

2008-1248

THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ARIAD PHARMACEUTICALS, INC.,
MASSACHUSETTS INSTITUTE OF TECHNOLOGY,
THE WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH, and
THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE,

Plaintiffs-Appellees,

v.

ELI LILLY AND COMPANY,

Defendant-Appellant.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF MASSACHUSETTS IN 02-CV-11280,
JUDGE RYA W. ZOBEL.

BRIEF FOR AMICUS CURIAE ROBERTA J. MORRIS, ESQ., PH.D.
IN SUPPORT OF NEITHER PARTY, URGING ATTENTION TO THE
GRAMMATICAL STRUCTURE AND WORDS OF 35 USC § 112 ¶ 1

ROBERTA J. MORRIS, ESQ., PH.D.

Attorney for Amicus Curiae Roberta J. Morris

October 13, 2009

CERTIFICATE OF INTEREST

Counsel for the AMICUS certifies the following:

1. The full name of every party or amicus represented by me is:

ROBERTA J. MORRIS, ESQ., Ph.D.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

NOT APPLICABLE.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

NOT APPLICABLE.

4. There is no such corporation as listed in paragraph 3.

5. The names of all law firms and partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

NONE (other than myself).

Dated: October 13, 2009

ROBERTA J. MORRIS

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RULE 29(c)(3) STATEMENT OF *AMICUS CURIAE*
ROBERTA J. MORRIS, ESQ., PH.D.

Identity: Roberta J. Morris, Esq., Ph.D., has been a lecturer on patent law and related subjects since 1991. She taught at the University of Michigan Law School until 2005 and has been at Stanford Law School since 2006. From 1986 to 1990 she was an associate at the patent litigation firm of Fish & Neave (now Ropes & Gray). Her law degree is from Harvard (1975) and her Ph.D. in Physics is from Columbia (1986). She is a member of the patent bar and of the bars of New York and Michigan.

Interest in the Case: Morris has no stake in this case. Her interest in it lies in the opportunity to improve patent law. In particular: She has long taught that it is easier to read and to understand complicated text if you reformat it, in a process similar to diagramming a sentence. When she began teaching patent law in 1991, she presented 112 P1 with **two** requirements, reflecting her understanding since her first days at Fish & Neave. After this Court's decision in *Gentry Gallery*, she had no choice but to attempt to reformat the provision as if there were three requirements, although this was at odds with the grammatical structure and the words of the sentence.

Authority to File: This Court's August 21, 2009 Order for rehearing en banc authorized the filing of amicus briefs without leave of court.

RESPONSE TO THE COURT'S QUESTIONS

The Court posed two questions when it ordered this case to be reheard en banc (*Ariad Pharmaceuticals Inc., v. Eli Lilly and Company*, No. 2008-1248 slip op. (Fed Cir. Aug. 21, 2009)). This amicus addresses only question 1:

"Question 1. Whether 35 U.S.C. § 112, paragraph 1, contains a written description separate from an enablement requirement?"

Response: No. In 35 U.S.C. § 112, paragraph 1, the written description is part of the enablement requirement, not a separate requirement. That is the plain meaning of the sentence's words and grammatical structure.

ARGUMENT

Amicus Roberta J. Morris, Esq., Ph.D. respectfully submits that the question whether the single sentence in 35 USC § 112, paragraph 1 ("112p1") has a separate written description ("WD") requirement, that is, three rather than two requirements, can and must be answered by reference to the plain words and grammatical structure of that sentence. That analysis yields only one conclusion: there is no separate WD requirement. Only by torturing the structure to pluck out a phrase without consideration for the sentence as a whole can a case be made for three requirements.

This point has, of course, been made by others, including the first Chief Judge of this Court, Howard Markey, *In re Barker*, 559 F.2d 588, 594 (C.C.P.A. 1977) (Markey, J. dissenting). I write primarily to supply a visual aid for better appreciating the grammatical structure and plain language of the provision. The method, which I refer to as reformatting, may be helpful for visual thinkers. In reformatting, the words are quoted exactly and completely. Instead, however, of appearing in the standard run-on block, the words are separated into phrases whose relationships are indicated by their horizontal starting position. (see below p. 5).

I. A TECHNIQUE FOR UNDERSTANDING PATENT CLAIMS IS APPROPRIATE FOR STATUTES

In patent law, the task of analyzing complicated text is a common one. Patent claims are often long and complex, especially when they have been amended over a period of months or years.

Among the rules for construing claims is that all the words in the claim, and only the words in the claim, should be considered: it is wrong to "read out" a limitation included in the claim, *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970), and it is wrong to "read in" concepts not included in the claim language itself (such as by importing them from the specification),

Arlington Indus., Inc. v. Bridgeport Fittings, Inc., 345 F.3d 1318, 1327 (Fed. Cir. 2003).

The careful approach used for construing patent claims can be used for understanding statutes, too: "[T]he interpretation of claims, as with the interpretation of statutes and contracts, turns on the actual wording of the claim" *Digital Biometrics v. Identix, Inc.*, 149 F.3d 1335, 1344 (Fed. Cir. 1998); *see also Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 987 (en banc) (Fed. Cir. 1995), *affirmed* 517 U.S. 370 (1996)). The words, all of them and only them, must govern the analysis.

II. THE TEXT OF 112p1, REFORMATTED

Here is 112p1 in typical block form:

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.

For many people, block format is rather impenetrable. Worse, it makes it entirely too easy to ignore words and to overlook the grammatical structure of the whole. One method to ensure a correct and complete reading of

complicated text is to make an electronic copy - or use a pen and paper - and break the text down into phrases, one phrase per line, positioning each phrase to begin at the horizontal position that reflects the relationships among the phrases. Some are subordinate to others, some are parallel, some may be overarching, etc. Reformatting thus renders visible the grammatical structure as well as the meaning, where block format may obscure both. My reformatting of 112p1 reads as follows (with line numbers added to aid discussion):

1 The specification
 shall contain a written description
 of the invention, and
 of the manner and process of making and using **it**,
5 in such
 full, clear, concise, and exact
 terms
 as to enable any person skilled in the art
 to which **it** pertains, or
10 with which **it** is most nearly connected,
 to make and use **the same**,
 and
 shall set forth the best mode
 contemplated by the inventor
15 of carrying out his invention.

(emphasis by boldface supplied).

The careful reading required for reformatting reveals several things.
(Here, ALL CAPS indicate quoted words of major significance; longer phrases are presented in quotation marks.)

1. The word SHALL appears twice (lines 2 and 3). This tells the reader that there are TWO requirements.

2. The phrase WRITTEN DESCRIPTION follows the first of the SHALLs and is preceded by the single article A (line 2).

3. The phrase WRITTEN DESCRIPTION is followed by two prepositional phrases each beginning with the word OF (lines 3 and 4). This indicates that within the one written description there must be information concerning two things.

4. After the two OF phrases that follow WRITTEN DESCRIPTION, there are two explanatory prepositional phrases, one introduced by the words IN SUCH CLEAR and one introduced by AS TO ENABLE (lines 5 and 8). These are intimately related and inseparable: the word SUCH requires completion: such as what? The answer is AS TO ENABLE.

5. In the first SHALL requirement, the noun INVENTION is the antecedent for THE SAME ("making and using THE SAME") and three occurrences of IT ("the manner ... of making IT," "the art to which IT pertains and to which IT is most closely...") (lines 4, and 9-11)

6. The IN SUCH ... AS TO language (lines 5-11) applies to WRITTEN DESCRIPTION in its entirety, that is, to both the OF phrases not

just the second OF phrase. To truncate the sentence after OF THE INVENTION leaves dangling the language from the next OF phrase through IN SUCH and AS TO ... THE SAME (lines 4-11).

7. The admonition to state everything in FULL, CLEAR, CONCISE and EXACT terms (lines 5-7) must apply to the entire (single) written description. It would make no sense to permit the INVENTION to be described in language that was other than "full, clear, concise and exact," and only require such precision for the description of MAKING AND USING. The language immediately after lines 5-7, that is, the ENABLEMENT requirement (lines 8-10), cannot then be separately applied only to the MAKING/USING phrase (line 4). It must apply to both OF phrases and to the single WRITTEN DESCRIPTION required by the first SHALL.

8. Both the second OF phrase (line 4) and the AS TO ENABLE phrase (lines 8-11) employ forms of the verbs make and use. This reinforces the conclusion that AS TO ENABLE applies to both OF phrases.

Otherwise, the second OF phrase has make/use twice.¹

1. The first patent act, that of 1790, 1 Stat. 109, had no duplication of verbs but explicitly recited two separate purposes for the "specification in writing, containing a description ...": it had to be "so particular...**as not only**

There is no redundancy, of course, if the statute is not truncated before the second OF phrase. This odd mutilation was first perpetrated in an alternative holding in *In re Ruschig*, 379 F.2d 990, 995 (CCPA 1967).

Ten years later, in *In re Barker*, 559 F.2d 588 (CCPA 1977), both Judge Miller, writing for the majority (559 F.2d at 591-2) and concurring Judge Rich (at 594), dismissed the redundancy for different reasons, instead of reading the statute and appreciating that it could not be read as *Ruschig* had suggested.

The two occurrences of make/use are understandable without invoking patent law history if the words in the current statute are respected. AS TO ENABLE applies to the information specified in both OF phrases. The description of the inventor's manner of making and using might, in

to distinguish the invention or discovery from other things before it ... but also to enable..." (emphasis mine). The next patent act, that of 1793, 1 Stat. 318, included duplication of a longer set of verbs than is in 112p1, and also included the same two purposes for the description: **to distinguish** over what was known before, **and to enable**. This was the statute analyzed in *Evans v. Eaton*, 20 US 356 (1822). The existence of a second purpose makes questionable the statement in *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 925 (Fed. Cir. 2004) that "the language of the present statute is not very different in its articulation of the written description requirement" from that in *Evans*.

some cases, need supplementation concerning the invention in order to enable the making and using by the ordinary artisan (a hypothetical person of inferior ability compared to a person capable of invention).

When reformatting has been done correctly, ellipses inserted in conformity with horizontal position should result in language that is comprehensible and grammatically correct. All phrases farther to the right than a phrase of interest are replaced with "..." while all phrases at the same horizontal position or to the left are included. Here, the short version of 112p1 becomes:

“The specification
[a] shall contain a written description ... in such ... terms
as to enable any person skilled in the art ... to make and use
the same,
and
[b] shall set forth the best mode

III. OTHER CITATIONS TO THE GRAMMAR AND WORDS OF 112p1

As mentioned above, others have also pointed out that the grammatical structure and plain words of 112p1 do not support a separate written description requirement. Judge Markey, the first Chief Judge of this

Court, dissenting from a decision relying on the *Ruschig* interpretation of 112p1, pointed out:

There is no surplusage in saying, as the Congress in effect did, “ * * * a written description of the invention * * * in such full, clear, concise, and exact terms as to enable,” and “(a written description) of the manner and process of making and using it in such full, clear, concise, and exact terms as to enable * * *.” On the contrary, Congress saved words by specifying, in a single prepositional phrase, that the description of the invention, and the description of the manner of making and using it, shall both be in “such full, clear, concise, and exact terms as to enable.” Section 112, first paragraph, is a simple sentence, with a comma after “it,” making the phrase “in such full * * * the same” a modifier of both objects of the verb “contain.” All before that comma prescribes what shall be described. The phrase following the comma prescribes how and for whom it shall be described.

In re Barker, 559 F.2d 588, 594 (CCPA 1977). (The language of 112p1 is even better than Judge Markey stated: The verb CONTAIN has but one object, “written description;” it in turn is modified by the two prepositional phrases starting with “of.”) Judge Markey went on to state:

We should not hesitate to recognize that it would have been better if the court had held, in certain past chemical cases, that whatever "enablement" was present, it was not in "full, clear, concise and exact terms," rather than to have created a "separate description" gloss. We certainly should not hesitate to do so when the court finds its creation being bent out of shape, as here.

Judge Rader, in his dissent to the denial of rehearing en banc in

Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1313 (Fed. Cir. 2004) collected quotations from academic commentary on 112p1 in an Appendix. Among the quotations, the following referred to the grammatical structure or plain words or both:

Laurence H. Pretty in his treatise PATENT LITIGATION § 1:3.3, Defenses Against Patent Validity, 1-44 (2003) [now at 1-46 to 1-47 (PLI 2008)]:

The term ‘written description’ appears grammatically as the subject for the verb ‘enable’ in the enablement section of 35 U.S.C. § 112. However, the written-description requirement has been judicially construed to have a separate and additional purpose.

Maebius, et al, acknowledging the similar conclusion of Pretty, state:

[T]here is nothing in the wording of 35 USC § 112, ¶ 1, that suggests a “written description” requirement, per se; rather, the “written description” spoken of in the law is *of the enabling disclosure*.

Maebius, Stephen B., Passino, Sean A. and Wegner, Harold C.,

“Possession” Beyond Statutory Enablement: A New Written Description Requirement For All Technologies, 805 PLI/Pat 33, 46, text accompanying n24 (2004).

Rachel Krevans and Cathleen Ellis, *Preparing for Biotech Patent Litigation*, 760 PLI/Pat 529, 555-56 (2003) point to the plain language of the statute:

The Federal Circuit doctrine that makes enablement a separate requirement from the written description requirement contradicts the plain language of the statute.

Kevin S. Rhoades, *The Section 112 Description Requirement – A Misbegotten Provision Confirmed*, 74 J. Pat. & Trademark Off. Soc’y 869, 870 (1992): “[T]he language and history of the statute support no such separate requirement ...”

IV. ADDITIONAL THOUGHTS ON 112p1, *GENTRY GALLERY* AND 112p2

Two of the people associated with the drafting of the Patent Act of 1952, Giles S. Rich and P. J. Federico, wrote contemporaneously about the new statute. Neither mentioned that 112p1 had three requirements. In fact, neither thought much was noteworthy about 112p1 other than that the best mode requirement, which before had been only for machines, now was applicable to all inventions. See Rich, Giles S., *Address of Giles S. Rich* (address delivered in 1952, reprinted in 75 J. Pat. & Trademark Off. Soc’y 3, 11 (1993)). Federico stated that the language of 112p1, from “a written description” through “use the same,” is “the same as in the old statute [R.S. 4888] with only some slight reduction in wording.” (Federico, P.J. , *Commentary on the New Patent Act*, originally published in 1954, reprinted

in 75 J. Pat. & Trademark Off. Soc'y 161, 185 (1993)). Yet in *Ruschig*, it is noteworthy that the Court failed to cite any decision under RS 4888 to support the separate WD requirement.

Ruschig was new law. It is good news that the Court now is following Judge Bryson's remarks in his concurrence in *Moba v. Diamond Automation*, 325 F.3d 1306, 1328 (Fed. Cir. 2003) to take this matter up en banc because "Perhaps the entire line of cases stemming from *Ruschig* is wrong."

If there is concern that without a separate WD requirement, the patent statute will provide no basis for invalidating claims that - while somehow enabled - are broader than what the applicant regards as his invention as explained in the specification, the next paragraph of 35 USC § 112 is available (112p2). The underutilization of this provision stems from dicta in a CCPA opinion from the same era as *Ruschig*. *In re Ehrreich*, 590 F.2d 902, 906-7 (CCPA 1973), quoting from *In re Borkowski*, 422 F.2d 904, 909 (CCPA 1970), stated that "what the applicant regards as his invention" under 112p2 must never be determined from the specification, but only from the claims or what today we would call extrinsic evidence. Subsequent decisions cited this odd notion, and today it is stated unequivocally in the Patent Office's Manual of Patent Examining Procedure (MPEP), § 2172 Part II (8th ed. rev. 7).

This is strange. Section 112 is entitled SPECIFICATION. The basic method of claim interpretation always proceeds from a consideration of the specification, as well as the claim in question and the other claims.

Indeed, someone reading *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998), who knew the plain words of 112p2, would have expected the bottom line there to be that the patentee had failed to "particularly point[] out and distinctly claim[] what he regarded as his invention." Yet the court chose instead to rely on *Ruschig* and a separate WD requirement, ushering in the three-requirement interpretation of 112p1 for the next decade.

It is time to distinguish between dicta and holdings, and to read section 112, both paragraphs 1 and 2, the way that claims and statutes alike should be read: with careful regard for the grammatical structure and the plain words.

For the reasons set forth above, amicus Roberta J. Morris, Esq., Ph.D. respectfully requests this Court to hold that the answer to question 3a of the August 21, 2009 Order is: No, 35 USC § 112, paragraph 1, does not have a written description requirement separate from the enablement requirement.

Respectfully submitted,

October 13, 2009

Roberta J. Morris, Esq., Ph.D.
as attorney for herself as
amicus curiae

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Roberta J. Morris, Esq., Ph.D.

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for Self as Amicus Curiae

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October 13, 2009

(Date)

CERTIFICATE OF SERVICE

I hereby certify that on October 13, 2009, via Landon IP Inc., I caused the
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