Rochester v. G.D. Searle & Co.*, the court — in a 7 to 5 vote — left divergent Federal Circuit case law intact, thus perpetuating uncertainty in the patent law.

As is often the case, the issue is simple to frame and hard to resolve: just what does Section 112, paragraph 1 require? More specifically, is there a “written description” requirement that is separate and distinct from the requirements of enablement and best mode?

Attempts to answer this question have created considerable disagreement among the Federal Circuit judges. On one hand, some Federal Circuit judges believe that Section 112, paragraph 1 has only two requirements: first, the patent must *enable* one skilled in the art to make and use the invention; and second, the patent must set forth the *best mode* known to the inventor to carry out the invention. If a patent’s specification achieves these two criteria, the patent is valid insofar as Section 112, paragraph 1 is concerned.

However, other judges on the court believe that there is a third requirement to Section 112,

¹Section 112, paragraph 1, of the Patent Act provides:

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, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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paragraph 1. According to these judges, a patent specification must also contain a *written description* of the claimed invention that is independent of the enablement requirement. To these judges, if the specification does not provide a written description of the subject matter of the claims, the patent is invalid.²

The judges who believe that Section 112, paragraph 1 has only two requirements are concerned that many patents will be invalidated if they are found lacking of a separate written description. They say the written description requirement is a new attack on patent validity that was improperly introduced to patent law in the 1997 decision of *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

In contrast, those judges who believe that Section 112, paragraph 1 has three requirements maintain that the separate written description requirement is and always has been a requirement of the patent law, and that reading Section 112, paragraph 1 as having only two requirements violates stable precedent that can be traced at least as far back as the 1967 case of *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967).

Considering the Federal Circuit has now twice refused to consider and resolve the issue *en banc*, and it has not spoken with a clear and unified voice about the requirements of Section 112, paragraph 1, the stage appears to be set for the Supreme Court to resolve the issue once and for all.

In particular, the opportunity for *en banc* resolution first presented itself two years ago in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002). In *Enzo*, the Federal Circuit vacated the initial panel decision, 285 F.3d 1013 (Fed. Cir. 2002), and granted a petition for rehearing. The reissued opinion, following *Lilly*, maintained that Section 112, paragraph 1 sets forth three requirements, including a written description requirement that is separate from the enablement requirement. A petition for rehearing *en banc* was also filed in *Enzo*, but this petition was denied. Thus, the Federal Circuit in *Enzo* never resolved the issue *en banc* of whether Section 112, paragraph 1 has two or three separate requirements in an invalidity context.

The requirements of Section 112, paragraph 1 were again at issue this year in *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004), *reh'g en banc denied*, No. 03-1304, 2004 WL 1489101 (Fed. Cir. July 2, 2004). In February, a unanimous three-judge panel held that Section 112, paragraph 1 has three distinct requirements. In so finding, the court upheld the lower court's grant of summary judgment of invalidity under 35 U.S.C. § 112, paragraph 1.

The invention in *Rochester* relates to the human body's biological production of a compound associated with inflammation and diseases such as arthritis. In the early 1990's, scientists discovered two types of compounds called cyclooxygenases, now referred to as "COX-1" and "COX-2." The human body manufactures COX-1 in the gastrointestinal tract, and it provides protection for the stomach lining. COX-2, on the other hand, is believed to be responsible for the inflammation associated with arthritis.

²All members of the court seem to agree that in a priority context, as opposed to the validity context described herein, Section 112, paragraph 1 has three requirements: 1) *enablement*, 2) *best mode*, and 3) *written description*. In the priority context, the written description requirement prohibits patent applicants from adding new inventions, or new matter, to the original patent disclosure.

Older drugs such as aspirin inhibit both COX-1 and COX-2, and thus their use led to undesirable side effects, such as an upset stomach. The University's patent claims a method for administering a compound that inhibits COX-2 but not COX-1. All of the claims require a method "for selectively inhibiting [COX-2] activity in a human host" by "administering a non-steroidal compound that selectively inhibits activity of the [COX-2] gene product to [or in] a human host in need of such treatment."

The problem, said Judge Allan Lourie writing for the three judge panel, is that the patent does not disclose any "compound" that can be used in the claimed methods. Because the University did not disclose any compounds in the patent's specification, and because the University did not set forth any evidence that a person of ordinary skill in the art would have this knowledge when the patent application was filed, the Federal Circuit affirmed summary judgment of invalidity under 35 U.S.C. § 112, paragraph 1.

The University then petitioned the Federal Circuit to (1) rehear the case, and (2) to rehear the case *en banc*. Both petitions were denied. The denial to rehear the case *en banc* was a seven to five vote that generated two concurring and three dissenting opinions. Judge Lourie and Judge Dyk concurred and each authored separate opinions. Judge Newman dissented and authored an opinion. Judge Rader also authored a dissenting opinion, in which Judges Gajarsa and Linn joined. Finally, Judge Linn authored the third dissenting opinion, in which Judges Rader and Gajarsa joined.

Judge Lourie explained that there always has been a separate written description requirement distinct from the enablement requirement under Section 112, paragraph 1, and that this requirement is not confined to priority issues. He observed that a reading of Section 112, paragraph 1 shows this. He then noted that the written description requirement serves the function of giving the public a meaningful disclosure. In other words, the *quid pro quo* for the patent monopoly is the written description requirement. He disagreed with the contention that the advent of claims under the 1870 Patent Act made the written description requirement redundant.

Moreover, Judge Lourie observed that Federal Circuit precedent, as well as cases decided by the Court of Claims and Patent Appeals, recognized a separate written description requirement. Citing *Enzo*, he explained that while the specification need not recite the language of the claims, the written description requirement mandates, at a minimum, that the patent explains to one skilled in the art what is claimed.

Again citing *Enzo*, Judge Lourie refuted the criticism that *Lilly* was the first decision to apply the written description requirement outside the priority context. He noted that an 1822 United States Supreme Court case expounded upon the separate description and enablement requirements. He also explained that while *Lilly* and *Enzo* both centered on DNA-based inventions, the written description requirement was equally applicable in a chemical arts context. Thus, Judge Lourie concluded that Section 112, paragraph 1 has a distinct written description requirement with respect to both priority and invalidity.

Judge Rader, on the other hand, believes that the written description requirement of Section 112, paragraph 1 is solely a priority doctrine. In his dissent, he explained that the first time the Federal Circuit introduced the written description requirement as an invalidity doctrine was the 1997 *Lilly* decision, authored by Judge Lourie. He stated that after the 1870 Patent Act created the requirement of claims, they served the notice function of what rights the inventor had, while Section 112, paragraph 1 simply required

enablement (and that the best mode be disclosed).

Judge Rader further explained that the purpose of the written description requirement is to police priority. In other words, the requirement ensures that when the inventor filed for a patent, he or she possessed the subject matter claimed. Judge Rader noted that before *Lilly*, every case involving the written description requirement did so only in the priority context, and not in an invalidity context. In closing, Judge Rader observed that *University of Rochester* does not clarify the *Lilly* doctrine, and thus he stated that the Federal Circuit should have reviewed this case *en banc*.

Judge Linn concurred in Judge Rader's dissent, but authored a separate dissenting opinion. According to Judge Linn, *Lilly* changed the course of the law. Furthermore, the appropriate question is not whether the written description discloses what the invention is; rather, the appropriate question is whether the written description describes the invention in the claims such that one of ordinary skill in the art could practice the invention. Judge Linn also noted that the claims define the rights of the patentee, and that a written description requirement independent of the enablement requirement creates a clash as to which determines the scope of patent coverage.

In her dissent, Judge Newman explained her agreement with Judge Lourie that the written description requirement is a separate requirement of Section 112, paragraph 1. She dissented, however, because she believes that this issue has percolated through various panels of the court long enough, and thus should be resolved *en banc*.

In his concurrence, Judge Dyk agreed with the panel and Judge Lourie's opinion that Section 112, paragraph 1 contains a separate written description requirement. However, according to Judge Dyk, the court has not articulated satisfactory standards that can be applied to all technologies. He concurred to explain that a future panel might provide the necessary clarity. If not, he explained, then a future decision might warrant *en banc* resolution, but that *Rochester* was not the right case in which to resolve the issue.

Thus, we are still left with the question: does Section 112, paragraph 1 require a written description distinct from the enablement requirement, or are they the same requirement? In *University of Rochester*, the Federal Circuit once again declined to answer the question. With Federal Circuit panels sharply divided and seemingly unwilling to resolve the issue *en banc*, perhaps the time is right for the Supreme Court to clarify what Section 112, paragraph 1 requires. Until then, the state of Section 112, paragraph 1 law will remain uncertain.