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

I. INTRODUCTION

For a patent to be valid, it needs to be useful, novel, nonobvious, and adequately described in the patent application.[1] 35 U.S.C. § 112 sets forth the requirement for a written description that supports the claimed invention:

> 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]

The Federal Circuit reads § 112 as requiring two independent elements: enablement requirement and written description requirement, both are guards against overly broad patent rights claimed by inventors. The enablement requirement is often used to invalidate patents that require "undue experimentation" by a person skilled in the art to reduce the invention to practice.[3] To satisfy the enablement requirement, the disclosure of specifications must "enable any person skilled in the art . . . to make and use" the patented invention without undue experimentation.[4]

In addition, in an effort to prevent overreaching by inventors through amendment of later-filed claims, 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

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[1] 35 U.S.C. §§ 101-103, 112.

[2] 35 U.S.C. § 112, ¶ 1.

[3] *See generally*

[4] *Id*. *See also*

art that . . . [the patentee] was in possession of the invention."[5] By insisting that the inventor discloses his invention in details, the Federal Circuit hopes to limit the inventor's future claims within the bounds of his original invention.

In a recent decision in *Purdue Pharma L.P. v. Faulding Inc.*, the Federal Circuit reinforced its heightened written description standard.[6] It invalidated a patent for methods of treating pain in patients by orally administering an opioid such as morphine once a day for lack of sufficient written description.[7] The court reasoned that the broad specification of the patent lacked adequate description of 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.[8] The court articulated that the claims, including the amended claims, define the invention, but the support for the invention must be found "in the specification as filed" rather than in the amended claims.[9]

II. FACTS AND PROCEDURAL HISTORY

In 1984, Purdue Pharma L.P. and the Purdue Frederick Company (collectively "Purdue") successfully developed and marketed a sustained-release, twice-a-day oral morphine formulation.[10] Subsequently, Purdue allegedly sought to develop a sustained-release, once-a-day oral morphine formulation with three specific design goals: (1) a relatively early time to

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

[6] 230 F.3d 1320 (Fed. Cir. 2000).

[7] *Id*. at 1322.

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

[9] *Id*. at 1329.

[10] *Id*. at 1322.

maximum blood opioid concentration (T submax), which is in about 2 to 8 or 10 hours; (2) a larger fluctuation in blood opioid concentration, where the variation between the maximum and minimum concentrations exceeds 100%; and (3) effective treatment of pain for about 24 hours.[11] Purdue claimed that by 1993, it had developed a morphine formulation that clinically satisfied all three design goals. In late 1993, Purdue filed with the United States Patent and Trademark Office ("PTO") an application for U.S. Patent No. 5,478,577 ("the '577 patent"), which was issued in late 1995.[12] Within a year of initial filing of the '577 patent application, Purdue filed with the PTO U.S. Patent Application Serial No. 08/578688 ("the '688 application"), which claimed priority to the application that led to the '577 patent.[13]

In 1987, Faulding Inc., Faulding Pharmaceutical Co., Faulding Services, Inc., and Purepac Pharmaceutical Co. (collectively "Faulding") began developing a sustained-release morphine formulation that could be administered once or twice a day, and would provide pain relief for a minimum of 12 hours.[14] In 1996, upon United States Food and Drug Administration's ("FDA") approval, Faulding began marketing its sustained-release once- or twice-a-day oral morphine formulation in the United States under the trade name Kadian.[15]

Shortly after Faulding launched its sales of Kadian in this country, Purdue brought suit in the United States District Court for the District of Delaware against Faulding for infringement of

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[11] Purdue Pharma, L.P. v. F.H. Faulding & Co., 48 F.Supp. 2d 420, 424 (D. Del 1999).

[12] *Id*. at 425. *See also Purdue Pharma L.P.*, 230 F.3d at 1322. The '577 patent application was filed with the United States Patent and Trademark Office ("PTO") on November 23, 1993, and was issued on December 26, 1995. *See* US PAT 5478577 ("the '577 patent").

[13] *See Purdue Pharma L.P.*, 230 F.3d at 1322. The '688 application was filed on November 22, 1994. *See* US PAT 5672360 ("the '360 patent").

[14] *Purdue Pharma, L.P.*, 48 F.Supp. 2d at 425.

[15] *Id*. at 426. *See also Purdue Pharma L.P.*, 230 F.3d at 1322.

the '577 patent.[16] After commencement of the suit, Purdue canceled the pending claims of the '688 application before the PTO and amended the application to add all new claims. The amended application was issued as U.S. Patent No. 5,672,360 ("the '360 patent") on September 30, 1997.[17] Thereafter, Purdue amended its complaint by dropping claims of infringement of the '577 patent and asserting instead infringement of the '360 patent.[18]

The district court found the '360 patent invalid for lack of sufficient written description.[19] The court held that the specification of the '360 patent failed to convey that the requirement that the maximum blood opioid concentration level be more than twice the blood opioid concentration at about 24 hours after administration of the morphine formulation (C submax / C sub24 > 2) was encompassed in Purdue's original invention.[20] Consequently, the court found that the specification failed to convey that Purdue was in possession of the invention set forth in the '360 patent at the time of the filing, and therefore failed to satisfy the written description requirement under 35 U.S.C. § 112.[21] Purdue appealed from the finding of invalidity.

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[16] *Purdue Pharma L.P.*, 230 F.3d at 1322.

[17] *Id*.

[18] *Id* at 1323.

[19] *See Purdue Pharma, L.P.*, 48 F.Supp. 2d at 428.

[20] *See id*.

[21] *See id*. at 432-33.

III. THE FEDERAL CIRCUIT'S ANALYSIS

The Federal Circuit affirmed the district court's finding of invalidity.[22] Like the district court, the Federal Circuit focused on the written description requirement rather than the enablement requirement in striking down the '360 patent as invalid.

The court held that neither the text in the specification nor the examples set forth in the patent provide adequate support for the C submax / C sub24 ratio recited in the claims.[23] Specifically, the court found that language in the specification describing the invention as not having a generally or substantially flat blood morphine concentration curve was insufficient to suggest to one skilled in the art that the C submax / C sub24 ratio was one of the characteristics of the invention.[24] Likewise, the court found that nothing in the examples would "suggest to one skilled in the art that the C submax / C sub24 ratio is an important defining quality of the formulation," or "even motivate one to calculate the ratio."[25]

The court rejected Purdue's argument that because its claim limitation requiring C submax / C sub24 > 2 was narrower than the range a skilled artisan could establish from the examples set forth in the patent, its written description was adequate.[26] The court considered the range immaterial where the specification did not "clearly disclose to the skilled artisan that the inventors of the '360 patent considered the C submax / C sub24 ratio to be part of their invention."[27]

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[22] *Purdue Pharma L.P.*, 230 F.3d at 1322.
[23] *See id*. at 1324-26.

[24] *See id*.

[25] *Id*. at 1327.

[26] *See id*. at 1327-28.

[27] *Id*. at 1328.

While reiterating that "naming is not essential," the court nevertheless insisted on having "blaze marks."[28] The court reasoned that "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."[29] To prevent this type of overreaching by the inventor, the court held that "to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the *originally filed* disclosure."[30]

Moreover, the court held that courts are not bound by the PTO examiner's finding in an amendment proceeding that the added claims are supported by the specification, particularly where the court has before it much more extensive evidence on the issue.[31]

[28] *Id*. at 1326 (citing In re Ruschig, 379 F.2d 990, 994-95 (C.C.P.A. 1967)).

[29] *Id*.

[30] *Id*. at 1326-27 (emphasis added).

[31] *Id*. at 1329.