A Review of
Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co., 598 F.3d (Fed. Cir. March 22, 2010) (en banc)

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May 18, 2010

I. INTRODUCTION

II. DISCLOSURE REQUIREMENTS GENERALLY

A. Enablement

1. Single embodiment issues

a. How to make

b. How to use

c. Inventive configuration

2. Multiple embodiment issues

a. Scope of claim vs. scope of disclosure

b. Two must be “commensurate”

c. Different rules for predictable and non-predictable arts

(1) Predictable: generic coverage earned with disclosure of one specie

(2) Non-predictable: generic coverage only upon disclosure of “representative” number of species

B. “Description” requirement

1. Assumptions from filing

a. Filing date of application taken as date of invention

b. Act of invention requires appreciation

c. Therefore, application must evidence appreciation

2. Problem:

a. Later amendments to application may add new inventions, not appreciated when application was filed originally.

b. Typical scenario:

(1) Claims amended to be broader than originally filed

(2) Applicant is reacting to follow-on inventive work of a competitor

3. Policing Solution:

a. Amendments to disclosure: additional material prohibited as new matter

b. Amendments to claims: additional material prohibited as not "described"

C. ARIAD PHARMACEUTICALS, INC. v. ELI LILLY AND CO., 598 F.3d 1336 (Fed. Cir. March 22, 2010)

1. Facts:

a. University researchers discover chemical pathway by which human cells become inflamed in response to outside stimuli

b. No disclosure of any specific embodiment for interrupting this pathway.

c. Application filed claiming generically all methods of interfering with the pathway

d. Suit filed against maker of drug with anti-inflammatory effect.

2. Prior Procedural History:

a. District Court jury trial results in judgment in favor of patent owner. . Ariad Pharms., Inc. v. Eli Lilly & Co., 529 F.Supp.2d 106 (D. Mass. 2007).

b. Appeal to Federal Circuit

c. Initial panel opinion reverses, holding claims invalid as improperly described. Ariad Pharms., Inc. v. Eli Lilly & Co., 560 F.3d 1366 (Fed. Cir. 2009).

d. Court withdraws initial opinion and issues order to hear case *en banc*). See Lizardtech, Inc. v. Earth Res. Mapping, Inc., 433 F.3d 1373 (Fed. Cir. 2005) (denying rehearing en banc on the question whether a separate written description requirement exists in § 112, first paragraph); Univ. of Rochester v. G.D. Searle & Co., Inc., 375 F.3d 1303 (Fed. Cir. 2004) (same); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 970 (Fed. Cir. 2002) (same).

(1) Order poses questions: "(1) Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement? (2) If a separate written description requirement is set forth in the statute, what is the scope and purpose of that requirement?"

3. Opinion:

    a. Heavy initial focus on grammatical structure of first paragraph of section 112, first paragraph.

        (1) Statutory language: “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.”

        (2) “[T]he specification must contain a written description of the invention to establish what the invention is.”

        (3) “[W]e see nothing in the statute's language or grammar that unambiguously dictates that the adequacy of the ‘written description of the invention’ must be determined solely by whether that description identifies the invention so as to enable

one of skill in the art to make and use it."

(4) "[A] separate requirement to describe one's invention is basic to patent law. Every patent must describe an invention. It is part of the quid pro quo of a patent; one describes an invention, and, if the law's other requirements are met, one obtains a patent. The specification must then, of course, describe how to make and use the invention (i.e., enable it), but that is a different task. A description of the claimed invention allows the United States Patent and Trademark Office to examine applications effectively; courts to understand the invention, determine compliance with the statute, and to construe the claims; and the public to understand and improve upon the invention and to avoid the claimed boundaries of the patentee's exclusive rights."

b. As to amended claims:

(1) Review of prior statutes and Supreme Court decisions. Particularly interesting are:

(a) Schriber-Schroth Co. v. Cleveland Trust Co., 305 U.S. 47, 58-59 (1938)

(b) MacKay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 98-102 (1939) (amended claims)

(2) Reaffirmance of In re Ruschig, 379 F.2d 990 (CCPA 1967)

c. As to original claims:

(1) "no principled basis for restricting [the description] requirement to establishing priority"

(2) “Although many original claims will satisfy the written description requirement, certain claims may not. For example, a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus. The problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing species that achieve that result. But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.”

(3) "[A] sufficient description of a genus instead requires the disclosure of either 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 skill in the art can "visualize or recognize" the members of the genus." (*citing with approval* Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997)).

(4) "[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed."

(5) "[A] description that merely renders the invention obvious does not satisfy the requirement."

(6) "[A]lthough written description and enablement often rise and fall together, requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described."

(7) "Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others. . . . Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of "invention" – that is, conceive of the complete and final invention with all its claimed limitations-and disclose the fruits of that effort to the public."

D. SUBSEQUENT FEDERAL CIRCUIT CASES

1. Anascape, Ltd. v. Nintendo of America Inc., 601 F.3d 1333 (April 13, 2010) (Newman) (benefit of earlier filing date under section 120)

2. Bradford Co. v. Conteyor North America, Inc., --- F.3d ----, 2010 WL 1711307 (April 29, 2010) (Lourie) (dicta; benefit of earlier filing date under section 120)