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BRIEFING PAPER:
Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320 (2000)

I. INTRODUCTION

In a recent decision in *Purdue Pharma L.P. v. Faulding Inc.*,[1] the Federal Circuit toughened its already stringent written description standard for biomedical patents. It invalidated a patent for methods of treating pain in patients for lack of sufficient written description.[2] The court reasoned that the original specification of the patent failed to describe a crucial characteristic that was later claimed as part of the invention, and thus failed to convey to one skilled in the art that the inventor was in possession of the invention at the time of the original filing.[3] As the court put it, "one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention."[4]

The court may have a justifiable concern about the problem of overreaching, especially in situations where claims were amended after the original filing. Nevertheless, the court failed to articulate clearly the standard for written description. The decision only adds to the ever growing uncertainty about how specific one's disclosure should be to survive the written description scrutiny. Given the court's recent trend of hostility towards biomedical patents, the decision is likely to discourage innovation in the pharmaceutical industry, where broad patent

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[1] 230 F.3d 1320 (Fed. Cir. 2000).

[2] *Id*. at 1322.

[3] *See id*. at 1324-26.

[4] *Id*. at 1326.

rights are crucial for a full appropriation of the economic rewards generated by the enormous research and development efforts.[5]

II. THE EVOLUTION OF THE WRITTEN DESCRIPTION REQUIREMENT

The goal of the U.S. patent system is to promote the progress of science and technology.[6] To that end, limited monopoly rights, in the form of patents, are granted to inventors in exchange for a full and early disclosure of the inventions.[7] To obtain a patent and for a patent to withstand judicial scrutiny, the claimed invention needs to be useful, novel, nonobvious, and adequately described in the patent application.[8]

The first paragraph of section 112 of the Patent Act of 1952 sets forth the statutory requirement for a written description that supports the claims:

> 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.[9]

The Federal Circuit has interpreted § 112 as mandating three distinctive requirements: (1) the written description requirement; (2) the enablement requirement; and (3) the best mode requirement.[10] While the "best mode" requirement is designed to prevent a patentee from

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[5] *See* WESLEY COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000) (concluding that patent rights, relative to other mechanisms of appropriation, are particularly important in the pharmaceutical industry).

[6] U.S. CONST. art. I, § 8, cl. 8.

[7] A patent granted in the United States is "for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed[.]" 35 U.S.C. § 154(a)(2).

[8] 35 U.S.C. §§ 101-103, 112 (1994 & Supp. II 1996).

[9] 35 U.S.C. § 112, ¶ 1.

[10] Although the precedent before *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991), was inconsistent as to whether written description was a separate requirement. *See* Vas-Cath, 935 F.2d at 1560.

concealing part of the invention while obtaining patent protection for the whole,[11] the written description and the enablement requirements serve as guards against overly broad patent rights.

A. THE ENABLEMENT REQUIREMENT

Because of the close relationship between the enablement and the written description requirements, this note will first briefly describe the enablement requirement as developed in case law.

To satisfy the enablement requirement, the specifications must teach a skilled artisan how to make and use the invention without "undue experimentation."[12] In addition, the teaching must be conveyed at the time the application was originally filed.[13] The Federal Circuit in *In re Wands* set forth a list of factors that may be considered in determining whether or not the disclosure requires "undue experimentation," including "the predictability and unpredictability of the art."[14] The more unpredictable an art is, the more disclosure required to avoid undue experimentation.[15] Chemical and biotechnological arts are generally considered unpredictable because unlike mechanical or electrical arts, a slight change in composition may cause unexpected activities and behaviors.[16] Commentators have observed that this may have led the

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[11] *See In re* Gay, 309 F.2d 769, 772 (C.C.P.A. 1962) ("the sole purpose of [the best mode] requirement is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived."). The best mode requirement will not be discussed in this note.

[12] *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

[13] *See* Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986).

[14] *See In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) ("(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.").

[15] *See In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970).

[16] *See id*.

court to require a higher level of disclosure in biotechnology patents in order to satisfy the enablement requirement.[17]

B. THE WRITTEN DESCRIPTION REQUIREMENT

It has been standard practice for patent attorneys to file a patent application that vaguely describes an invention, and later broaden or narrow the claims through amendments to reflect the results of follow-up research and/or to include competitor's newly developed variants.[18] In an effort to prevent overreaching through abusive amendment practice and to preclude patentees from later claiming what they did not possess at the time they filed their applications, the Federal Circuit has promulgated a separate "written description requirement," which requires that the disclosure "must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the patentee] was in possession of the invention."[19]

The written description doctrine was first introduced in patent cases involving chemical arts, where the court used the requirement to limit the changes that can be made to the original claims during patent prosecution.[20] However, because the holdings were often intermingled with other doctrinal rules such as the enablement requirement, they were attacked for redundancy or lack of clarity.[21] In addition, the decisions by the Federal Circuit were conflicting as to whether

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[17] *See*, *e.g.*, Amgen, Inc. v. Chugai Pharmaceutical, Co., 927 F.2d 1200, 1214 (Fed. Cir. 1991) (finding Amgen's claims to all analogs of human erythropoietin invalid for lack of enablement because the specification only disclosed how to make "the gene and a handful of analogs whose activity has not been clearly ascertained[.]"). For a detailed discussion about the enablement requirement in biotechnology patents, see Margaret Sampson, Comment, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 Berkeley Tech. L.J. 1233, 1239-51 (2000).

[18] *See* ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 225 (Aspen Law & Business 2d ed. 2000) (1997).

[19] Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).

[20] *See*, *e.g.*, Application of DiLeone, 436 F.2d 1404, 1405 (C.C.P.A. 1971) (reasoning that "it is possible for a specification to enable the practice of an invention as broadly as it is claimed, and still not describe that invention.").

[21] *See*, *e.g.*, *id*. at 1406 (Baldwin, Judge, dissenting).

written description and enablement requirements were separate or intertwined.[22] As a result, the written description requirement almost completely disappeared in the court's subsequent decisions.

The court finally revived the written description requirement in *Vas-Cath*, where it affirmatively stated that written description and enablement are two separate and distinct requirements.[23] The court stated that the purpose of the written description requirement is "to put the public in possession of what the party claims" as its invention.[24] Therefore, the patent applicant must "convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession of the invention . . . now claimed."[25]

III. THE WRITTEN DESCRIPTION REQUIREMENT IN BIOTECHNOLOGY PATENTS

To encourage early disclosure, patent law generally allows an inventor to patent an invention that has not yet been reduced to practice, so long as the inventor exercises due diligence in reducing the invention to practice after filing of the application.[26] However, the court's decisions since *Amgen, Inc. v. Chugai Pharmaceutical, Co.* have applied a heightened level of scrutiny under the written description requirement to "unpredictable arts," which essentially requires actual reduction to practice at the time of filing in biotechnology patents.[27]

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[22] *See* Vas-Cath, 935 F.2d at 1563 (discussing conflicting precedents).

[23] *Id*.

[24] *Id*. at 1561 (citing Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 400 (1822)).

[25] *Id*. at 1563-64 (emphasis added).

[26] *See* Hybritech, 802 F.2d at 1376.

[27] 927 F.2d 1200, 1206 (Fed. Cir. 1991).

In Amgen, the court found that since Genetics Institute, one of the defendants in the suit, had not actually isolated the claimed human erythropoietin DNA at the time of filing the application, a mere description of the method to isolate the DNA and a statement that the said DNA encodes human erythropoietin protein are inadequate for purpose of written description requirement.[28]

In *Fiers v. Revel*,[29] the court rejected Revel's claim of priority to the DNA sequence coding for human beta-interferon on the grounds that he had not included the actual DNA sequence in his patent application.

More recently, the Federal Circuit addressed the issue of the written description requirement for genomic patents in *Regents of the University of California v. Eli Lilly & Co*.[30] The court invalidated University of California's patent on human insulin cDNA because the specification only contained a recitation of the rat insulin cDNA sequence, even though the examples in the specification described how to isolate the human insulin cDNA.[31] The court stated that adequately describing a cDNA in a patent specification "requires the kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA."[32]

All of these cases involve claims that are broader in scope than what are disclosed in the specifications. They may reflect the court's unwillingness to grant broad patents to unpredictable

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[28] *See id*.

[29] 984 F.2d 1164, 1170-71 (Fed. Cir. 1993).

[30] 119 F.3d 1559 (Fed. Cir. 1997).

[31] *Id*. at 1567-68.

[32] *Id*. at 1569.

arts.[33] As one commentator observed, the primary goal of the Federal Circuit in the biotechnology cases is to limit patentees to their actual inventions, rather than research plans.[34]

IV. PURDUE PHARMA: AN EVER MORE CONFUSING WRITTEN DESCRIPTION REQUIREMENT

In *Purdue Pharma*, the court deemed the '360 patent invalid for lack of adequate written description.[35] The court was obviously bothered by the plaintiff's amendment practice, where the plaintiff amended its application after commencement of the suit to add limitations to claims allegedly infringed by the defendants.[36] The court ruled that the specification, as originally filed, failed to provide support for the inventions now claimed.[37]

Specifically, the court found that the claimed subject matter, i.e. the C submax / C sub24 ratio, was not encompassed in the original disclosure, and therefore the inventor failed to establish that he was in possession of the invention at the time of the original filing.[38] The court's reasoning, however, is elusive. First, it is hard to comprehend why a disclosure that one of the goals of the invention was to achieve a non-substantially flat blood morphine concentration curve, as opposed to the state of art approach of having "minimal peak to trough fluctuation in opioid levels," would not convey to one skilled in the art that a comparison of blood concentration over time (in fact, that is all a "concentration curve" is designed to illustrate)

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[33] Although *Gentry Gallery, Inc. v. Berkline Corp*., 134 F.3d 1473 (Fed. Cir. 1998), indicates that predictability of the arts may have nothing to do with how strict the court applies the written description requirement. In *Gentry*, the patent at issue involved a sectional sofa with side-by-side recliners separated by a "fixed console." The court found that the disclosure, which stated that the recliner control was located on the console, did not adequately support the claims in which the location of the control was other than the console. *See id*. at 1479.

[34] *See* Sampson, *supra* note __, at 1259.

[35] *See* Purdue Pharma, 230 F. 3d at 1324.

[36] *See id*. at 1322.

[37] *See id*. at 1323.

[38] *See id*. at 1324.

is one of the important parameters that will help to define the invention.[39] Second, the court turned a blind eye towards a disclosure that provided the "blaze marks" that the court was looking for - that the formulation had a T submax (time to maximum blood morphine concentration) between 2 and 10 hours.[40] While reiterating that "[i]n order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter[,]" the court failed to explain why a disclosure of T submax was insufficient to "convey with reasonable clarity to those skilled in the art that . . . [the inventor] was in possession of the invention."[41] Rather than providing the public with much needed guidance, the court circumvented once again the issue of how specific an adequate disclosure should be with terms of art.

Instead of striking down the later-amended claims with written description requirement, the court could have invalidated the patent either for lack of enablement or for failure to disclose best mode. Here, the plaintiff disclosed multiple "preferred embodiments," at least some of which, including the one illustrated in the examples, actually would result in a formulation that was not within the C submax / C sub24 > 2 limitation. It appeared from the record that it took the plaintiff a long time to finally reduce the invention to practice, from which (one assumes) it claimed C submax / C sub24 > 2. Therefore, the original disclosure, with numerous "preferred embodiments," would require "undue experimentation" for a skilled artisan to make and use the claimed invention, and thus failed the enablement requirement. In fact, the "blaze marks" that

[39] *See id*. at 1324 (block quote of the specification of the '360 patent).
[40] *See* the '360 patent, cl. __

[41] *Id*. at 1323 (quoting Fujikawa v. Wattanasin, 93 F.3d 1559, 1570 (Fed. Cir. 1996); Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991)).

would direct a skilled artisan to the tree are not a disclosure of the tree, but a disclosure of how to get to the tree.

As it has been criticized in the *Eli Lilly* case, the court once again "has lost sight of the real culprit - lack of enablement - and directed its ire at an innocent bystander - the description requirement . . . [and] takes description requirement jurisprudence in an unjustifiably new and reckless direction[.]"[42] The written description requirement fashioned by the court in *Purdue Pharma* will virtually eliminate the practice of filing continuations or seeking reissues. Any such act could easily be interpreted as an admission that the original claims were either too broad or too narrow as compared to the original specifications, both are grounds for invalidation under the current written description doctrine.

The court's rigid application of written description requirement to biotechnology patents have been criticized for departing "recklessly" from written description precedents, which only require disclosure in particularity some subset of the information rather than precisely naming the claimed invention.[43] On the other hand, they have been viewed as necessary steps to ensure that overly broad patent rights are not granted to DNA sequences of unknown function, which may have significant yet unforeseeable impact on future downstream research.[44] Indeed, granting overly broad patent rights to upstream research product has raised antitrust concerns that may chill the efforts by other researchers to take multiple research paths, which are characteristic and crucial for biotechnology innovations.[45]

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[42] Harris A. Pitlick, *The Mutation on the Description Requirement Gene*, 80 J. Pat. & Trademark Off. Soc'y 209, 222-23 (1998).

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[44] *See* Sampson, *supra* note ___, at 1259-61.

[45] *See generally* Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 Berkeley Tech. L.J. 813 (2001).

However, drug therapy innovations usually represent the downstream end of biopharmaceutical research, where broad patent rights not only can be afforded without having a heavy toll on competition, but are desired. [Discuss why broad patent rights is critical for a full appropriation of economic rewards in pharmaceutical industry.]

Moreover, some commentators have identified an "anticommons" tragedy in biomedical research, where fragmented intellectual property rights result in an underuse of scarce resources.[46] This tragedy can be limited by offering broad patent rights, which ensure that at least someone has an effective privilege of use. By bundling the rights rather than fragmenting them, broad patent rights may also lower transaction costs to facilitate the use of the resources.

It may be argued that morality concerns mandate a narrow scope on patents for life-saving drugs. After all, a doctor who has come up with a revolutionary surgical technique is not allowed to exclude others from practicing her invention.[47] However, the cost associated with the research and development of a clinically tested new drug is usually much higher than the cost associated with a doctor's improvement on a surgical procedure, which is often a product of her already well-compensated medical practice. A publication in a world renowned medical journal may provide sufficient incentive for a doctor to engage in innovation, while it can hardly be enough to drive a pharmaceutical company to invest millions of dollars into developing a new drug. If the scope of the patent is narrowed to a point that there is little incentive left for a pharmaceutical company to engage in high-cost research and development, the society can only be worse off.

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[46] *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698 (1998).

[47] *See* 35 U.S.C. § 287(c).