PURDUE PHARMA L.P. V. FAULDING INC.

By Limin Zheng

In *Purdue Pharma L.P. v. Faulding Inc.*,[1] the Federal Circuit invalidated the claims of a patent for lack of adequate written description.[2] The court found that the original specification failed to describe a later-amended claim limitation as being the "important defining quality" of the invention,[3] 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] This is the first time that the Federal Circuit has invalidated patent claims on written description grounds when the amended limitation *narrowed*, rather than *broadened*, the scope of the challenged claims.

While the court may have had justifiable concerns about abusive amendment practice, it failed to articulate a workable standard for the written description requirement. The court used a "defining quality" test that was explicitly rejected by its predecessor and was unwarranted by the purpose of the written description requirement. The decision, perhaps itself the result of an unstructured written description jurisprudence, 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. Combined with the court's repeated practice of using the written description requirement to narrow the scope of chemical and biotechnology patents, the *Purdue Pharma* decision is likely to discourage inventors in the pharmaceutical industry from seeking patent protection. Further, the court's recent decisions signal its willingness to overlook the distinction between predictable and unpredictable arts when imposing a stringent written description requirement. As such, the harm of a standardless and unworkable written description requirement goes beyond the chemical and biomedical fields, and threatens to weaken patent rights in general.

1. 230 F.3d 1320 (Fed. Cir. 2000).
2. *Id.* at 1322.
3. *Id.* at 1327.
4. *Id.* at 1324-26.

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 must 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 statutory 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

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

Courts, however, have interpreted the first paragraph of section 112 as mandating three distinctive requirements: (1) the written description requirement; (2) the enablement requirement; and (3) the best mode re-

---

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). As of November 29, 2000, a patent application will be published "after the expiration of a period of 18 months from the earliest filing date" for a subset of patents unless the applicant opts to seek patent protection only in the United States. Act of November 29, 1999, Pub. L. No. 106-113, Div. B, § 1000(a)(9), 113 Stat. 1536 (codified as amended at 35 U.S.C. § 122(b)(1)).

7. 35 U.S.C. §§ 101-103, 112.

8. 35 U.S.C. § 112, ¶ 1.

9. *Id.*

quirement.[10] The enablement requirement ensures effective teaching of the invention to the public to avoid "undue experimentation."[11] The best mode requirement is designed to prevent a patentee from concealing part of the invention while obtaining patent protection for the whole.[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 her infringement of the patent.[14] Since the enactment of the Patent Act of 1952, this purpose is fulfilled by a requirement to disclose claims as set forth in the second paragraph of section 112.[15]

Although no longer necessary as a notice, the written description requirement has been assigned a second function—to preclude patentees from later claiming what they did not possess at the time they filed their applications.[16] It has been standard practice for patent attorneys to file a patent application that broadly describes an invention, and later broaden or narrow the claims through amendments to reflect the results of follow-up research and/or to include a 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]

In *In re Ruschig*,[19] the Federal Circuit's predecessor court promulgated a separate written description requirement independent of the enablement requirement in a patent case involving chemical arts.[20] The court found that section 112 required the patentees to "convey clearly to those skilled

10. *See* 3 DONALD S. CHISUM, CHISUM ON PATENTS § 7.01 (2001).

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

12. *See In re* Gay, 309 F.2d 769, 772 (C.C.P.A. 1962).

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

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

15. 35 U.S.C. § 112, ¶ 2. The earlier patent statutes did not require an inclusion of the claims. *See Vas-Cath*, 935 F.2d at 1561.

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 (2d ed. 2000).

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

19. 379 F.2d 990 (C.C.P.A. 1967).

20. *Id.* at 995-96.

in the art" that they invented the specific chemical compound claimed.[21] Later, in *In re DiLeone*,[22] the court held 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."[23] However, the court's subsequent decisions often intermingled the written description requirement with the enablement requirement, and were criticized for redundancy and lack of clarity.[24]

2. Vas-Cath, Inc. v. Mahurkar

In *Vas-Cath, Inc. v. Mahurkar*,[25] the Federal Circuit examined whether the drawings in the specification provided an adequate written description to support the claim limitation describing the range of sizes of a return lumen in a patent for a double-lumen hemodialysis catheter.[26] Acknowledging the confusion about "what the law of the Federal Circuit is" regarding the written description requirement,[27] the court reviewed the written description doctrine, and affirmatively stated that written description and enablement are two separate and distinct requirements.[28]

The court recognized that written description cases often stressed the fact specificity of the holdings, making the precedential value of the cases extremely limited.[29] However, the court also noted:

> [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.'[30]

---

21. *Id.* at 996. The case involved a subgenus claim of a chemical compound. The court found that the compound was insufficiently disclosed because the general disclosure in the specification encompassed about half a million compounds. *Id.* at 993.

22. 436 F.2d 1404 (C.C.P.A. 1971).

23. *Id.* at 1405.

24. *See* Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (discussing the confusion in the court's decisions concerning the written description requirement).

25. *Id.*

26. *Id.* at 1558. The catheter at issue comprised a pair of joined, semi-circular lumens designed to allow blood to be removed from an artery, processed in an apparatus that removes impurities, and returned close to the place of removal. *Id.*

27. *Id.* at 1560.

28. *Id.* at 1560-64.

29. *Id.* at 1562.

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

Because the written description requirement often comes up in cases where amendments of claims are involved,[31] 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.[32] The court emphasized that it is not required that the specification label what features are "novel or important."[33] However, as will be discussed in Part III.B.1, *infra*, the court has yet to provide guidance as to exactly what is needed to establish that one "had possession" of the invention at the time of the filing.

II. CASE SUMMARY

Purdue Pharma L.P. and the Purdue Frederick Company (collectively "Purdue Pharma") brought suit against Faulding Inc., Faulding Pharmaceutical Co., Faulding Services, Inc., and Purepac Pharmaceutical Co. (collectively "Faulding") in the United States District Court for the District of Delaware, alleging infringement of its United States Patent No. 5,672,360 ("the '360 patent").[34] Faulding challenged the validity of the '360 patent on the grounds of, *inter alia*, inadequate written description.[35] The district court held that the claims of '360 patent were invalid for lack of written description.[36] On appeal, the Federal Circuit affirmed.[37]

A. Facts

Purdue Pharma owned United States Patent No. 5,478,577 ("the '577 patent") for a method of treating pain using a once-a-day morphine formulation.[38] In late 1994, Purdue Pharma filed with the United States Patent and Trademark Office ("PTO") a related patent application, Serial No. 08/578688 ("the '688 application"), which disclosed sustained-release, once-a-day oral morphine formulations for long-lasting and effective pain

31. *See id.* at 1560.

32. 935 F.2d at 1563 (quoting Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575 (Fed. Cir. 1985)).

33. *Id.* at 1565.

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

35. *Id.*

36. *Id.* at 433.

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

38. *Id.* The '577 patent issued December 26, 1995. U.S. Patent No. 5,478,577.

relief.[39] In 1996, Faulding began marketing its sustained-release morphine formulation in the United States.[40] Shortly after, Purdue Pharma brought suit against Faulding for infringement of the '577 patent in the United States District Court for the District of Delaware.[41] After commencement of the suit, Purdue Pharma canceled the pending claims of the '688 application before the PTO and amended the application to add all new claims.[42] The amended application was issued as the '360 patent.[43] Thereafter, Purdue Pharma amended its complaint by dropping claims of infringement of the '577 patent and asserting instead infringement of the '360 patent.[44]

The amended claims in the '360 patent included a newly added limitation requiring that the maximum blood morphine concentration ("C submax") in a patient be more than twice the concentration at about 24 hours ("C sub24") after administration of the formulation (*C submax / C sub24 > 2*), i.e., a blood morphine fluctuation of greater than 100 percent.[45] The specification of the '360 patent did not explicitly disclose the *C submax / C sub24 > 2* limitation, or expressly describe the limitation as one of its design goals.[46] Instead, it characterized the inventive formulation as "designed to provide an initially rapid rate of rise in the plasma concentration of [the morphine]"[47] and as "having a surprisingly fast time to peak drug plasma concentration."[48] 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."[49] In addition, the '360 patent contained five examples of the inventive formulations exhibiting various *C submax /*

39. *See Purdue Pharma*, 230 F.3d at 1322. 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].

40. *Purdue Pharma*, 48 F. Supp. 2d at 426.

41. *Purdue Pharma*, 230 F.3d at 1322.

42. *Id.*

43. *Id.*

44. *Id.* at 1323.

45. *See Purdue Pharma*, 48 F. Supp. 2d at 428.

46. *See* the '360 patent.

47. *Id.*, col. 6, ll. 1-7.

48. *Id.*, col. 6, ll. 10-12.

49. *Id.*, col. 5, ll. 40-47 (emphasis added).

C sub24 ratios, with the lowest ratio illustrated being 1.48 and the highest being 3.43.[50]

B. The District Court's Ruling

The district court held that the claims of the '360 patent were invalid for lack of written description under section 112.[51] Specifically, the court found that the specification failed to convey that the *C submax / C sub24 > 2* requirement was encompassed in the original invention, and consequently held that Purdue Pharma was not in possession of the claimed invention at the time of the original filing.[52]

The court reasoned that the original claim language did not define the invention in terms of concentration ratios, and that the specification did not describe the *C submax / C sub24 > 2* limitation as critical to the invention.[53] The court rejected Purdue Pharma's claim that the limitation was adequately disclosed by the language in the specification describing its inventive formulation as exhibiting a not "substantially flat" concentration curve.[54] According to Purdue Pharma, a skilled artisan would understand "flat" to mean a *C submax / C sub24* ratio of greater than two.[55] However, the court found that "not substantially flat" did not necessarily mean *C submax / C sub24* ratios greater than two or refer to any precise quantifica-

---

50. *Purdue Pharma*, 48 F. Supp. 2d at 430-31. *See also* the '360 patent, cols. 17-18, Tables 4 & 6; cols. 22-23, Tables 11 & 13 (the respective *C submax / C sub24* ratios that could be calculated from the data presented in the tables were 1.48, 1.56, 2.60, 2.98, and 3.43).

51. *See Purdue Pharma*, 48 F. Supp. 2d at 432-33. Faulding challenged the validity of the '360 patent on the grounds of inadequate written description, obviousness, anticipation, and public use. *See id.* at 423. Because the court found the claims invalid for lack of adequate written description, it did not address the other grounds raised by Faulding. *Id.* at 433.

52. *Id.* at 433. The court also found that the '360 patent omitted essential elements of the invention as originally filed, which in the court's view supported a finding that Purdue Pharma was not in possession of the invention at the time of the filing. *See id.* at 431 (citing Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473 (Fed. Cir. 1998)). The Federal Circuit avoided addressing this issue on appeal. This Note will not discuss whether the "omitted essential element" test should be used to determine the adequacy of written description. For a discussion about the omitted essential element test in *Gentry Gallery* and subsequent judicial reactions to the test, see Mark D. Janis, *On Courts Herding Cats: Contending with the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U. J.L. & POL'Y 55, 74-79 (2000).

53. *Purdue Pharma*, 48 F. Supp. 2d at 429.

54. *Id.*

55. *Id.*

tion.[56] In addition, the court found that the isolated examples of formulations with *C submax / C sub24* ratios greater than 2 were insufficient to support the claim limitation because there were also examples of formulations having *C submax / C sub24* ratios less than two.[57] The court found that collectively, the examples established a *C submax / C sub24* range between 1.48 and 3.43.[58]

C. The Federal Circuit's Ruling

The Federal Circuit affirmed the district court's finding that the term "not substantially flat" in describing a concentration curve did not refer to the peak to trough ratio of morphine concentrations, but instead referred to the feature of rapid initial morphine release, because only the latter was described in the specification as critical to the invention.[59] The court held that neither the text nor the examples set forth in the specification provided adequate written description to support the later-amended *C submax / C sub24* > 2 claim limitation.[60]

The court reasoned that nothing in the specification conveyed that the *C submax / C sub24* ratio was a critical aspect of the invention.[61] Moreover, the court concluded that a skilled artisan would not necessarily understand "flat" to mean a *C submax / C sub24* ratio of two or less.[62] Although acknowledging that a *C submax / C sub24* > 2 limitation could be derived from some of the examples,[63] the court found that nothing in the examples emphasized this ratio as "an important defining quality of the formulation," or would "even motivate one to calculate the ratio."[64] 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."[65] Consequently, the court invalidated the claims for lack of written description.[66] In doing so, the Federal Circuit in essence created a new rule that would prevent a patent applicant from narrowing the scope of her

56. *Id.* The court noted that Purdue Pharma's own expert witness characterized a drug exhibiting *C submax / C sub24* > 2 as "flat," and at least one of the publications that Purdue Pharma relied on described a formulation with a *C submax / C sub24* ratio of 2.05 as having "low" fluctuations. *See id.*

57. *Id.*

58. *Id.* at 431.

59. Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1324 (Fed. Cir. 2000).

60. *Id.* at 1324-26.

61. *Id.* at 1324.

62. *Id.* at 1324-26.

63. *Id.* at 1326.

64. *Id.* at 1327.

65. *Id.* at 1328.

66. *Id.*

claims through amendment if the narrowing limitations were not specifically described in the original application as being critical for the invention.

III. DISCUSSION

In *Purdue Pharma*, the Federal Circuit fashioned a "defining quality" test, which requires that the specification, as originally filed, clearly identify each and every amended claim limitation as an important defining quality of the invention.[67] This test is not only at odds with the court's written description precedent, but also unjustified by the purpose of the written description requirement. The decision may be the result of an incoherent written description jurisprudence. The court's continuing use of an inconsistent and often overly-stringent written description requirement leaves inventors, especially those in the pharmaceutical industry, with little incentive to disclose, and is likely to discourage inventors from seeking patent protection. The harm of an inconsistent and unworkable written description doctrine may extend beyond the "unpredictable" arts such as chemical and biological arts, and impose a heavy toll on the patent system.

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

1. Purdue Pharma*'s Defining Quality Test Is Inconsistent with the Written Description Precedents*

In *Purdue Pharma*, the Federal Circuit focused on whether the specification labeled the amended claim limitation as crucial to the invention, finding inadequate disclosure because the specification did not indicate that the *C submax / C sub24* ratio was "an important defining quality of the formulation."[68] Analogizing the pharmacokinetic parameters disclosed in the '360 patent to a forest, the court remarked, "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."[69] Instead, "to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure."[70]

For the first time, the Federal Circuit used the written description requirement to strike down claims, the scope of which was *narrowed* through amendment during patent prosecution. Under the court's rationale,

67. *Id.* at 1327.
68. *Id.*
69. *Id.* at 1326.
70. *Id.* at 1326-27.

one cannot first disclose and claim the entire forest as one's invention, describing the general features of the trees and the surroundings in a way that would demonstrate her possession of the forest and enable others to find the forest, but later change her mind and only claim the part of the forest starting from the second row of the trees. This is particularly odd given the prevalence of dependent claims. Under *Purdue Pharma*, all the dependent claims, if amended during prosecution, must have been individually and separately described in the original application in order to maintain their validity.

Although the court never explicitly explained what kind of "blaze marks" would suffice under a high level of written description scrutiny, it seems that the court equated leaving the "blaze marks" with labeling the features as having the "defining quality." In finding adequate support only where the claim limitations were described by the specification as a "defining quality" of the invention, the court in essence required the patentee to define the invention using the specification, a test expressly rejected by the *Vas-Cath* court.[71]

In *Vas-Cath*, the claim limitation at issue was the range of sizes of a return lumen in a patent for a double-lumen hemodialysis catheter.[72] In finding that the trial court's requirement that the drawings in the specification "describe what is novel or important" constituted legal error, the court noted that the claims did not "recite *only* a pair of semi-circular lumens, or a conical tip, or a ratio at which the tip tapers, or the shape, size, and placement of the inlets and outlets," but claimed "*a double lumen catheter* having a *combination* of those features."[73] Similarly, in the instant case, the patent did not claim *only* the *C submax / C sub24 > 2* limitation, but a formulation for treating pain that had a *combination* of pharmacokinetic parameters, including the *C submax / C sub24 > 2* limitation.[74] Using the court's metaphor, the invention was the forest, which included the tree. No precedent requires that each tree be the defining quality of the claimed forest. An inventor should be free to narrow the scope of the patent, and thereby her own patent rights, by limiting the claims with nonessential elements, so long as the elements are adequately disclosed.[75] To render disclosure of a limitation adequate only when it identifies the limitation as being a critical aspect of the invention is to bar inclusion of any nonessen-

71. Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1565 (Fed. Cir. 1991) (finding "the district court's concern with 'what the invention is' misplaced").

72. *Id.* at 1565-66.

73. *Id.* at 1565 (emphasis original).

74. *See, e.g.*, the '360 patent, Claim 1.

75. *See* Hyatt v. Boone, 146 F.3d 1348, 1353 (Fed. Cir. 1998).

tial elements during prosecution, a judgment that should be left to the inventor, not the court.

2. Purdue Pharma's *Defining Quality Test Is Inconsistent with the Purpose of the Written Description Requirement*

In *Purdue Pharma*, the court acknowledged that the examples provided data from which a skilled artisan could piece together the *C submax / C sub24* > 2 limitation.[76] The court also agreed that two of the formulations disclosed in the '360 patent *possessed* the limitation.[77] Nevertheless, the court considered the examples inadequate because they did not emphasize the *C submax / C sub24 ratio*.[78] The court noted that the examples would not even motivate one skilled in the art to calculate the ratio.[79] Quoting *Vas-Cath*, the court recited that an adequate disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention,[80] but went on to define "reasonable clarity" as allowing one skilled in the art to "immediately discern the limitation at issue" from reading the specification.[81]

The purpose of the written description requirement is not to influence the conduct of the public, but to shape the behavior of the inventor.[82] It is an insurance against fraud rather than a motivation for the public to study the invention. It purports to prevent overreaching by the inventor by ensuring that the inventor "had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him."[83] The goal of an adequate written description, therefore, is to demonstrate possession by providing support for the claimed invention. To that end, it is irrelevant whether a skilled artisan would be motivated to calculate the *C submax / C sub24* ratio or how fast she could derive that ratio from the

---

76. Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1326 (Fed. Cir. 2000).

77. *Id.* at 1327.

78. *Id.* at 1326.

79. *Id.* at 1327.

80. *Id.* at 1323 (quoting Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991)).

81. *Id.* (citing Waldemar Link GmbH & Co. v. Osteonics Corp., 32 F.3d 556, 558 (Fed. Cir. 1994)).

82. *See* Rengo Co. v. Molins Mach. Co., 657 F.2d 535, 551 (3d Cir. 1981) (distinguishing written description requirement and definiteness requirement as the latter shapes the future conduct of persons other than the inventor).

83. *In re* Edwards, 568 F.2d 1349, 1351-52 (C.C.P.A. 1978). Whether a separate written description requirement is necessary to serve that purpose is not always clear. *See* Janis, *supra* note 52, at 69 ("Proponents of the written description requirement have yet to explain exactly what benefits the requirement provides that are not already provided by the enablement requirement.").

specification, even though that might matter for enablement purpose. What is important is that a skilled artisan would be able to find the support for the claimed ratio if she needed to. In the instant case, the support for the *C submax / C sub24 > 2* limitation could be found in two of the formulations disclosed, which, as the court acknowledged, "possessed" the desired characteristic.[84]

Possession of an invention necessarily extends to all aspects of the invention, including those noncritical characteristics. To require disclosure of each limitation and to simultaneously require labeling of each disclosed limitation as a defining quality of the invention in order to demonstrate possession are two standards that cannot easily be reconciled, especially if one were to take the view that an inventor is within her own rights to limit the scope of her invention.

Moreover, an inventor may have disclosed some inherent characteristics of an invention she possessed at the time of filing without even realizing it. For purposes of demonstrating possession, it should be irrelevant whether an inventor appreciates the value or even existence of those characteristics. Therefore, whether a patentee had possession of an invention with certain characteristics should not turn on whether the patentee recognized the importance of those characteristics at the time of the filing.

B. An Obscure Written Description Doctrine

The difficulty in finding a reasonable and well-balanced test for adequate written description perhaps lies in the unfortunately cryptic and incoherent nature of the written description jurisprudence. The Federal Circuit has yet to clearly define what "in possession" means. The written description doctrine, as it has developed, is inconsistent with some patent law doctrines and redundant with others.

1. A Standardless "in Possession" Test

Although the Federal Circuit has at instances made clear what is *not* required to demonstrate possession,[85] what *is* required is a question yet to be answered. The judicially created written description doctrine has been criticized as being "standardless."[86] Although the court's decisions have

84. *Purdue Pharma*, 230 F.3d at 1327 (stating that two of the examples "possessed" the *C submax / C sub24 > 2* characteristic).

85. *See, e.g.*, Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1565 (Fed. Cir. 1991) (holding that the specification does not have to identify the novel or important features of the invention).

86. *See* Janis, *supra* note 52, at 72 ("Although the Federal Circuit nibbles around the edges of the standard, it has rarely, if ever, succeeded in giving the standard any real content.").

often recited that the test for adequate written description is whether it "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter,"[87] the court has yet to breathe life and meaning into the term "in possession." To simply say that "[o]ne shows that one is in 'possession' of the invention by describing the invention"[88] provides no guidance as to how the invention should be described in order to demonstrate possession.

One uncertainty arises from the lack of consensus for what constitutes "reasonable clarity." The Federal Circuit stated that the disclosure as originally filed "does not have to provide *in haec verba* support for the claimed subject matter,"[89] but nevertheless must convey with "reasonable clarity" to one skilled in the art that the patentee was in possession of the invention.[90] On one end of the spectrum, the court used a "support" standard, requiring that the disclosure *reasonably* support the claim limitations.[91] On the other end of the spectrum, the court required that the disclosure must constitute "a full, clear, concise and *exact* description . . . of the invention claimed."[92] Although the Federal Circuit tried to reconcile the two standards as of no real distinction,[93] such a baffling characterization would only confirm that there actually is no standard for an adequate written description. In *Purdue Pharma*, the court went further to require that the disclosure must allow one skilled in the art, "reading the original disclosure, [to] *immediately discern* the limitation at issue in the claims."[94] The multiple standards for "reasonable clarity" prescribed by the Federal Circuit make the "in possession" test unworkable.

---

87. *Vas-Cath*, 935 F.2d at 1563-64 (quoting Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1572 (Fed. Cir. 1985), which in turn was quotes *In re* Kaslow, 707 F.2d 1366, 1375 (Fed. Cir. 1983)).

88. Lockwood v. Am. Airlines, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

89. *Purdue Pharma*, 230 F.3d at 1323 (citing Fujikawa v. Wattanasin, 93 F.3d 1559, 1570 (Fed. Cir. 1996)).

90. *Id.* (citing *Vas-Cath*, 935 F.2d at 1563-64).

91. *See Vas-Cath*, 935 F.2d at 1563 n.6 (citing various Federal Circuit cases that require specification to support the claims).

92. *In re* Wertheim, 646 F.2d 527, 538 (C.C.P.A. 1981) (emphasis added).

93. *See* Hyatt v. Boone, 146 F.3d 1348, 1354 (Fed. Cir. 1998) ("We do not view these various expressions as setting divergent standards for compliance with § 112.").

94. *Purdue Pharma*, 230 F.3d at 1323 (emphasis added) (citing Waldemar Link GmbH & Co. v. Osteonics Corp., 32 F.3d 556, 558 (Fed. Cir. 1994)). But the source of that premise is not entirely clear. *Waldemar* in turn cited *In re* Rasmussen, 650 F.2d 1212, 1215 (C.C.P.A. 1981). *Waldemar*, 32 F.3d at 558-59. *Rasmussen*, however, does not support such a proposition. In fact, *Rasmussen* represents a time when the court viewed enablement and written description as one requirement. *See Rasmussen*, 650 F.2d at 1214 ("Disclosure is that which is taught . . . .").

2. *An Overly Stringent Written Description Requirement Is Hard to Reconcile with the Established Canon That Claims Should be Read to Preserve Their Validity*

The *Purdue Pharma* decision is in keeping with the Federal Circuit's approach to patent claims involving chemical or genetic material, where the court often applied a heightened "in possession" test in examining the validity of the claims.[95] Such an unduly stringent written description requirement is at odds with the long-standing judicial practice of construing the claims "so as to sustain their validity."[96] For example, a court is to construe a claim element narrowly in order to preserve its validity over prior art.[97] And under a related rule, if a claim is subject to two viable alternative interpretations, the narrower one should apply.[98] It is a waste of the court's and the parties' resources to ask a court to go through lengthy claim construction and construe the claim narrowly to preserve its validity, but only to invalidate it later because the written description supports, in *Purdue Pharma*'s case, a broader interpretation of the claim.

3. *Redundancy of a Separate Written Description Requirement Independent of the Enablement Requirement*

The Federal Circuit has attempted to justify having a separate written description requirement on grounds ranging from a historical notice function to the contemporary role as a safeguard against overreaching.[99] However, as one commentator argues, the Federal Circuit has yet to demonstrate a compelling justification for recognizing a distinct written descrip-

---

95. *See infra* notes 114-19 and accompanying text.

96. Carman Indus., Inc. v. Wahl, 724 F.2d 932, 937 n.5 (Fed. Cir. 1983) (citing *Klein v. Russell*, 86 U.S. 433, 466 (1874); Turrill v. Michigan S. & N.I.R.R. Co., 68 U.S. 491, 510 (1864)).

97. *See* Apple Computer, Inc. v. Articulate Sys., Inc., 234 F.3d 14, 24 (Fed. Cir. 2000) (acknowledging that "claims should be read in a way that avoids ensnaring prior art if it is possible to do so") (quoting Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1556 (Fed. Cir. 1997)).

98. *See* Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1581 (Fed. Cir. 1996). The court stated:

> [W]here there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning.

Id.

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

tion requirement.[100] The redundancy of the two disclosure doctrines may have contributed to the court's continuing struggle in separating the two in practice.[101]

A separate written description requirement independent of enablement may be at odds with the Supreme Court's decision in *Pfaff v. Wells Electronics, Inc.*[102] In *Pfaff*, the Court held that in addition to evidence of commercial marketing, the invention must be "ready for patenting" in order to invoke the statutory on-sale bar of section 102(b).[103] The latter condition may be satisfied "by proof that . . . the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention."[104] The Court found that the drawings the patentee sent to the manufacturer was sufficiently enabling, and thus "*fully disclosed* the invention," and triggered the on-sale period even though invention was not yet reduced to practice.[105] Therefore, a separate written description requirement for patentability possibly renders a claim invalid, while the same enabling specification is enough under *Pfaff* to trigger the statutory on-sale bar. This is a peculiar result.

The goal of the patent system is to promote science and technology,[106] that is, to encourage a free flow and exchange of ideas that can be readily converted into creating useful things. To that end, what the patent law should be concerned with is whether the patent effectively teaches the making and use of the useful things. In that regard, if the disclosure can enable one skilled in the art to "make and use the same,"[107] the patentee should be presumed to have possession of the invention, which may be overcome by clear and convincing evidence that the patentee had not actually thought of the invention at the time of filing.

---

100. *See* Janis, *supra* note 52, at 62-69 (criticizing the distinction made by the Federal Circuit between written description and enablement as artificial).

101. *See* Harris A. Pitlick, *The Mutation on the Description Requirement Gene*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 209, 222-23 (1998) (criticizing Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997), by stating that the court "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").

102. 525 U.S. 55 (1998) (finding that an invention was offered for sale and ready for patenting because the drawings the plaintiff sent to the manufacturer fully disclosed the invention).

103. *Id.* at 67.

104. *Id.* at 67-68.

105. *Id.* at 68.

106. U.S. CONST. art. I, § 8, cl. 8.

107. 35 U.S.C. § 112, ¶ 1.

Arguably, the court may be concerned with fairness issues. It may seem unfair, as in *Gentry Gallery, Inc. v. Berkline Corp.*,[108] for a patentee to broaden the claims through amendment just to cover its competitor's products.[109] However, the final result in *Gentry* may remain the same under a rule that a patentee is presumed to have had possession of the invention under an enabling disclosure unless there is clear and convincing evidence that he had not actually thought of the invention at the time of filing. Unlike in *Purdue Pharma*, where the inventors testified that one of the specific goals was to develop a formulation that would provide a *C submax / C sub24 ratio* of greater than two,[110] in *Gentry*, the inventor admitted that he did not even think of placing the controls outside the console before he learned about the competitors' designs.[111] In addition, in *Gentry*, a related enablement argument could be made to invalidate the claim in that the disclosure did not enable one skilled in the art to make sofas with controls located other than on the console because the disclosure in effect specifically directed a skilled artisan *not* to do so.[112]

Moreover, patent law is not all about fairness. It may seem at least equally unfair that patent law gives a patentee the right to exclude those who independently come up with an identical or substantially similar invention from making and using that invention, which might even be a better one than the patentee's. But the law must compromise on fairness to achieve its constitutional goal—to promote innovation in science and technology.[113]

---

108. 134 F.3d 1473 (Fed. Cir. 1998)

109. *See id.* In *Gentry*, the patent at issue involved a sectional sofa with side-by-side recliners separated by a fixed console. *Id.* at 1475. The specification disclosed that the console was to accommodate the controls for both the reclining seats, and specifically limited the control to the console as part of the objective of the invention. *Id.* at 1478. The broadest original claim was directed to a sofa comprising "control means located upon the center console." *Id.* at 1479. The claims were broadened during prosecution to include placing the controls outside the console after the inventor learned that the competitors were so locating the recliner controls. *Id.* The court invalidated the claims on grounds of written description, finding that the original disclosure did not adequately support the claims in which the location of the control was other than the console. *Id.*

110. Purdue Pharma, L.P. v. F.H. Faulding & Co., 48 F. Supp. 2d 420, 424 (D. Del 1999) (citing the transcripts).

111. *Gentry*, 134 F.3d at 1479.

112. *Id.*

113. U.S. CONST. art. I, § 8, cl. 8.

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

Biotechnology and chemical patents have received more than their fair share of a harsh written description inquiry. The Federal Circuit's decisions since *Amgen, Inc. v. Chugai Pharmaceutical, Co.*[114] have applied a heightened level of scrutiny under the written description requirement to "unpredictable arts" involving DNA sequences.

Drawing a line between predictable and unpredictable arts, 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."[115] 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 were inadequate for the purpose of the written description requirement.[116]

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.*[117] 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.[118] 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."[119]

The court's rigid application of the written description requirement to biotechnology patents has been criticized as departing recklessly from written description precedents.[120] On the other hand, the decisions have

---

114. 927 F.2d 1200 (Fed. Cir. 1991).

115. *Id.* at 1206.

116. *See id.* Similarly, in *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993), 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. *Id.* at 1170-71.

117. 119 F.3d 1559 (Fed. Cir. 1997).

118. *Id.* at 1567-68.

119. *Id.* at 1569.

120. *See* Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 649 (1998).

been viewed as necessary steps to ensure that overly broad patent rights are not granted to DNA sequences of unknown function, which may have a significant, yet unforeseeable impact on future downstream research.[121] Indeed, granting overly broad patent rights to upstream research products 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.[122]

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, thereby depriving the inventors of the most, and perhaps the only, effective protection. Although secrecy is commonly the dominant appropriability mechanism across all industries,[123] trade secret protection may be a weak form of protection, especially in this day and age, where information and communication technology makes it difficult to conceal one's research advancements within the walls of an institution. In the biotechnology and pharmaceutical industry, research efforts usually require a large amount of collaborative work. Coupled with the increased mobility of employees, trade secrecy may be hard to manage. Moreover, trade secret law does not protect against reverse engineering, which would allow a pharmaceutical company to figure out, and then legally make and use its competitor's newest drug formulations with relatively little effort and expense. Therefore, trade secret protection may not give a pharmaceutical company enough incentive to invest in research and development ("R&D").

In theory, patent law provides incentive to invest in innovation by allowing the inventor to appropriate fully the economic returns of her invention.[124] Empirical studies have shown that in some R&D intensive industries such as the pharmaceutical industry, patent protection provides the second most effective appropriability mechanism, closely trailing se-

121. *See* Margaret Sampson, *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, 1259-61 (2000).

122. *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); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

123. WESLEY M. 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).

124. *See* MERGES, *supra* note 17, at 137.

crecy.[125] 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, because it allows a competitor to easily and legally invent around the patent.[126] The approach adopted by the Federal Circuit in recent written description cases, which not only requires an extremely specific disclosure, but also limits the scope of the patent to the minimum, will undoubtedly deter pharmaceutical companies from seeking patent protection. In fact, the studies by Wesley Cohen et al. indicate that the importance of secrecy has increased dramatically in recent years, albeit the weak protection it provides.[127] Curiously, although empirical studies found that the absence of patent protection would have had little impact on the innovative efforts of a majority of firms in most industries, the pharmaceutical industry was a "clear exception."[128] Therefore, the court's almost abusive use of written description requirement against biomedical patents may have a much greater negative impact than it intended.

D. The Uncertainty Generated by an Amorphous Written Description Doctrine May Harm the Patent System

The biotechnology cases may reflect the court's unwillingness to grant broad patents to unpredictable arts. However, some commentators have suggested that *Gentry Gallery* signals that predictability of the arts may have nothing to do with how strictly the court applies the written description requirement.[129]

A poorly developed doctrine without a workable standard, the written description requirement generates grave uncertainty that would impose a huge cost to the society as well as the patent system.[130] The PTO, for example, has been burdened by the court's written description requirement, and struggled with the task of coming up with a better-defined "posses-

125. COHEN, *supra* note 123, at 6.

126. *Id.* at 14.

127. *Id.* at 3.

128. *Id.* at 2.

129. *See, e.g.*, Cynthia M. Lambert, Note, *Gentry Gallery and the Written Description Requirement*, 7 B.U.J. SCI. & TECH. L. 109, 139 (2001) (concluding that *Gentry* is perceived as unifying the standard of all arts to the stricter written description standard that was previously only applied to unpredictable arts); Laurence H. Pretty, *The Recline and Fall of Mechanical Genus Claim Scope Under "Written Description" in the Sofa Case*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 469, 479-80 (commenting that it remains to be seen whether *Gentry* will become an influential precedent in permitting a stringent and limiting written description requirement in predictable arts).

130. *See* Janis, *supra* note 52, at 69.

sion" standard in its written description requirement guidelines.[131] However, as one commentator remarked, the PTO Guidelines "do little to bring the written description requirement out from the shadow of enablement."[132] And the PTO's "admirable effort to create something from nothing"[133] is unlikely to pay off. As its Director of biotechnology admitted, "Every time I think we're getting a handle on biotech, something new crops up."[134]

A more serious threat is the judges' ability to use written description as a means to serve policy ends as they see fit with little judicial restraint. The Federal Circuit has reiterated that written description inquiry "must be assessed on a case-by-case basis."[135] The court even went so far to declare that "the precedential value of cases in this area is extremely limited."[136] Given the almost unchecked freedom to make law granted by an unstructured and standardless doctrine, judges might be tempted to use the written description requirement to invalidate claims even when the facts should have been assessed on other legal grounds.

This is undesirable even if the judges have justified policy concerns. It is Congress' job to make law, not the courts'. Courts often reveal their zealousness to invalidate patents on written description grounds in cases where the patentee broadens the claims in order to exclude a competitor's product, like *Gentry*, or where the patentee narrows the claims with the intent to avoid prior art, like *Purdue Pharma*. To be sure, it is not prohibited to amend claims with an intent to exclude a competitor's product that the inventor has learned about, or to avoid prior art that the inventor has discovered during the prosecution.[137] In fact, this is what amendment prac-

131. *See, e.g.*, Guidelines for the Examination of Patent Applications Under 35 U.S.C.§ 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1101 (2001) (commenting on whether actual reduction to practice is required for demonstration of possession) [hereinafter the "Guidelines"]. *See also* Eli Loots, Note, *The 2001 USPTO Written Description Guidelines and Gene Claims*, 17 BERKELEY TECH. L.J. 117 (2002).

132. Janis, *supra* note 52, at 71.

133. *Id.*

134. Anthony Shadid, *Battle Turns Fierce Over Biotech Patents Agency Struggles Over What's Covered and What Rights are Offered*, BOSTON GLOBE, July 18, 2001, at D1 (quoting the PTO's Director of Biotechnology Division).

135. Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323 (Fed. Cir. 2000) (citing Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991)).

136. *Vas-Cath*, 935 F.2d at 1562 (quoting *In re* Driscoll, 562 F.2d 1245, 1250 (C.C.P.A. 1977)). This perhaps defeats the purpose of the Congress in creating the Court of Appeals for the Federal Circuit—to establish a more uniform and coherent body of patent law.

137. *See* Kingsdown Med. Consultants, Ltd., v. Hollister Inc., 863 F.2d 867, 874 (Fed. Cir. 1988).

tice is for. Undoubtedly, there are attorneys who will abuse the amendment practice. But unless the court can develop a clear and workable written description doctrine, a more prudent way for the court to channel its disapproval of such practice is to expand or redefine the scope of the inequitable conduct doctrine.

IV. CONCLUSION

Like all written description cases, *Purdue Pharma* may have little precedential value according to the Federal Circuit.[138] But that in itself does not eliminate the harm. The decision adds to the incoherency of the written description jurisprudence. Together with the recent line of cases, the decision represents judicial hostility towards amendment practice and a trend towards using the written description requirement to unduly narrow the scope of a patent. The court's willingness to expand the use of a standardless written description requirement will create great uncertainty, which in turn will impose an unjustifiably high cost on the patent system.

138. *See Vas-Cath*, 935 F.2d at 1562 (stating that the precedential value of cases in the written description area is extremely limited).