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PURDUE PHARMA L.P. V. FAULDING INC.

"The life of a patent solicitor has always been a hard one."[1] And the uncertainty generated by the written description requirement has only made it even more difficult. In *Purdue Pharma L.P. v. Faulding Inc.*,[2] the Federal Circuit invalidated a patent for a method of treating pain by administering 24-hour sustained-release morphine formulations for lack of adequate written description.[3] The court found that the specification in the original patent application failed to describe a crucial limitation 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.[4]

While the court may have justifiable concerns about the problem of overreaching in amendment practice, it applied an at best confusing, and at worst erroneous, test for adequate written description that was contradictory to the existing case law and unwarranted by the purpose of the written description requirement. The decision added to the ever growing uncertainty as to how specific one's disclosure must be to survive the written description scrutiny, especially in cases of subgenus claims or later-amended claim limitations. Combined with the court's repeated practice of using the written description requirement to narrow the scope of biotechnology patents, the decision is likely to discourage inventors in the biomedical field to seek patent protection. Further, the court's recent decisions signal its willingness to

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[1] *In re* Ruschig, 379 F.2d 990,993 (C.C.P.A. 1967).

[2] 230 F.3d 1320 (Fed. Cir. 2000).

[3] *Id*. at 1322.

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

expand the stringent written description requirement to all arts, not just biotechnology or chemical arts, which threatens to weaken patent protection in general.

I. BACKGROUND

A. The Statutory Written Description Requirement

The goal of the U.S. patent system is to promote the progress of science and technology.[5] 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.[6] To obtain a valid patent, the claimed invention needs to be useful, novel, nonobvious, and adequately disclosed in the patent application.[7]

The first paragraph of section 112 of the Patent Act of 1952 sets forth the statutory requirement for an adequate disclosure:

> 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.[8]

On its face, the statute does not explicitly call for a distinct written description requirement, as the recited purpose of the written description is to allow any person skilled in the art "to make and use the same." and to "set forth the best mode" of carrying out the invention.[9]

B. Judicial Interpretation of the Written Description Requirement

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[5] U.S. CONST. art. I, § 8, cl. 8.

[6] 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) (1994 & Supp. II 1996).

[7] 35 U.S.C. §§ 101-103, 112 (1994 & Supp. II 1996).

[8] 35 U.S.C. § 112, ¶ 1 (1994 & Supp. II 1996).

[9] *Id*.

1. *Written Description As a Separate Disclosure Requirement Independent of Enablement*

Courts, however, have interpreted section 112 as mandating three distinctive requirements: (1) the written description requirement; (2) the enablement requirement; and (3) the best mode requirement.[10] The "best mode" requirement is designed to prevent a patentee from concealing part of the invention while obtaining patent protection for the whole.[11] The enablement requirement ensures effective teaching of the invention to the public to avoid "undue experimentation."[12]

The purpose of the written description requirement has evolved from serving as a notice to the public to functioning as a safeguard against overreaching by the inventors.[13] Historically, the written description was to "put the public in possession of what the [inventor] claims as his own invention" so as to warn an innocent purchaser or user of his infringement of the patent.[14] Since the enactment of the Patent Act of 1952, this purpose is fulfilled by a requirement of disclosing claims as set forth in the second paragraph of section 112.[15]

Although no longer necessary as notice, the written description requirement has been viewed as having a second function—to preclude patentees from later claiming what they did not

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[10] *See* DONALD S. CHISUM, CHISUM ON PATENTS § 7.01 (Lexis Publishing 2000).

[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* Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560-61 (Fed. Cir. 1991).

[14] *See id*. at 1561 (citing *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433 (1822)).

[15] 35 U.S.C. § 112, ¶ 2 (1994 & Supp. II 1996). The earlier patent statutes did not require a disclosure of the claims. *See Vas-Cath*, 935 F.2d at 1561.

possess at the time they filed their applications.[16] 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.[17] The written description requirement serves to "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."[18]

The Federal Circuit's predecessor, the Court of Customs and Patent Appeals (C.C.P.A.), first promulgated a distinctive written description requirement separate from the enablement requirement in a patent case involving chemical arts.[19] There, the court found that section 112 required the patentees to "convey clearly to those skilled in the art" that they invented the specific chemical compound claimed.[20] Later, in another chemical case, the court used the written description requirement to limit the changes that can be made to the original claims during patent prosecution.[21] However, the courts' subsequent decisions often intermingled the written description requirement with other doctrinal rules such as the enablement requirement, and were attacked for redundancy or lack of clarity.[22]

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[16] *See Vas-Cath*, 935 F.2d at 1561 (quoting *Rengo Co. v. Molins Mach. Co*., 657 F.2d 535, 551 (3d Cir. 1981)).

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

[18] *Vas-Cath*, 935 F.2d at 1563-64.

[19] *In re* Ruschig, 379 F.2d 990, 995-96 (C.C.P.A. 1967).

[20] *Id*. at 996.

[21] *See In re* 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.").

[22] *See Vas-Cath*, 935 F.2d at 1563 (discussing the confusion in the court's decisions concerning the written description requirement).

Acknowledging the confusion about "what the law of the Federal Circuit is" regarding the written description requirement, the court in *Vas-Cath, Inc. v. Mahurkar*[23] finally reviewed the written description requirement, and affirmatively stated that written description and enablement are two separate and distinct requirements.[24]

2. *The Standard and Test for Adequate Written Description*

a) *Vas-Cath, Inc. v. Mahurkar*[25]

In *Vas-Cath*, the court recognized that the written description cases often stressed the fact specificity of the holdings, making the precedential value of the cases extremely limited.[26] However, the court also noted that "a fairly uniform standard for determining compliance with the 'written description' requirement has been maintained throughout: 'Although [the applicant] does not have to describe exactly the subject matter claimed, . . . the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."[27] Because written description requirement often comes up in cases where amendments of claims are involved,[28] the court adopted a possession test for adequate written description: whether the disclosure "'reasonably conveys to the artisan that the inventor had possession'" of the later claimed subject matter at the time of the filing.[29] The court emphasized that it is not

[23] 935 F.2d 1555 (Fed. Cir. 1991).

[24] *Id*. at 1560-64.

[25] 935 F.2d 1555.

[26] *Id*. at 1562.

[27] *Id*. at 1562-63 (quoting *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)).

[28] *See id*. at 1560.

[29] *Id*. at 1563 (quoting *Ralston Purina Co. v. Far-Mar-Co, Inc*., 772 F.2d 1570, 1575 (Fed. Cir. 1985)).

required that the specification "describe what is novel or important."[30] Such a requirement constitutes a "legal error."[31]

b) *Amgen, Inc. v. Chugai Pharmaceutical, Co.* and biotechnology cases

The court's decisions since *Amgen, Inc. v. Chugai Pharmaceutical, Co.*[32] have applied a heightened level of scrutiny under the written description requirement to "unpredictable arts" involving DNA sequences.

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.[33] However, the court in *Amgen* required actual reduction to practice at the time of filing "when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials."[34] 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.[35]

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[30] *Id*. at 1565.

[31] *Id*.

[32] 927 F.2d 1200 (Fed. Cir. 1991).

[33] *See* Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986).

[34] 927 F.2d 1200, 1206 (Fed. Cir. 1991).

[35] *See id*.

In *Fiers v. Revel*,[36] 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*.[37] 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.[38] 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."[39]

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 arts. 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.[40]

However, the *Gentry Gallery, Inc. v. Berkline Corp*[41] case signals 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

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[36] 984 F.2d 1164, 1170-71 (Fed. Cir. 1993).

[37] 119 F.3d 1559 (Fed. Cir. 1997).

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

[39] *Id*. at 1569.

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

[41] 134 F.3d 1473 (Fed. Cir. 1998).

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.[42]

3. *Adequate Written Description for Claim Limitations*

The written description requirement often comes into play when a newly amended claim adds a narrowing limitation, often to avoid prior art. The limitation so added must also be supported by the specification as originally filed.[43] The issue remains the same: whether the specification "reasonably conveys to the artisan that the inventor had possession" of the invention, including all the limitations.[44]

An often related issue involves range limitations. The precedent is clear that it is not necessary to disclose the exact range of limitations in the specification in order to establish possession of the invention, including all the amended limitations, at the time of original filing.[45] In *Ralston Purina Co. v. Far-Mar-Co., Inc.*,[46] the Federal Circuit examined the adequacy of disclosure regarding to later claimed range limitations. One of the limitations involved a range of moisture. In the original specification, the examples allowed one skilled in the art to derive a moisture range between 25% and 39%.[47] The court found that the disclosure supported claims of "total moisture 'at least about 25%'" and "added moisture 'at least 25%,'" but not claims of "total

[42] *See id*. at 1479.

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[45] *See Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, __ (Fed. Cir. 1985).

[46] 772 F.2d 1570 (Fed. Cir. 1985).

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moisture 'at least about 20%,'" or "added moisture 'in the range of 20%-30%.'"[48] The court stressed that compliance with the written description requirement must be determined on a case-by-case basis.[49] The open ended range claims would be limited by what one skilled in the art would understand to be workable.[50]

II. CASE SUMMARY

Purdue Pharma brought suit against Faulding in the United States District Court for the District of Delaware, alleging literal infringement of its United States Patent No. 5,672,360 ("the '360 patent").[51] In defense, Faulding contended, *inter alia*, that the '360 patent was invalid on the grounds of inadequate written description, obviousness, anticipation, and public use.[52] The district court held that the '360 patent was invalid for lack of written description, and found it unnecessary to address the other grounds raised by Faulding.[53] On appeal, the Federal Circuit affirmed the district court's holding of invalidity of the '360 patent.[54]

A. Background of the '360 Patent

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.[55] Subsequently, Purdue sought to develop a once-a-day sustained-release oral

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51 Purdue Pharma, L.P. v. F.H. Faulding & Co., 48 F. Supp. 2d 420, 423 (D. Del. 1999).

52 *Id*.

53 *Id*. at 433.

54 Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1322 (Fed. Cir. 2000).

55 *Id*.

morphine formulation.[56] In late 1993, Purdue filed with the United States Patent and Trademark Office ("PTO") an application for United States Patent No. 5,478,577 ("the '577 patent"), which was issued in late 1995.[57] The '577 patent disclosed a once-a-day morphine formulation exhibiting a rapid initial rise in the patient's blood morphine concentration.[58] Within a year of initial filing of the '577 patent application, Purdue filed with the PTO United States Patent Application Serial No. 08/578688 ("the '688 application"), which claimed priority to the application that led to the '577 patent.[59]

In 1987, Faulding Inc., Faulding Pharmaceutical Co., Faulding Services, Inc., and Purepac Pharmaceutical Co. (collectively "Faulding") also began to develop a long-lasting morphine formulation for pain relief.[60] In 1996, Faulding began marketing its sustained-release morphine formulation in the United States under the trade name Kadian.[61]

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 the '577 patent.[62] 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.[63] The

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[56] *Id*.

[57] *Id*. *See also Purdue Pharma*, 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* U.S. Patent No. 5,478,577 (issued Dec. 26, 1995).

[58] *Purdue Pharma*, 230 F.3d at 1322.

[59] *See id*. The '688 application was filed on November 22, 1994. *See* U.S. Patent No. 5,672,360 (issued Sept. 30, 1997) [hereinafter the '360 patent].

[60] *Purdue Pharma*, 48 F.Supp. 2d at 425.

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

[62] *Purdue Pharma*, 230 F.3d at 1322.

[63] *Id*.

amended application was issued as United States Patent No. 5,672,360 ("the '360 patent") on September 30, 1997.[64] Thereafter, Purdue amended its complaint by dropping claims of infringement of the '577 patent and asserting instead infringement of the '360 patent.[65]

The amended claims in the '360 patent included a limitation, which was absent from the original claim language in the '688 application, requiring that the maximum blood morphine concentration level be more than twice the level at about 24 hours after administration of the formulation (C submax / C sub24 > 2), i.e. a fluctuation of greater than 100%.[66]

The specification of the '360 patent did not explicitly recite the C submax / C sub24 > 2 limitation, or expressly claim the limitation as one of its design goals.[67] Instead, it characterized the inventive formulation as "designed to provide an initially rapid rate of rise in the plasma concentration of [the morphine]"[68] and "having a surprisingly fast time to peak drug plasma concentration."[69] Nevertheless, the specification stated that "it has now been surprisingly discovered that quicker and greater analgesic efficacy is achieved by 24 hour oral opioid formulations, *which do not exhibit a substantially flat serum concentration curve*, but which instead provide a more rapid initial opioid release. . ."[70] In addition, the '360 patent contained both examples of the inventive formulations illustrating C submax / C sub24 ratios greater than

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[64] *Id*.

[65] *Id*. at 1323.

[66] *See Purdue Pharma*, 48 F.Supp. 2d at 428.

[67] *See generally* the '360 patent.

[68] *Id*., cl. 6, ll. 2-4.

[69] *Id*., cl. 6, ll. 10-12.

[70] *Id*., cl. 5, ll. 40-44 (emphasis added).

2, and those illustrating C submax / C sub24 ratios less than 2,[71] with the lowest ratio illustrated being 1.48 and the highest being 3.43.[72]

B. Procedural History

1. *The District Court's Ruling*

Faulding contended that the written description was inadequate because the specification of the '360 patent did not disclose the C submax / C sub24 > 2 limitation.[73] Purdue argued that the limitation was adequately disclosed by the language in the specification describing its invented formulation as exhibiting a not "substantially flat" concentration curve.[74] According to Purdue, a skilled artisan understood "flat" to mean a fluctuation equals to or less than 100%.[75] In addition, Purdue relied on the examples that illustrated C submax / C sub24 ratios greater than 2 as providing sufficient written description of the claimed limitation.[76]

The district court found the '360 patent invalid for lack of sufficient written description.[77] The court held that the text of the specification failed to convey that the C submax / C sub24 > 2 requirement was encompassed in Purdue's original invention.[78] The court based its finding on the fact that (1) the original claim language did not define the invention in terms of concentration

[71] *Purdue Pharma*, 48 F.Supp. 2d at 430.

[72] *Id*. at 431.

[73] *Id*. at 427.

[74] *Id*. at 428.

[75] *Id*. at 429.

[76] *Id*. at 430.

[77] *See id*. at 428.

[78] *See id*.

ratios;[79] (2) the specification did not define the C submax / C sub24 > 2 limitation as one of the design goals;[80] or (3) describe it as critical to the invention.[81]

The court rejected Purdue's claim that a skilled artisan understood "flat" to mean a fluctuation equals to or less than 100%.[82] The court noted that Purdue's own expert witness characterized a drug exhibiting fluctuations greater than 100% as "flat," and at least one of the publications that Purdue relied on described a formulation with a C submax / C sub24 ratio of 2.05 as having "low" fluctuations.[83] Therefore, the court found that "not substantially flat" did not necessarily mean C submax / C sub24 >2, or referred to any precise quantification.[84] In addition, the court found that the examples in the specification did not provide support for the C submax / C sub24 > 2 limitation because they only established a C submax / C sub24 range between 1.48 and 3.43.[85]

Consequently, the court held that the '360 patent was invalid because the specification failed to convey that Purdue was in possession of the invention at the time of the filing, and therefore failed to satisfy the written description requirement under 35 U.S.C. section 112.[86] Purdue appealed from the finding of invalidity.

2. *The Federal Circuit's Ruling*

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[79] *Id*. at 428.

[80] *Id*.

[81] *Id*. at 429.

[82] *Id*.

[83] *Id*.

[84] *Id*.

[85] *Id*. at 431.

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

The Federal Circuit affirmed the district court's ruling.[87] Borrowing the metaphor from *Ruschig*, the court held 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."[88] Instead, "the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure" in order to satisfy the written description requirement.[89]

The court found that neither the text nor the examples set forth in the specification provided the blaze marks required to support the C submax / C sub24 > 2 limitation recited in the claims.[90] Specifically, the court found that the text describing the surprising discovery of a not substantially flat concentration curve exhibited by an effective sustained-release formulation failed to convey that the C submax / C sub24 ratio was critical to the invention.[91] Moreover, the court agreed with the district court that a skilled artisan not necessarily understood "flat" to mean a C submax / C sub24 ratio of two or less.[92]

The Federal Circuit also upheld the district court's finding that the examples were inadequate in providing support for the C submax / C sub24 < 2 limitation, but based on a different reasoning.[93] Although acknowledging that a C submax / C sub24 ratio greater than two could be derived from some of the examples,[94] the court found that nothing in the examples

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[87] Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1322 (Fed. Cir. 2000)..

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

[89] *Id*. at 1326-27.

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

[91] *Id*. at 1324

[92] *Id*. at 1324-26.

[93] *Id*. at 1326.

[94] *Id*.

emphasized this ratio as "an important defining quality of the formulation," or "even motivate one to calculate the ratio."[95] Therefore, the court found it "immaterial what range for the C submax / C sub24 ratio can be gleaned from the examples when read in light of the claims."[96]

In addition, 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.[97]

III. DISCUSSION

A. *Purdue Pharma* Adds Uncertainty to the Standard of Adequate Written Description

1. *The District Court Erred in Invalidating the '360 Patent on the Grounds of Written Description*

The district court erroneously applied the written description test ruled as "legal error" by the *Vas-Cath* court.[98] As the trial court in *Vas-Cath*, the district court in *Purdue Pharma* was preoccupied by novelty and importance of the limitation. The court found disclosure of the C submax / C sub24 > 2 limitation inadequate because the specification did not indicate that the limitation was one of the design goals or crucial to the invention.[99] But what one possesses is not necessarily what reflects the novelty of the invention, especially in combination claims. The correct standard is not what is novel or important, but whether the specification supports a finding that the inventor possessed what he now claims at the time of the filing.

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[95] *Id*. at 1327.

[96] *Id*. at 1328.

[97] *Id*. at 1329.

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The court also applied an unduly stringent range limitation test. In essence, it requires a disclosure of the exact range claimed. The harm becomes greater when the court deduced the wrong implication from the evidence at trial because of faulty logic. Although not defining any precise range, the "not substantially flat" language in the specification suggested a C submax / C sub24 ratio of *at least* greater than 2 (i.e. a fluctuation of at least greater than 100%). The fact that a C submax / C sub24 ratio of 2 or 2.05 exhibited by some formulations may be considered as "flat" does not contradict, but instead supports, an understanding that a non-flat formulation calls for a C submax / C sub24 ratio greater than 2. That is, a C submax / C sub24 ratio greater than 2.05 (which might be accepted by the court as "not substantially flat") is always greater than 2. When viewed together with the examples that illustrated C submax / C sub24 ratios between 1.48 and 3.43, the specification provided a range of at least greater than 1.48, which well encompassed the C submax / C sub24 > 2 limitation.

2. *The Federal Circuit Failed to Articulate a Workable Test for Adequate Written Description*

Nevertheless, the Federal Circuit found no clear error in the district court's decision.[100]

Perhaps realizing the district court's mistake in deriving the range of limitations, the Federal Circuit declared the range irrelevant. Instead, it solely focused on the erroneous novelty and importance test, finding inadequate disclosure because the specification did not indicate that C submax / C sub24 is a crucial ratio. The court claimed that the examples would not even motivate one skilled in the art to calculate the ratio. However, the purpose of written description is not to influence the conduct of the public, but to shape the behavior of the inventor. It is irrelevant whether a skilled artisan would be motivated to calculate the C submax / C sub24 ratio; what is important is that he would be able to find a ratio to support the claimed limitation if

[100] Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323 (Fed. Cir. 2000).

need to. As the court itself recognized, an evaluation of compliance with the written description requirement starts at the claims. The test is not whether one can deduce from the specification, without knowing about the claims, a list of elements that match the claimed invention, but whether one can confirm the inventor's possession by examining the original specification he disclosed. However, by asking for "blaze marks,"[101] the court in essence required a backward reading—from specification to claims.

B. Forest, Tree, and Trail: Continuing Uncertainty of the Written Description Requirement

Although *In re Ruschig*[102] has been credited as the first post-1956 case that sever the written description requirement from enablement,[103] it inevitably co-mingled the two requirements when it recited its famous, and often borrowed, metaphor, creating a perhaps unanticipated hurdle for establishing a clear written description doctrine.

In *Ruschig*, the Federal Circuit stated:

> It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared— or have not yet been made, which is more likely the case here—to be confronted simply by a large number of unmarked trees.[104]

The *Ruschig* case involved a subgenus claim of a chemical compound. The court found that it was insufficiently disclosed for lack of specificity in the written description.[105] It is reasonable to assume that the court intended to use trails as the metaphor for the claimed compound. Then requiring blaze marks on the trees so that one could be led to the trails is a

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

[102] 379 F.2d 990 (C.C.P.A. 1967).

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[104] *Ruschig*, 379 F.2d at 994-95.

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requirement for enablement. To demonstrate possession of the trail, all that required is a disclosure of the trail itself. Unless where a trail is defined by the surrounding trees, then a disclosure of the particular trees is necessary.

The *Ruschig* metaphor has often been cited in subsequent written description cases, and in some cases reinvented.[106] In *Purdue Pharma*, the court held 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."[107] Instead, "the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure" in order to satisfy the written description requirement.[108] But how can one have possession of a forest without having possession of the trees within? If one adequately disclosed the forest, it is irrelevant whether the later claimed trees had been blaze-marked for their importance. The forest disclosed might encompass prior art, and the limitations to certain trees might be rendered obvious. But that is an entirely different issue. In fact, what the *Purdue Pharma* court should have done is to examine the newly amended claims more closely on anticipation and obviousness grounds.

C. Uncertainty in Written Description Requirement Is Likely to Discourage Inventors in the Pharmaceutical Industry From Seeking Patent Protection

The court's rigid application of written description requirement to biotechnology patents have been criticized for departing "recklessly" from written description precedents, which do not require precise naming of the claimed invention.[109] 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

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

[108] *Id*. at 1326-27.

[109]

unknown function, which may have significant yet unforeseeable impact on future downstream research.[110] 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.[111]

However, the fact remains that the effect of the Federal Circuit's recent written description cases may not stop at just narrowing the scope of the biomedical and chemical patents, but may force inventors in this area to avoid seeking patent protection entirely. Empirical studies have shown that in some R&D intensive industries such as pharmaceutical industry, patent protection provides the second most effective appropriability mechanism, closely trailing secrecy, which is commonly the dominant appropriability mechanism across all industries.[112] The same studies also indicate that one of the top reasons for not applying for a patent is the amount of information disclosed in a patent application.[113] The concern is greater when coupled with the ease of legally inventing around the patent.[114] The approach adopted in recent written description cases, which not only requires extremely specific disclosure, but also limits the scope of the patent to the minimum, will undoubtedly enhance the unwillingness to patent. In fact, the studies by Cohen et al. indicate that importance of secrecy have increased dramatically in recent years.[115] Curiously, although Mansfield's 1986 survey found that the

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

[111] *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).

[112] WESLEY COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) 6 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000).

[113] *Id*. at 14.

[114] *Id*.

[115] *Id*. at 3.

absence of patent protection would have had little impact on the innovative efforts of a majority of firms in most industries, pharmaceutical industry was a "clear exception."[116] Therefore, the court's almost abusive use of written description requirement against biomedical patents may have a much greater negative impact than it intended.

III. CONCLUSION

[116] *Id*. at 2.