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IP FRONTIERS

'Ariad' much ado about nothing

In order to receive a U.S. patent, an inventor must make a full disclosure of his or her invention to the public.

In return for the disclosure — provided the invention meets the statutory requirements — the government may grant a patent, which provides up to 20 years of exclusive right to prevent others from making, using, selling, offering to sell, or importing the invention in the United States.

Patent applicants must meet certain requirements meant to ensure the public receives a full disclosure of the invention, so that once the term of the patent has expired, the public can make and use the invention freely. One of the requirements meant to ensure full disclosure is the application's written description requirement.

The written description requirement has a basis in 35 U.S.C. §112, specifically in the first paragraph of the statute. An applicant for a patent must show, through the disclosure, that he or she invented what is claimed. The way most courts have described the requirement is by saying an applicant must show that he or she was "in possession" of the claimed invention at the time the patent application was filed. Recently, the Federal Circuit, an appellate court tasked with handling appeals in patent cases, handed down an *en banc* decision in *Ariad Pharmaceuticals Inc. v. Eli Lilly and Co.* The issues in *Ariad* centered on the existence and scope of the written description requirement as interpreted in 35 U.S.C. §112, first paragraph.

Ariad originally brought suit against Eli Lilly, asserting that Lilly's Evista and Xigris products infringed U.S. Patent No. 6,410,516 (the '516 patent). The '516 patent was directed to methods of inhibiting the binding of a human transcription factor, NF- κ B, to its recognition sites. The U.S. District Court for the District of Massachusetts tried the case and the jury held in favor of *Ariad*, finding infringement of the '516 patent and asserting the '516 patent's claims were not invalid for anticipation, lack of enablement or lack of written description, as Lilly alleged. On appeal, the Federal Circuit reversed, finding the '516 patent's claims invalid because the application failed to meet the written description requirement. *Ariad* petitioned for a rehearing *en banc*, which the Federal Circuit granted.

In the rehearing, the Federal Circuit posed two questions —

does 35 U.S.C. §112, first paragraph, contain a written description requirement separate from an enablement requirement and, if there is a separate written description requirement in the statute, what is the scope and purpose of that requirement? During oral argument it became apparent quickly that both parties agreed there is a written description requirement separate from enablement. The real question simply is what is the standard to be applied in analyzing the written description requirement, and does it apply to original claims or just to amended claims? The claims section of a patent determines the metes and bounds of the legally protected invention. Claims can be found either in the application as filed (original) or added/changed during examination (amended).

In a 38-page opinion, the Federal Circuit held that there is a separate written description requirement and that it applies to both original and amended claims. In effect, the court decided there should be no change to current practice, one many practitioners in the chemical and biotechnology arts believe is unfairly burdensome. In trying to provide additional guidance to the current "possession" language used to analyze written description issues, the court said that perhaps "possession as shown in the disclosure" was more clear formulation of the standard.

The court went on to say that "whatever the specific articulation, the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art," and that the inquiry is a question of fact.

The court admitted there are no bright line rules to guide judges or practitioners in analyzing whether the written description requirement has been met, stating "the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology."

Perhaps in an attempt to provide some guidance, the court listed previously known factors used in analyzing generic claims, including the existing knowledge in the field, the extent and content of the prior art, the maturity of the science and technology and the predictability of the aspect at issue. Because those fac-

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tors have been discussed in previous opinions and the court merely listed them again in *Ariad*, the language did not provide anything new for judges or practitioners to use to measure whether a particular disclosure is sufficient. Instead, the court avoided the difficult question of how to apply the “objective” inquiry demanded by the written description requirement, and left the patent community to continue to struggle with existing jurisprudence.

While the decision was not the change some practitioners had hoped for, it was a bold policy statement with which universities cannot be happy. The court made it clear that patent law always has been direct to the “useful Arts,” or “inventions with a practical use,” as the court stated. Basic research, such as that conducted at most universities, is not intended to be protected by patent law unless researchers work out the “practical implications” of the research. The court provided essentially no guidance on how to draw the line between permissible use of prophetic examples and impermissibly overstepping that which the inventor possesses. For resource-limited universities, such language is not only unhelpful, but potentially harmful.

Practitioners in the biotechnology and chemical arts also did

not get any help from the decision. The court provided no new guidance, stating simply that “[t]he doctrine never created a heightened requirement to provide a nucleotide-by-nucleotide recitation of the entire genus of claimed genetic material; it has always expressly permitted the disclosure of structural features common to the members of the genus.”

What the court did not say is how many structural features are required, or what types might suffice. Thus, as captured by Judge Gajarsa in his concurring opinion, “district courts and practitioners ... are currently left to trudge through a thicket of written description jurisprudence that provides no conclusive answers and encourages a shotgun approach to litigation.”

In deciding the case as it did, the Federal Circuit missed a tremendous opportunity to clarify one of the more opaque areas of patent law, particularly in the life sciences. While it is currently unclear whether *Ariad* will appeal to the U.S. Supreme Court, it is clear that, at least to the Federal Circuit, it is simply another day at the office for patent practitioners.

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