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Recent IP Decisions – April 2010

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Agenda

- *Ariad v. Eli Lilly* (Fed. Cir. 2010) – affirming that written description and enablement are two separate requirements
- *Marrin v. Griffin* (Fed. Cir. 2010) – anticipation found even when distinguishing feature was a limitation in the preamble
- *Pressure Products Medical Supplies v. Greatbatch Ltd.* (Fed. Cir. 2010) – citation in a spec is insufficient structure to support means plus function claim
- *Laboratory Corp. of America v. Metabolite Labs* (Fed. Cir. 2010) – appeal in a DJ action



Ariad Pharmaceuticals, Inc., Massachusetts Institute
of Technology, The Whitehead Institute for
Biomedical Research, and the President and Fellows
of Harvard College

v.

Eli Lilly and Company

(March 2010)



Ariad v. Eli Lilly

- Facts:
 - Ariad owns '516 Patent and asserted claims 80, 95, 144, 145 as being infringed by Eli Lilly
 - Four genus claims that encompass use of material that achieve the result of reducing NF-kB binding to NF-kB recognition sites in response to external stimuli
 - Specifically, reduce binding in response to bacterial lipopolysaccharides
 - However, the specification fails to disclose a variety of species that accomplish this desired result
 - Eli Lilly alleged that the asserted claims are invalid for failing to satisfy written description requirement because it describes only a generic invention



Ariad v. Eli Lilly

- Case History
 - Trial court found infringement and no claims invalid
 - Jury trial on infringement and validity
 - Bench trial on additional defenses of unpatentable subject matter, inequitable conduct, prosecution laches
 - Eli Lilly brought JMOL motion that trial court denied
 - Eli Lilly appealed trial court findings
 - JMOL motion reversed and asserted claims were held invalid for lack of written description
 - Ariad petitioned for rehearing *en banc*
 - Challenged the existence of a written description requirement as being separate from the enablement requirement



Ariad v. Eli Lilly

- Questions Presented:
 - Whether 35 U.S.C. 112, paragraph 1, contains a written description requirement separate from enablement requirement?
 - If a separate written description requirement is set forth in the statute, what is the scope and purpose of that requirement?



Ariad v. Eli Lilly

- Ariad's position:
 - 112, first paragraph, does NOT contain a written description requirement separate from enablement
 - Statute requires specification to describe:
 1. What the invention is
 2. How to make and use it
 - Thus, there is a two pronged written description requirement that is judged by whether it enables one of skill in the art to make and use the claimed invention
 - Written description does not apply to original claims



Ariad v. Eli Lilly

- Eli Lilly's position:
- Statute requires, first, a written description of the invention, and second, a written description of how to make and use the invention so as to enable one of skill in the art to make and use it
- Separate written description requirement applies to all claims – both original and amended



Ariad v. Eli Lilly

- Focal point of dispute:
 - Both agreed that specification must contain a written description of the invention to establish what the invention is
 - Differed on:
 - The standard to be applied
 - Whether the standard applies to original claim language



Ariad v. Eli Lilly

- Analysis:
 - Statutory Interpretation
 - Supreme Court Precedent
 - Stare Decisis
 - Original/Amended Claims
 - “fairly uniform standard”



Ariad v. Eli Lilly

- Statutory Interpretation
 - Section 112, first paragraph:
 - 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



Ariad v. Eli Lilly

- Ariad's position:
- Plain reading shows two components: a written description of the invention and of the manner and process of making and using it
 - both components must be judged by the final prepositional phrase
- Parsed the statute to read:
The specification shall contain:
 - [A] a written description
 - [i] of the invention, and
 - [ii] of the manner and process of making and using it
 - [B] in such full, clear, and 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



Ariad v. Eli Lilly

- Ariad's position (continued)
 - Legislative support:
 - First Patent Act in 1790 required written description to:
 - Distinguish the invention from prior art
 - Enable a person skilled in the art to make and use the invention
 - Patent Act in 1836, congress amended written description requirement to serve a single purpose: enablement



Ariad v. Eli Lilly

- Eli Lilly's position:
 - 112, first paragraph, contains three separate requirements
 - Parsed stated to read:
 - The specification shall contain a written description of the invention, AND
 - The specification shall contain a written description...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
 - The specification...shall set forth the best mode contemplated by the inventor of carrying out the invention.
- Long line of judicial precedent interprets statute as having three separate written description requirements



Ariad v. Eli Lilly

- Statutory Interpretation
 - Section 112, first paragraph:
 - 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



Ariad v. Eli Lilly

- Court's decision on statutory interpretation:
 - Ariad conceded that written description requirement exists but contended that requirement exists to identify the invention that must comply with the enablement requirement
 - Rejected Ariad's contention that written description must be determined solely by enablement
 - Eli Lilly's interpretation of the statute does not violate the rules of grammar
 - "That the adequacy of the description of the manner and process of making and using the invention is judged by whether that description enables one skilled in the art to make and use the same follows from parallelism of the language."



Ariad v. Eli Lilly

- Court's decision on statutory interpretation (continued):
 - Congressional intent: statute would have been worded differently if congress intended enablement to be the sole description requirement of 112
 - Ariad's construction would render "and of the manner and process of making and using it" and "of the invention" to be surplusage thus violating canons of statutory interpretation
 - Congress recodified language in 1952 Patent Act which reinforced requirement
 - "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 (ie., enable it), but that is a different task"



Ariad v. Eli Lilly

- Supreme Court Precedent
 - Ariad's position -
 - *Evans v. Eaton*: SC recognized just two requirements of the 1793 act (to enable the invention and to distinguish it from all things known)
 - Since the 1836 Act, SC has consistently held patentee needs to fulfill only a single written description requirement – measured by enablement
 - Eli Lilly's position -
 - *Evans* recognizes written description to be separate from enablement
 - SC continually confirmed that written description is separate requirement:
 - *O'Reilly v. Morse*
 - *Schriber-Schroth v. Cleveland Trust*
 - *Festo*



Ariad v. Eli Lilly

- Court's decision on precedent:
 - Agreed with Eli Lilly that precedent recognizes a written description requirement that is separate from enablement
 - Subordinate court cannot dismiss statements as dicta
 - "Claims define the subject matter that, after examination, has been found to meet the statutory requirements for a patent. Their principal function, therefore, is to provide notice of the boundaries of the right to exclude and to define limits; it is not to describe the invention, although their original language contributes to the description and in certain cases satisfies it. Claims define and circumscribe, the written description discloses and teaches."



Ariad v. Eli Lilly

- Analysis:
 - Statutory Interpretation
 - Supreme Court Precedent
 - Stare Decisis
 - Original/Amended Claims
 - “fairly uniform standard”



Ariad v. Eli Lilly

- Stare Decisis:
 - Ariad's position
 - Incorrect reading of *In re Ruschig* (CCPA 1967) created the idea that written description requirement is separate from enablement
 - Cases before *In re Ruschig* that applied a separate written description requirement were only testing whether the specification identified the same invention that was defined by later-added amended claims
 - Court's decision:
 - Ariad's argument is that written description of the invention is requirement but is not separate from enablement because it identifies the invention that must be enabled
 - This is different from first requiring the invention to be described and then separately requiring it to be enabled
 - Difference in position amounts to little more than semantics



Ariad v. Eli Lilly

- Original Claims
 - Ariad's position:
 - Requirement to describe the invention does not apply to original claims because original claims are part of the original disclosure
 - Eli Lilly's position:
 - Written description requirement applies to all claims
 - No basis to apply a different standard to amended vs. original claims



Ariad v. Eli Lilly

- Court's decision on Original/Amended claims:
 - No basis in 112 to restrict written description requirement to establishing priority
 - Although original claims are part of disclosure, they may not always satisfy the written description requirement:
 - Ex. Generic claim may define a vast genus of compounds but the specification may not show that applicant invented a species sufficient to support a claim to a genus
 - Invention may not be sufficiently described just because it appears in the original claim
 - “Generic claim language appearing in *ipsis verbis* in the original specification does not satisfy the written description requirement if it fails to support the scope of the genus claimed”



Ariad v. Eli Lilly

- Court further defined “fairly uniform standard” for written description:
 - Test: whether disclosure reasonably conveys to one skilled in the art that the applicant had possession of the claimed subject matter as of the filing date
 - Possession: shown when one can produce records documenting a written description of a claimed invention
 - “possession as shown in the disclosure” is a more complete formulation
 - 4 corners test – specification must describe an invention understandable to one skilled in the art and show that inventor actually invented the claimed invention



Ariad v. Eli Lilly

- Broad Principals adopted by the court
 - Generic claims – factors to evaluate sufficiency of the disclosure include existing knowledge in the field, extent and content of prior art, maturity of the technology, and predictability of the technology
 - No requirement for examples or actual reduction to practice
 - Actual “possession” or reduction to practice outside of specification is not sufficient
 - No such thing “super enablement” standard for chemical and biotech inventions
 - Permit disclosure of structural features common to members of the genus



Ariad v. Eli Lilly

- Justifications for having two separate requirements:
 - Curtail claims that do not require undue experimentation to make and use but have not been invented
 - Ensures specification provides sufficient materials to accomplish a function recited in a genus claim
 - Limits patent protection to those who actually perform the invention and disclose the limitations to the public



Ariad v. Eli Lilly

- Review of denial of JMOL
 - To satisfy written description, specification must demonstrate that Ariad possessed the claimed methods
 - ie. sufficiently disclose molecules capable of reducing NF-kB activity
 - Spec identifies three classes of molecules that reduce NF-kB activity:
 - Specific inhibitors – disclosed in FIG. 43 but not in original application
 - Dominantly interfering molecules – no examples in spec
 - Decoy molecules – examples present in spec but no link presented between decoy molecules and reducing NF-kB activity
 - Provides mere hypothesis and asserted claims are much broader



Ariad v. Eli Lilly

- RADER dissent (joined by LINN)
 - No statutory support for separate written description requirement
 - Test for adequacy of specification is enablement
 - No “quixotic possession requirement”
- LINN dissent (joined by RADER)
 - Majority failed to apply a workable legal standard to the written description requirement
 - “possession as shown in the disclosure” fails to distinguish the test for written description from the enablement test



Michael Marrin and Etch-It, Inc.,

v.

Jeffrey and Claudia Griffin

(March 2010)



Marrin v. Griffin

- Facts:
 - Griffin owns '448 patent entitled "Scratch-Off Marking Label" to mark beverage containers.
 - Claim 1 reads:
 1. A scratch-off label for permitting a user to write thereon without the use of a marking implement, comprising:
 - a permanent base having a colored near side which is normally visible to the user and having a far side; and
 - a coating of scratch-off non-transparent material having a color which contrasts with the color of the near side of the permanent base, which coating is applied directly onto the near side of the permanent base with sufficient thickness so as to obscure the color of the permanent base, and which when scratched off reveals the color of the near side of the permanent base.



Marrin v. Griffin

- Case History:
 - Griffin licensed use of patent to Marrin but license was soon terminated
 - Marrin later formed a company to sell scratch-off labels and brought an action seeking to invalidate '448 patent
 - Griffins filed suit against Marrin alleging willful infringement of '448 patent
 - On SJ, court ruled '448 patent invalid and thus not infringed
 - Griffin now appeals



Marrin v. Griffin

- Discussion:
 - On SJ, ruled that “for permitting a user to write thereon without the use of a marking implement” language is not a claim limitation
 - Statement of purpose or intended use
 - Patentee did not demonstrate reliance on the preamble during prosecution to distinguish invention over prior art
 - Fed. Cir. affirmed



Marrin v. Griffin

- Discussion (continued)
 - Statement of purpose or intended use:
 - Use descriptions are not treated as claim limitations (*Bicon*)
 - Patentability depends on claimed structure (*Catalina Marketing*)
 - Reliance on preamble during prosecution
 - Clear reliance on preamble during prosecution renders it a claim limitation
 - Prosecution history indicated that use is not patentably significant



Marrin v. Griffin

- Original claim 1:
 1. A scratch off marking label, comprising:
 - (a) a layer of scratch off non-transparent coating, and;
 - (b) a permanent base layer of such color so as to contrast with said scratch off coating;
 - (c) said scratch off coating being applied directly onto said permanent layer of contrasting color, whereby upon scratching through of said scratch off coating reveals the contrasting color of said permanent layer in legible lines, thereby providing a writing means whereby a person can mark on the label without the need for a writing implement
- “writing means is not an element of Applicant’s claim, and does not appear in the new claims” – Amendment after NOA
 - Cannot now assert that writing means is a claim language



Marrin v. Griffin

- NEWMAN Dissent:
 - Majority misunderstands anticipation and misapplies claim construction
 - Incorrect to delete limitations in the claim and then hold the claim to be anticipated based on the deleted limitation
 - Preamble limits the claim when it
 - distinguishes use of the claimed article from the prior art
 - contains language that is essential to the description of the invention
 - “necessary to give life, meaning, and vitality to the claim”
 - Proper inquiry is to construe the claims according to rules of claim construction. The law of anticipation is then applied to “the invention so defined.”
 - Applicant distinguished claim from prior art based, in part, on preamble



Pressure Products Medical Supplies, Inc.

v.

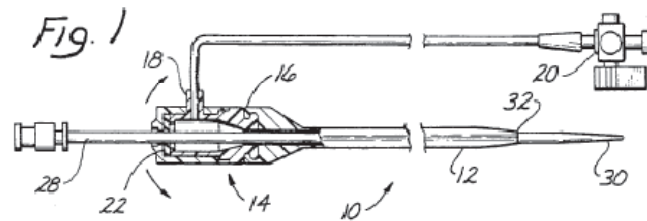
Greatbatch Ltd.

(March 2010)



Pressure Products Medical Supplies v. Greatbatch Ltd. (March 2010)

- Facts:
 - Pressure Products owns exclusive license for medical device called introducer:



- allows a doctor to place and remove catheter or pacemaker leads into blood vessels
- disclosed apparatus uses a splitting process to remove both the valve and the sheath



Pressure Products v. Greatbatch

- Claim 1 limitation:
 - “means for permitting removal of said hemostatic valve and introducer sheath from said lead or catheter disposed therethrough without requiring said introducer sheath and hemostatic valve to be removed from an end of said lead or catheter”



Pressure Products v. Greatbatch

- Case History
 - Pressure Products sued Enpath for infringement
 - *Markman* hearing:
 - Structure that corresponds to the claimed function – “score lines defined in the hemostatic valve and introducer sheath, and equivalents thereof”
 - “score lines” defined to be “one or more line(s) defined in the hemostatic valve and introducer sheath”
 - District court:
 - redefined “score lines” sua sponte as “linear perforation; slit; slot; tab; line; severing; weakening; or tear that can be partial or incomplete” based on expert testimony
 - Jury found patents valid and infringed
 - After trial, district court denied Enpath’s JMOL motion that patents are invalid



Pressure Products v. Greatbatch

- Discussion:
 - District court was in a better position to supplement definition for “score lines” and may engage in “rolling claim construction” as understanding of technology evolves (*Pfizer v. Teva Pharm*)
 - District court improperly expanded the definition of “score line” to include structure not defined in specification
 - Improper to include structure disclosed within list of prior art references
 - Mere citation is not “described in the specification”
 - Incorporation by reference is not sufficient to include a structure in the prior art as a corresponding structure for means-plus-function claim (*Amtel v. Info Storage Device*)



Pressure Products v. Greatbatch

- Discussion (continued)
 - *Amtel*: title of a prior art reference could provide the structure
 - However, structure in the prior art reference cannot provide corresponding structure
 - Pressure Products argument based on doctrine of claim differentiation
 - Claims 4-8 claim “a score line defined in said hemostatic valve and introducer sheath” as means for permitting removal
 - Thus, claim 1 must encompass structure other than score lines (ie, structure found in prior art)
 - Argument failed – means-plus-function claim element already includes equivalents of corresponding structure so no violation of claim differentiation



Pressure Products v. Greatbatch

- NEWMAN Dissent:
 - Incorporated references show prior art, not define what was new
 - Not error to recognize that splittable sheaths were well known and to construe “means for permitting removal” in include this
 - *Amtel*: no structure was defined in spec and structure cannot come solely from incorporated reference
 - Here, patent describes splittable sheaths of various forms including the many known ways of splitting or peeling plastic
 - Information incorporated by reference into a specification illustrate known structures that are alternatives or equivalents
 - Enables patents to be concise statements of what is new



Laboratory Corporation of America Holdings

v.

Metabolite Laboratories

(March 2010)



LabCorp. V. Metabolite Lab.

- Facts
 - Metabolite owns an non-exclusive license (with right to sublicense) of '658 patent (owned by CTI) which claims a method for detecting deficiencies of vitamin B12 and folate by assaying total homocysteine levels
 - Metabolite developed know-how to automate the process and entered into an agreement to license the know-how and sublicense the '658 patent with LabCorp
 - LabCorp soon began using an alternative homocysteine assay for serum samples and stopped paying both patent and know-how royalties on the serum-based homocysteine assays



LabCorp. V. Metabolite Lab.

- Case history:
 - Metabolite I: Jury found patent infringement and breach of contract by LabCorp
 - Metabolite II: affirmed patent infringement and breach of K
 - Appealed to SC where cert. was denied
 - LabCorp began outsourcing homocysteine assays to third party company (Specialty Labs) that also owned non-exclusive license from CTI for same patent
 - Metabolite III (current case): LabCorp seeks a declaratory judgment that Metabolite cannot recover damages for activity occurring after Metabolite I. Metabolite counter-claimed for breach of contract
 - District court held on SJ that there was no breach of contract because the court in Metabolite I held that the contract was terminated
 - Metabolite appealed and LabCorp sought to transfer to 10th Circuit for lack of jurisdiction



LabCorp. V. Metabolite Lab.

- Discussion:
 - Under 28 USC 1295, Federal Circuit has exclusive jurisdiction over an appeal from a final decision of a district court if the jurisdiction of the district court was based at least in part on Section 1338
 - Section 1338: district courts have original jurisdiction over any civil action “arising under any Act of Congress relating to patents”
 - Two part 1338 test: (*Christianson v. Colt Industries*)
 - Well-pleaded complaint establishes either that federal patent law creates the cause of action, or
 - That plaintiff’s right to relief depends on resolution of a substantial question of federal patent law
 - Look to the action that the declaratory defendant would have sought to determine jurisdiction – the hypothetical claim



LabCorp. V. Metabolite Lab.

- Discussion (continued)
 - Infringement already determined in Metabolite I
 - Metabolite would only need to show elements of breach of contract because it is undisputed that post trial conduct falls within the scope of the '658 patent
 - Neither party disputed that outsourced homocysteine assays were different from original assays
 - “Mere presence of a patent as evidence does not by itself present a substantial issue of patent law”



LabCorp. V. Metabolite Lab.

- DYK Dissent - Federal Circuit has jurisdiction:
 - res judicata effect of a prior judgment “arising under” the federal patent laws is itself a suit that arises under the federal patent laws
 - “look through” the prior judgment to determine whether it is predicated on an action that “arises under” the federal patent laws (*Semteck International*)
 - determination of contract issues rests on a substantial question of patent law
 - royalties under license agreement are only due if the assays LabCorp sold fall within the scope of the licensed patents
 - Metabolite II did not determine whether the outsourced assays (by third party company) are covered by the patent
 - controversy prevailing at the time of complaint provides jurisdiction. Later concessions do not defeat jurisdiction attached at outset