The Rise and Demise of the Written Description Requirement

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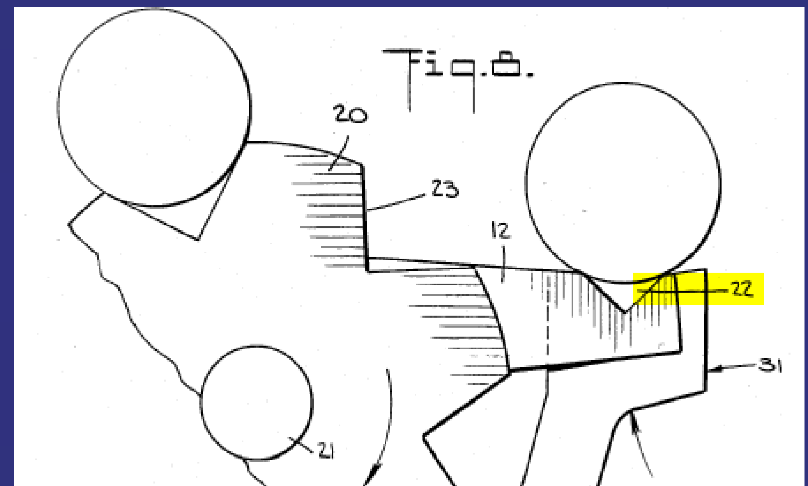
Introduction

- **Question:** Can originally filed claims violate the written description requirement?
- **Answer:** No, according to Judges Rader, Linn, Gajarsa, and perhaps others.
- **Reason:** Written description requirement is limited to "priority" issues.
- **Implication:** Written description is not a separate ground of invalidity.

Moba Facts

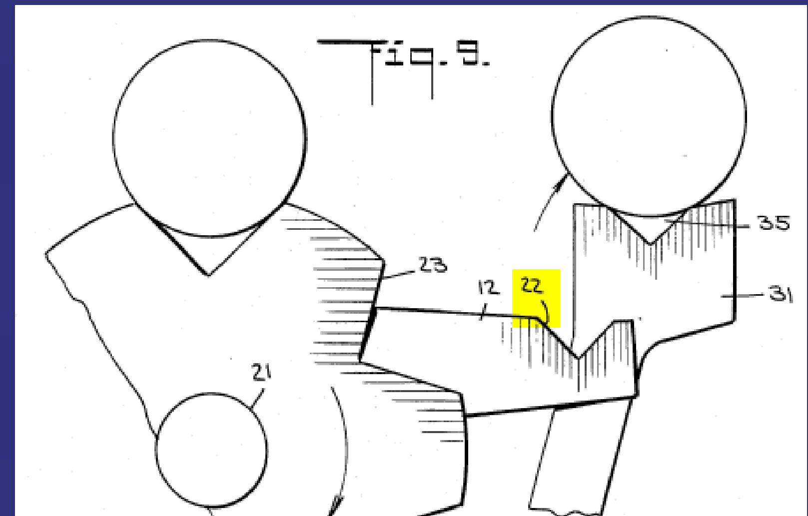
- **Invention:** High-speed egg processing machine to sort batches of eggs into different categories by weight and quality
- **Trial:** Jury found Diamond's patent not invalid and not infringed. District court denied JMOL motions.



Moba v. Diamond Automation, 325 F.3d 1306 (Fed. Cir. 2003).

Moba Issues

- **Claim Construction:** Does the term "holding station" require the eggs to cease motion before the lift to the conveyor?
- **Invalidity:** If not, are the claims invalid for lack of written description or lack of enablement?



Moba v. Diamond Automation, 325 F.3d 1306 (Fed. Cir. 2003).

Three Opinions

- Panel Rader, Schall, and Bryson
- Per Curium opinion.
- Concurring opinion by Rader
- Concurring opinion by Bryson

Claim Construction Issue

- District Court’s interpretation did not require egg to remain stationary.
- Federal Circuit agreed based on ordinary meaning of to “hold”—i.e., “to keep in position, guide, control, or manage.”
- Reversed denial of JMOL because only basis for non-infringement of this term was the fact that the eggs in the accused product “do not stop before they are picked up,” which is immaterial under proper construction.

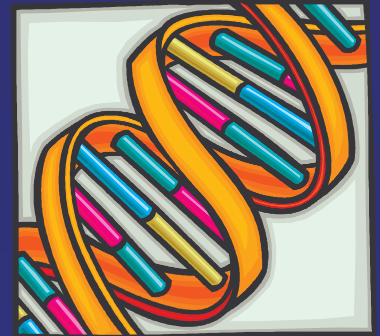
Invalidity Issue

- If the claim encompasses lifting eggs from a moving conveyor, as the court determined, “then the claim must be invalid because the ‘505 patent specification discloses no such conveyor mechanism.”
  - Invalid because not enabling
  - Invalid because no written description
- Federal Circuit rejected both challenges.
  - Court characterized written description defense as “reviv[ing] its non-infringement argument in the cloak of a validity challenge.”
  - No evidence of “undue experimentation.”

Rader’s Concurrence

- Written description requirement not implicated because the claims are “originally filed.”
- Written description requirement only applies to “priority” issues—i.e., later added claims.
- Written description coterminous with enablement. In other words, “to enable is to show possession, and to show possession is to enable.”
- “By making written description a free-standing disclosure doctrine [in *Lilly*], this court produces numerous unintended and deleterious consequences.”

Lilly Facts



- **Specification:**
  - amino acid sequences for rat insulin cDNA
  - amino acid sequences for human insulin cDNA
  - method for obtaining sequences based on rat cDNA
- **Issues:** Adequate written description support for human, vertebrate and mammalian cDNA based on disclosure?
- **Holding:** No. Claims were invalid for lack of written description, even though originally filed.

Regents of the Univ. of California v. Eli Lilly and Co., 119 F.3d 1559 (Fed. Cir. 1997).

Written Description after *Lilly*

- Heightened written description standard for genetic material:
  - Requires "a precise definition, such as by structure, formula, chemical name, or physical properties."
- To adequately describe a cDNA genus:
  - Describe the nucleotide sequences of a representative number of cDNA's
  - Recite structural features common to genus members that coincide in a substantial portion of the genus

Rader's Concurrence

- Institutional problems with the Federal Circuit
  - Uniform application of law (i.e., no inter-circuit conflicts)
  - [Lack of jury experience]
  - [Over exposure to patent issues]
- Turns "routine" claim construction into an invalidity challenge
- Burdens trier of fact: enablement v. possession
  - Because "possession" standard is more rigorous, written description is often asserted in conjunction with enablement.

Bryson's Concurrence

- *Lilly* not a departure from prior law
- If §112 , ¶1 is read to have a written description requirement there is no basis for restricting it to the priority context.
- Judge Rader's concern is more properly stated as whether the entire line of §112 , ¶1 cases is based on a fundamentally flawed construction of the statute.
- Judge Bryson took no stand on that issue.
  - He did note, however, that "there is something to be said for either side of that question of statutory construction."

Statutory Interpretation

- **Rader Interpretation:**

  “The specification

  > **(1) shall contain a written description of the invention [and], describing 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**
  >
  > **(2) shall set forth the best mode contemplated by the inventor of carrying out his invention.”**

Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002).

Statutory Interpretation

- **Rader's "Straightforward Reading":**

  "The specification shall contain a written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same…."

- **Supported by the PTO**

Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002).

Statutory Interpretation

- **Lourie Interpretation:**

"The specification

shall contain a written description:

(1) of the invention and,

(2) the manner and process of making and using [it] the invention 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

(3) shall set forth the best mode contemplated by the inventor of carrying out his invention."

Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002).

Historical Argument

- Patent Act of 1793:
  - "[Applicant must] deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear, and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science... to make, compound, and use the same...."
  - No claims at that time.

Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002).

Historical Argument

- **Two Purposes of Written Description Requirement:**
  - **"(1) to make known the manner of constructing the invention in order to enable artisans to make and use it, and**
  - **(2) to put the public in possession of what the party claims as his own invention in order to ascertain whether he claims anything in common use, or already known, and to protect the public from an inventor pretending that his invention is more than what it really is, or different from its ostensible objects...."** ***Evans v. Eaton, 20 U.S. (7 Wheat.) 161, 196 (1822).***

Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002).

Doctrinal Argument

- Rader:
  - Judge made doctrine that finds its origins in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).
  - This was the first case that the written description requirement was applied to an originally filed claim.
  - Prior to that time, all other written description issues arose in the context of later added claims.
  - Prior to *In re Ruschig*, 379 F.2d 990 (CCPA 1967), all priority issues were addressed by statute's prohibition against "new matter."
  - As long as written description was confined to "enforcing priority," it "did no harm."
  - *Lilly* for the first time extended it to originally filed claims.

Doctrinal Argument

- **Lourie:**
  - "New interpretations of old statutes in light of new fact situations occur all the time."
  - "Courts do not … purport to write treatises on the law, outlining all aspects of a statute that come before them."
  - The statute does not say "a written description of the invention for purposes of policing priority."

Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002).

Policy Argument

- Rader
  - Lilly WD requirement more demanding and will supplant statutory enablement requirement
    - WD in Lilly requires precise listing of DNA sequence nucleotide-by-nucleotide
    - Enablement only requires specification show one of skill in the art how to acquire that sequence on their own
  - Creates a technology-specific rule in a technology-neutral statute
  - Lilly Doctrine disrupts settled expectations of the inventing community
  - Lilly Doctrine prejudices university & small inventors who do not have the resources to determine nucleotide sequences

Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 983 (Fed. Cir. 2002).

Policy Argument

- Lourie
  - "Disclosure is the first role of a patent. … That is quite different from telling how to make and use it."
  - WD and Enablement are not the same in the biotechnical and chemical arts (though they may be similar in the electrical and mechanical arts)
  - More robust WD requirement benefits the public in terms of more usable disclosure
  - Prevents inventors from claiming sequences which they have not made

Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 983 (Fed. Cir. 2002).

Bottom Line

- What's really going on?
  - Growing frustration with written description challenges
  - *Gentry* and its ilk
  - Becoming particularly pronounced with the recent trend in broad constructions
  - Akin to pre-*Festo* DOE situation
  - Systemic problem with subject matter courts
- Prediction

Questions?

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