



Legal ALERT!

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PATENTS & PROSECUTION

Peter J. Bilinski, Co-Chair
315.425.2856
pbilinski@hblaw.com

Thomas F. FitzGerald, Co-Chair
585.295.4469
tfitzgerald@hblaw.com

Christopher E. Blank
Nicholas J. Gallo
Ronald S. Kareken
Alpa V. Patel
Richard A. Romanchik
Stephen R. Rosenholm
Thomas J. Wall
Jason Womer

Peter J. Mikesell, Patent Agent

INTELLECTUAL PROPERTY LITIGATION

Douglas J. Nash, Co-Chair
315.425.2828
dnash@hblaw.com

Christopher E. Blank, Co-Chair
585.295.4308
cblank@hblaw.com

Peter J. Bilinski
John D. Cook
Kathryn D. Cornish
Thomas B. Cronmiller
Keith E. Danish
Thomas R. FitzGerald
Nicholas J. Gallo
Ronald S. Kareken
John M. Nichols
Gabriel M. Nugent
Michael A. Oropallo
Alpa V. Patel
Mark I. Peroff
Stephen R. Rosenholm
Darren W. Saunders
Joseph L. Stanganelli
Jason Womer

Federal Circuit Confirms Independent Written Description Requirement

It is known that the claims of a patent application define the legal protection afforded to an applicant/inventor. In concert with the claims, however, considerable attention should be paid to the drafting of the patent specification in terms of how it describes the invention. More specifically and under 35 U.S.C. §112, a patent specification must “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” Recently and in a nearly unanimous (9 out of 11) decision rendered in *Ariad Pharms. Inc. v. Eli Lilly & Co.*, by the United States Court of Appeals for the Federal Circuit (CAFC) has confirmed, *en banc*, that 35 U.S.C. § 112, paragraph 1, that the written description and enablement requirements of 35 U.S.C. §112 are entirely separate. In reaching its decision, the Federal Circuit reaffirmed past precedent, but its decision will likely have a significant impact on a number of technical areas, most notably the chemical, pharmaceutical, and biotech arts.

The CAFC’s decision followed a jury trial in the United States District Court for the District of Massachusetts, where a verdict of infringement was rendered. Thereafter, a three-judge panel of the CAFC reversed the jury’s decision, and found that the claims of the asserted patent were invalid for lack of written description. The CAFC granted a petition for rehearing *en banc* to determine whether there is a separate written description requirement, if so, what is the scope and purpose of the requirement.

In response to the first question, the CAFC began with a textual analysis and determined that, giving effect to every clause and word, as a court must, the statute requires “a written description [i] of the invention, and [ii] of the manner and process of making and using [the invention]. In support of its plain reading, the CAFC further stated that “a separate requirement to describe one’s invention is basic to patent law . . . [i]t is part of the quid pro quo of a patent....” The CAFC found further justification in the over forty years of precedent upholding a separate written description requirement that it stated was better changed by Congress than the courts.

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While the CAFC's confirmation of a separate requirement was not particularly surprising, of greater practical importance were the holdings with respect to the scope and purpose of the written description requirement and its guidance with respect to the requirement's application. Initially, the CAFC agreed with Eli Lilly that original claims (those not yet amended during prosecution) do not *necessarily* satisfy the written description requirement. It provided, as an example, a generic claim to a vast genus of chemical compounds, and particularly one using functional language, which may not demonstrate that the inventor has invented species sufficient to support the claim to the genus. In other words, the inventor must disclose "a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of ordinary skill in the art can 'visualize or recognize' the members of the genus." Applying this test to the claims of the asserted patent, the CAFC held that neither element was satisfied, and adopted the three-judge panel's opinion affirming the patent's invalidity.

The purpose of the written description requirement is for the inventor to show possession of the invention, as determined solely by analysis of the four corners of the specification, and not merely the definition of a useful or desired result, a wish or a plan. However, this inquiry is fact-based and varies by context. Accordingly, the inquiry as to whether a sufficiently representative number of species, or sufficient common structural features, is disclosed in order to identify possession of the generically claimed invention is informed by "the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." Therefore, while the written description requirement applies equally to all areas of technology, the CAFC's previous identification of chemical arts, for example, as less predictable likely will result in a more stringent application of the requirement to patent applications in those technical areas as opposed to, for example, predictable arts, such as mechanical engineering.

Accordingly, as a suggested best practice for all technical fields, inventors should consider whether their patent specification adequately discloses a sufficient number of solutions to a problem and not just a description of the problem to be solved combined with a claim to all solutions. While the CAFC explicitly declined to articulate a bright-line rule in this regard, inventors might be best served to identify as many species as possible falling within a claimed genus and/or provide a thorough description of the common features/structural elements and their relation to claimed functions. Further, inventors should not rely on their original claims for satisfaction of the written description requirement without further analysis, particularly where the claims cover a broad genus and/or use functional language to identify the boundaries of the invention. By taking these steps, as well as others, inventors should be able to reduce the likelihood of a finding of failure to comply with 35 U.S.C. § 112, down the road. ■

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