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The Patent Written Description Requirement: A Requirement in Search of a Description

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THE PATENT WRITTEN DESCRIPTION REQUIREMENT: A REQUIREMENT IN SEARCH OF A DESCRIPTION

Darlene M.J. Staines*

Innovation often requires a hefty investment of time and money. The patent system exists to incentivize innovation by granting inventors the exclusive use of their invention for a set period of time. In return, the public receives the benefit of the inventor’s knowledge, as well as the use of the invention once the exclusivity period ends. One of the hurdles for obtaining a patent is the written description requirement, which demands that the inventor disclose enough information to prove that they actually invented what they are seeking patent protection for. This requirement serves to prevent an undeserving “inventor” from obtaining the right to exclude the public from using a technology that they did not actually invent.

The written description requirement has a reputation for being poorly defined and unpredictable. Recently, this requirement has become a popular target for parties defending against patent infringement suits, and patent practitioners have raised concerns that the U.S. Court of Appeals for the Federal Circuit is applying an increasingly heightened standard. This Note discusses two recent cases in which the Federal Circuit invalidated patents for insufficient written descriptions. Each case considered a patent covering a drug for multiple sclerosis that the innovating party sought to assert against competitors hoping to manufacture lower-cost generics. This Note explores the Federal Circuit’s reasoning for invalidating the patents and evaluates their treatment in light of precedent. It then proposes that the Federal Circuit establish a more concrete standard for the written description by adopting a goal-oriented approach to the requirement.

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INTRODUCTION

To promote innovation, the patent system must strike the correct balance between incentivizing inventors and benefiting society.¹ To ensure that patent rights are not granted to someone undeserving, an inventor must

1. See *infra* Part I.A.1.

demonstrate that they were in full possession of their claimed invention when they filed their patent application.² This is the purpose of the written description requirement, which was recently at the heart of two cases before the U.S. Court of Appeals for the Federal Circuit, both of which coincidentally involved treatments for multiple sclerosis (MS).³

MS is a chronic autoimmune disorder that attacks the central nervous system (CNS), resulting in severe neurological disability.⁴ It is estimated that close to one million people in the United States, and over two million worldwide, are affected.⁵ Most commonly, MS develops in young adulthood and progressively impairs neurological function over the course of decades.⁶

The most frequent form of MS, relapsing-remitting MS (RRMS), is characterized by periods of disability, followed by recovery; however, over time, the disease transitions to a secondary-progressive form, in which impairments persist and become progressively worse.⁷ Currently, the cause of MS is not understood, and there is no cure.⁸ Available treatments, called disease-modifying therapies (DMTs), act by reducing the immune system's attack on the CNS.⁹

Because MS is a chronic disorder that frequently begins in early adulthood, persons with RRMS often live with the disease for more than four decades.¹⁰ Considering that the median cost of brand-name DMTs is nearly \$94,000 per year, the treatment of MS presents a significant financial burden.¹¹ One way

2. See *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

3. *Biogen Int'l GmbH v. Mylan Pharms. Inc. (Biogen II)*, 18 F.4th 1333 (Fed. Cir. 2021), *reh'g denied*, 28 F.4th 1194 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 112 (2022); *Novartis Pharms. Corp. v. Accord Healthcare, Inc. (Novartis II)*, 21 F.4th 1362 (Fed. Cir. 2022), *vacated*, 38 F.4th 1013 (Fed. Cir. 2022), and *reh'g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom. Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023).

4. See Carolyn Goldschmidt & Marisa P. McGinley, *Advances in the Treatment of Multiple Sclerosis*, 39 NEUROLOGIC CLINICS 21, 21 (2021); Haley E. Titus, Yanan Chen, Joseph R. Podojil, Andrew P. Robinson, Roumen Balabanov, Brian Popko & Stephen D. Miller, *Pre-clinical and Clinical Implications of "Inside-Out" vs. "Outside-In" Paradigms in Multiple Sclerosis Etiopathogenesis*, FRONTIERS CELLULAR NEUROSCIENCE, Oct. 2020, at 1, 1–2.

5. See Goldschmidt & McGinley, *supra* note 4, at 21.

6. See Titus et al., *supra* note 4, at 2.

7. See Goldschmidt & McGinley, *supra* note 4, at 21 (reporting that RRMS affects 85 percent to 90 percent of MS patients); Titus et al., *supra* note 4, at 2 (reporting that RRMS affects 85 percent of MS patients).

8. See Titus et al., *supra* note 4, at 1–2 (“Although autoimmunity, inflammatory demyelination and neurodegeneration underlie MS, the initiating event has yet to be clarified.”).

9. See *id.*

10. See Hanne Marie Bøe Lunde, Jörg Assmus, Kjell-Morten Myhr, Lars Bø & Nina Grytten, *Survival and Cause of Death in Multiple Sclerosis: A 60-Year Longitudinal Population Study*, 88 J. NEUROLOGY NEUROSURGERY & PSYCHIATRY 621, 622–23 (2017) (reporting a median survival time of 42.8 years from RRMS onset).

11. *Affordability of and Access to MS Medications*, NAT'L MULTIPLE SCLEROSIS SOC'Y, <https://www.nationalmssociety.org/Get-Involved/Advocate-for-Change/Current-Advocacy-Issues/Affordability-of-and-Access-to-MS-Medications> [https://perma.cc/6T97-ESUY] (last visited Nov. 3, 2023) (noting the price as of February 2022).

of bringing the cost down is to promote the approval and manufacture of generic versions of brand-name drugs.¹²

The process of bringing generics to market is facilitated by the Drug Price Competition and Patent Term Restoration Act of 1984,¹³ also known as the Hatch-Waxman Act. The Hatch-Waxman Act provides an expedited pathway to obtain Food and Drug Administration (FDA) approval for generic versions of already-approved drugs.¹⁴ If the generic manufacturer can demonstrate that their version of the drug is absorbed into the body at a similar rate and in similar amounts as the approved version, the generic is considered to be the “bioequivalent” of the approved drug and need not go through additional clinical trials, saving both time and money for the generic manufacturer.¹⁵

In addition to FDA approval, patent protection is also an obstacle to bringing generic drugs to market.¹⁶ Although the goal of the patent system is to promote innovation,¹⁷ some criticize the biopharmaceutical industry in particular for abusing the patenting process to overprotect their products, thereby delaying patient access to generics.¹⁸ The Hatch-Waxman Act provides a process for generic manufacturers to challenge patents that they believe are invalid.¹⁹ However, they must notify the patent-holder of their intent, thereby triggering a forty-five-day window in which the patent-holder can sue for infringement.²⁰

Recently, the patents for two RRMS treatments, Biogen’s Tecfidera^{®21}—the first oral DMT approved by the FDA for RRMS²²—and Novartis’s Gilenya,²³ were successfully challenged under the Hatch-Waxman Act. In both cases, invalidity was based on a failure to satisfy the written description requirement under 35 U.S.C. § 112(a), which requires inventors to disclose sufficient information in a patent application to demonstrate that they had

12. See Exec. Order No. 14,036, 86 Fed. Reg. 36987, 36997 (July 14, 2021).

13. Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of the U.S.C.).

14. See 21 U.S.C. § 355(j); Winston Zou, *Fixing the Hatch-Waxman Imbalance: A Proposed Solution to the Problem Created by Inter Partes Review*, 47 AIPLA Q.J. 635, 642 (2019).

15. See Zou, *supra* note 14, at 642.

16. Blake Brittain, *U.S. Senators Ask Regulators to Clear Drug Patent ‘Thickets,’* REUTERS (June 8, 2022, 8:43 PM), <https://www.reuters.com/legal/litigation/us-senators-ask-regulators-clear-drug-patent-thickets-2022-06-08/> [<https://perma.cc/T4JY-LF42>].

17. See *infra* Part I.A.1.

18. See Exec. Order No. 14,036, 86 Fed. Reg. 36987, 36997 (July 14, 2021); Brittain, *supra* note 16.

19. See Zou, *supra* note 14, at 644.

20. See *id.* at 644–45. If the patent-holder does not respond, the FDA may approve the ANDA regardless of patent protection. See *id.* at 645.

21. See *Biogen II*, 18 F.4th 1333, 1335–36 (Fed. Cir. 2021), *reh’g denied*, 28 F.4th 1194 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 112 (2022).

22. See Goldschmidt & McGinley, *supra* note 4, at 22.

23. See *Novartis Pharms. Corp. v. Accord Healthcare, Inc. (Novartis III)*, 38 F.4th 1013, 1015 (Fed. Cir. 2022), *reh’g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom. Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023).

possession of the invention at the time the application was filed.²⁴ The Federal Circuit's decisions in these two cases have led some to ask if the standard for satisfying the written description requirement is becoming more stringent.²⁵

Although the U.S. Supreme Court appears disinclined to address the question of the written description requirement,²⁶ the U.S. Patent and Trademark Office (USPTO) recently requested public comments on potential policy changes, including those impacting the written description requirement.²⁷ However, any policy changes by the USPTO will be interpreted by the courts,²⁸ particularly the Federal Circuit.²⁹ Ultimately, a balance must be struck: patent protection must be robust enough to encourage inventors to pursue innovative solutions without also facilitating abuse of the system to overextend monopolies.³⁰ In the case of MS, for example, patent protection can incentivize investment in researchers seeking to move beyond suppressing the immune system toward quieting the autoimmune response, halting neurodegeneration, and encouraging repair.³¹ Overly strong protection, however, drives up drug costs and reduces the availability of already-existing treatments.³²

The written description requirement appears to be emerging as a favored tool for challenging existing patents,³³ and its correct application will likely play a role in maintaining the proper balance of patent protection.³⁴ Part I of this Note describes the purpose and structure of a patent and how the written description requirement emerged as a distinct criterion for the validity of a patent. Part II discusses two recent cases before the Federal Circuit, *Biogen*

24. See *infra* Part I.A.3.

25. See *infra* Part II.C.1.

26. *Biogen Int'l GmbH v. Mylan Pharms. Inc. (Biogen IV)*, 143 S. Ct. 112 (2022), *denying cert. to* 18 F.4th 1333 (Fed. Cir. 2021); *Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023), *denying cert. to* *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013 (Fed. Cir. 2022); Chris Holman, *After Granting Certiorari in Enablement Case, Supreme Court Declines Opportunity to Address Written Description*, PATENTLY-O (Nov. 11, 2022), <https://patentlyo.com/patent/2022/11/certiorari-opportunity-description.html> [<https://perma.cc/FJW4-8PAL>].

27. See *infra* Part II.C.2.

28. See *infra* Part III.A.3.

29. Cf. *infra* note 156 and accompanying text (demonstrating that USPTO practice follows court guidance, and that the court that has provided the greatest input on the written description standard thus far has been the Federal Circuit).

30. See Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. 60130, 60130 (proposed Oct. 4, 2022).

31. See Titus et al., *supra* note 4, at 2.

32. See Exec. Order No. 14,036, 86 Fed. Reg. 36987, 36997 (July 14, 2021); Brittain, *supra* note 16.

33. See Samantha Handler, *Biogen's Rehearing Denial Lays New Hurdles for Pharma Patents*, BLOOMBERG L. (Mar. 18, 2022, 5:10 AM), <https://news.bloomberglaw.com/ip-law/Biogens-rehearing-denial-lays-new-hurdles-for-pharma-patents> [<https://perma.cc/EH54-5M3R>].

34. See Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. at 60130–31, 60133.

*Int'l GmbH v. Mylan Pharms. Inc. (Biogen II)*³⁵ and *Novartis Pharms. Corp. v. Accord Healthcare, Inc. (Novartis III)*,³⁶ in which the written description requirement was used to challenge patent validity, as well as practitioner reactions to the rulings and proposed changes to patent practice. Lastly, Part III evaluates the written description requirement's usefulness, assesses whether the recent cases departed from precedent, and proposes how the courts may define a more concrete standard that will assist patent practitioners in drafting valid patents.

I. ORIGIN AND PURPOSE OF THE WRITTEN DESCRIPTION REQUIREMENT

The patent written description requirement emerged through the common law, and support for its existence in the text of the patent statute is less than obvious.³⁷ Part I.A describes the origin of the written description requirement. Part I.B explains its importance to the patent prosecution process. Part I.C discusses the Federal Circuit, the court that has provided the most detailed analysis of the written description requirement.³⁸

A. *The Purpose and Anatomy of a Patent*

The American patent system is as old as the country itself, established with the goal of promoting scientific progress.³⁹ Part I.A.1 traces the development of American patent law, Part I.A.2 describes the requirements for obtaining a patent, and Part I.A.3 explores the written description requirement in particular.

1. The Patent Bargain

The patent system is often presented as a bargain between the inventor and the public.⁴⁰ In this bargain, or *quid pro quo*,⁴¹ the inventor is granted exclusive use of an invention for a time in return for making the details of the invention available to the public for future use.⁴² The inventor benefits from the lack of competition in the marketplace and is able to charge a higher price to compensate for the “labor, toil, and expense” that went into developing the invention.⁴³ This promise of compensation is intended to

35. 18 F.4th 1333 (Fed. Cir. 2021), *reh'g denied*, 28 F.4th 1194 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 112 (2022).

36. 38 F.4th 1013 (Fed. Cir. 2022), *reh'g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom.* *Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023).

37. *See infra* Part I.A.3.

38. *See infra* note 156 and accompanying text.

39. *See* U.S. CONST. art. I, § 8, cl. 8.

40. *See, e.g.*, *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989); *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998).

41. *See, e.g.*, Sean B. Seymore, *Symposium: The Disclosure Function of the Patent System*, 69 VAND. L. REV. 1455, 1455 (2016).

42. *See Pfaff*, 525 U.S. at 63–64 (quoting *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 533–34 (1870)); Seymore, *supra* note 41, at 1455.

43. *See Seymour*, 78 U.S. (11 Wall.) at 533.

motivate inventors not only to create “new and useful improvements” but also to share with the public sufficient technical information about their invention, such that the discovery may “promote the progress of science and the useful arts.”⁴⁴

The exchange of exclusivity for the promotion of technological progress is embedded in the U.S. Constitution’s Intellectual Property Clause,⁴⁵ which grants Congress the power to draft laws for granting and regulating patents.⁴⁶ This clause has been implemented by a series of legislative acts, beginning with the Patent Act of 1790,⁴⁷ which required the inventor to produce “a specification in writing . . . so particular . . . not only to distinguish the invention” from previously known inventions, “but also to enable” a “person skilled in the art . . . to make . . . or use” it.⁴⁸

Although the wording evolved over time, each patent act that followed, prior to the modern form, continued to require a patent applicant to submit a “written description” of the invention intended to “distinguish” it from prior knowledge and to “enable” a “person skilled in the art” to make use of the discovery.⁴⁹ To secure the privilege of excluding others from the use of an invention, therefore, an inventor must not only explain the technology well enough for another with knowledge of the field to reproduce it,⁵⁰ but also define the boundaries of the technology, just as a surveyor would define the “metes and bounds” of a plot of land.⁵¹

In 1952, Congress passed a new patent act that streamlined and modernized patent law, codifying it in Title 35 of the U.S. Code.⁵² Yet, the essential patent bargain—exclusivity in return for disclosure—remained the same.⁵³ For an inventor to fulfill their side of the patent bargain, they must submit a document, known as a specification, to the USPTO.⁵⁴ If the USPTO

44. *See id.*

45. *See* U.S. CONST. art. I, § 8, cl. 8; *see also* Edward C. Walterscheid, *To Promote the Progress of Science and Useful Arts: The Background and Origin of the Intellectual Property Clause of the United States Constitution*, 2 J. INTELL. PROP. L. 1, 3 (1994). This clause is also known as the Progress Clause or the Patent and Copyright Clause. *See* David L. Cohen, *Figueroa v. United States: Does the Constitution Require Patent Fees to Stay with the Patent Office?*, 22 INTELL. PROP. L. NEWSL., No. 2, Winter 2004, at 4 n.5. Sometimes, it is referred to as the “Patent Clause.” *See, e.g., Bonito Boats*, 489 U.S. at 146.

46. *See* *Return Mail, Inc. v. U.S. Postal Serv.*, 139 S. Ct. 1853, 1859 (2019).

47. Ch. 7, 1 Stat. 109.

48. *See id.* at 110.

49. *See* Patent Act of 1793, ch. 11, 1 Stat. 318; Patent Act of 1836, ch. 357, 5 Stat. 117; Patent Act of 1870, ch. 230, 16 Stat. 198; *see also In re Barker*, 559 F.2d 588, 592 (C.C.P.A. 1977) (following the evolution of patent statute language).

50. *See, e.g., In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

51. *See In re Vamco Machine & Tool, Inc.*, 752 F.2d 1564, 1577 n.5 (Fed. Cir. 1985); MPEP § 2173.02 (9th ed. Rev. 10, June 2020).

52. Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792 (codified as amended at 35 U.S.C. §§ 1–376); *see* L. James Harris, *Some Aspects of the Underlying Legislative Intent of the Patent Act of 1952*, 23 GEO. WASH. L. REV. 658, 660 (1955).

53. *See, e.g., McRo, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1099–100 (Fed. Cir. 2020).

54. *See, e.g., id.*; 35 U.S.C. § 112(a).

is satisfied with the disclosure, the inventor is awarded a patent⁵⁵—the right to exclude others from using the invention for twenty years from the date the original application was filed.⁵⁶

2. The Patent Specification

The first patent issued by the U.S. government was a simple document: the specification was only one paragraph long.⁵⁷ Modern patents are more complex; at the very least, three elements are required⁵⁸: the specification, drawings (if necessary),⁵⁹ and an oath that the named inventor or joint inventors believe that the invention originated with them.⁶⁰ The specification, in turn, is divided into two sections: the written description and the claims.⁶¹

Although the written description comprises the bulk of the specification, the claims, found in a numbered list at the conclusion of the specification,⁶² are the heart of the patent.⁶³ The claims define the “metes and bounds” of the inventive idea,⁶⁴ “ensur[ing] that the public can understand the forbidden territory of the claims.”⁶⁵ In order to serve as proper notice of the boundaries of a patent, each distinguishing characteristic of an invention—called “limitations” or “elements”⁶⁶—that the inventor wishes to protect must be included in a claim.⁶⁷ Omitting an important limitation would result in a claim that can be read too broadly.⁶⁸

Each claim then serves as a standard by which to enforce the exclusion rights granted by the patent.⁶⁹ When assessing infringement, the court looks to see if every limitation in an individual claim is replicated in an allegedly infringing product, either exactly as stated in the claim or in a way that is essentially equivalent to the limitation; only if all of the limitations are

55. *See id.* § 151(a).

56. *See id.* §§ 154(a), 271(a).

57. *See* U.S. Patent No. X000001 (issued July 31, 1790), available at <https://patentimages.storage.googleapis.com/11/12/53/5cf8e215c6783c/USX1.pdf> [<https://perma.cc/Q6D4-GDGT>].

58. *See* 35 U.S.C. § 111(a)(2).

59. *See id.* § 113.

60. *See id.* § 115 (describing the inventor’s oath).

61. *See id.* § 112(a)–(b).

62. *See* JEFFREY G. SHELDON, *HOW TO WRITE A PATENT APPLICATION* § 8:3.6 (3d ed. 2023), PLI PLUS 151671.

63. *See id.* § 8:1.1 (“The claims are the most important part of the patent application.”).

64. *See* MPEP § 2173.02 (9th ed. Rev. 10, June 2020); *In re Vamco Machine & Tool, Inc.*, 752 F.2d 1564, 1577 n.5 (Fed. Cir. 1985).

65. SHELDON, *supra* note 62, § 8:2.1.

66. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 563 n.1 (Fed. Cir. 2000).

67. *See* SHELDON, *supra* note 62, § 8:6.5 (“The claims are supposed to give fair notice to competitors of the scope of the invention.”).

68. *See id.* § 8:2.1 (“[T]he claims cannot be broader than the disclosed invention by omitting a required element of the invention.”).

69. *See* 3 DONALD S. CHISUM, *CHISUM ON PATENTS* § 8.03 (2023).

present in a product can infringement be found.⁷⁰ These two purposes of a claim, giving notice and serving as a standard for judging infringement, combine to form the “definiteness” requirement of claims.⁷¹

Although much of the focus during both drafting⁷² and litigation⁷³ is on the claims, the written description section of the specification provides a vital contribution to the patent bargain.⁷⁴ The statutory requirements for the written description are found in § 112(a) of Title 35,⁷⁵ which requires a “written description of the invention” that is detailed enough “to enable any person skilled in the art . . . to make and use the same,” and includes “the best mode contemplated by the inventor.”⁷⁶ Though § 112(a) is only one sentence long, courts have found three separate disclosure requirements within: enablement, best mode, and written description.⁷⁷

The enablement requirement is the inventor’s contribution to the patent bargain.⁷⁸ To satisfy the enablement requirement, the specification must provide enough details for a “person having ordinary skill in the art” (PHOSITA)—patent law’s version of the hypothetical reasonable person⁷⁹—to “make and use the claimed invention.”⁸⁰ The classic test for enablement, derived from *Minerals Separation v. Hyde*,⁸¹ is whether “the experimentation needed to practice the invention [is] undue or unreasonable.”⁸² Whether experimentation is undue is judged by weighing several factors, such as “the nature of the invention,” what has previously been published and disclosed, and “the predictability or unpredictability of the art.”⁸³

The best mode requirement, which was introduced as a specification requirement for machine patents in 1870 and then expanded to all patents in

70. See, e.g., *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1579 (Fed. Cir. 1993) (“[I]nfingement cannot be established unless every limitation of a claim is satisfied either exactly or by an equivalent in the accused device.”).

71. 3 CHISUM, *supra* note 69, § 8.03 & n.2 (citing *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29, 33 (1997)).

72. See *Sheldon*, *supra* note 62, § 8:1.1.

73. See *Carroll Touch*, 15 F.3d at 1579.

74. See 3 CHISUM, *supra* note 69, § 7.01.

75. 35 U.S.C. § 112(a). Prior to the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended at 35 U.S.C. § 112(a)), this section was known as “§ 112 ¶ 1” or “§ 112, first paragraph.” See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 917 (Fed. Cir. 2004); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc); see also 3 CHISUM, *supra* note 69, § 7.02[5] for a comparison of the pre- and post-AIA § 112 wording and a more in-depth discussion of the changes.

76. 35 U.S.C. § 112(a).

77. See *Sheldon*, *supra* note 62, § 9:1.1.

78. See *supra* notes 41–42 and accompanying text.

79. See *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998) (describing the “hypothetical person having ordinary skill in the art” as a “legal construct . . . akin to the ‘reasonable person’ used as a reference in negligence determinations”).

80. MPEP § 2164.01 (9th ed. Rev. 10, June 2020).

81. 242 U.S. 261 (1916).

82. MPEP § 2164.01.

83. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

1952,⁸⁴ is relatively new as compared to enablement, which dates back to the original 1790 Patent Act.⁸⁵ The intent of the best mode requirement is to prevent inventors from disclosing “only what they know to be their second-best embodiment, while retaining the best for themselves.”⁸⁶ Because best mode refers to what the inventor believes is the best mode of the invention, not what is objectively so,⁸⁷ it is usually not detectable from the four corners of the patent itself, and the absence of best mode is rarely used to reject a patent application.⁸⁸ Rather, it has primarily been raised as a defense during infringement litigation.⁸⁹ However, best mode is no longer a viable defense against infringement⁹⁰ and may now be a requirement without any teeth.⁹¹

Whereas the first two requirements, enablement and best mode, focus on upholding the inventor’s side of the bargain by (eventually) putting the invention in the hands of the public, the third requirement, written description, focuses on demonstrating that the inventor actually invented the invention and deserves the benefit of the patent.⁹² In short, the inventor must demonstrate, to the satisfaction of a PHOSITA, that they were in possession of the invention, as claimed, at the time the application was filed.⁹³ The written description as a distinct requirement is discussed next.

3. Written Description: A Distinct Requirement

It is not immediately clear from the wording of 35 U.S.C. § 112(a)⁹⁴ (formerly ¶ 1)⁹⁵ that the statute calls for a written description requirement

84. See 3 CHISUM, *supra* note 69, § 7.05; see also Patent Act of 1870, ch. 230, § 26, 16 Stat. 198, 201; Patent Act of 1952, Pub. L. No. 82-593, § 112, 66 Stat. 792, 798 (codified as amended at 35 U.S.C. § 112(a)).

85. See Patent Act of 1790, ch. 7, § 2, 1 Stat. 109, 110.

86. MPEP § 2165 (citing *In re Nelson*, 280 F.2d 172, 126 (C.C.P.A. 1960)).

87. See *Philips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1333 (D. Del. 1987).

88. See SHELDON, *supra* note 62, § 9:4.1; MPEP § 2165.03 (“It is extremely rare that a best mode rejection properly would be made in *ex parte* prosecution.”).

89. See 3 CHISUM, *supra* note 69, § 7.05; MPEP § 2165.03 (“The information that is necessary to form the basis for a rejection based on the failure to set forth the best mode is rarely accessible to the examiner, but is generally uncovered during *inter partes* proceedings.”).

90. See *Leahy-Smith America Invents Act*, Pub. L. No. 112-29, § 15, 125 Stat. 284, 328 (2011) (codified as amended at 35 U.S.C. § 282(b)(3)(A)) (“[T]he failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable . . .”).

91. See SHELDON, *supra* note 62, § 9:4.1.

92. See *id.* § 9:2.

93. See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991).

94. Section 112(a) states:

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 or joint inventor of carrying out the invention.

35 U.S.C. § 112(a).

95. See *supra* note 75.

distinct from enablement and best mode.⁹⁶ However, the idea that an inventor must demonstrate possession of their invention predates the modern law, originating in the 1822 Supreme Court decision *Evans v. Eaton*,⁹⁷ which interpreted the 1793 version of the statute.⁹⁸ In *Evans*, the Court was concerned with preventing an inventor from claiming more than they had actually invented, lest their overbroad claim inhibit others from working in and contributing to the field or give the patentee the ability to extend the patent to new developments that did not originate with them.⁹⁹ According to the Court, disclosure serves two purposes, enablement and notice, and public notice encompasses both defining the claimed boundaries of the patent and preventing a patentee from “entitl[ing] himself to a patent for more than his own invention.”¹⁰⁰

Fourteen years after *Evans*, a new patent act changed the format of patent applications.¹⁰¹ The statute introduced new language requiring applicants to explicitly identify the elements of an application claimed as the invention,¹⁰² leading to the separation of the enablement (written description) and notice (claims) present in the modern statute.¹⁰³ Because the statute’s language and the form of the patent application both evolved after *Evans*, it was not obvious that a written description requirement, separate from enablement, remained after 1952, when the patent act’s current language was enacted.¹⁰⁴

In 1967, however, the U.S. Court of Customs and Patent Appeals (CCPA) confirmed that the written description requirement persisted.¹⁰⁵ In *In re Ruschig*, the court ruled that, even though the enablement requirement was met for a particular chemical used to treat diabetes, the written description requirement was not.¹⁰⁶ The specification was written as a choose-your-own-adventure, providing a PHOSITA with a variety of potential reagents that could lead to many different chemical products.¹⁰⁷ Although the court did not require that the specific claimed chemical be named in the written description, it wished to see instructional or

96. See Robert Greene Sterne, Patrick E. Garrett & Theodore A. Wood, *The Written Description Requirement*, 37 AKRON L. REV. 231, 232 (2004).

97. 20 U.S. (7 Wheat.) 356 (1822).

98. See *id.* at 440; see also Patent Act of 1793, ch. 11, § 3, 1 Stat. 318, 321.

99. See *Evans*, 20 U.S. (7 Wheat.) at 434 (explaining that the notice function of the specification includes “taking from the inventor the means of practising [sic] upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects”).

100. *Evans*, 20 U.S. (7 Wheat.) at 430, 433–34.

101. See Patent Act of 1836, ch. 357, § 6, 5 Stat. 117, 119; 3 CHISUM, *supra* note 69, § 8.03[2].

102. See § 6, 5 Stat. at 119 (“[A]nd [the applicant] shall particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery”).

103. See 35 U.S.C. § 112; SHELDON, *supra* note 62, §§ 8:2.1, 9:3.1.

104. See Sterne, *supra* note 96, at 232.

105. See *In re Ruschig*, 379 F.2d 990, 995–96 (C.C.P.A. 1967); 3 CHISUM, *supra* note 69, § 7.04[1][a][i].

106. See *Ruschig*, 379 F.2d at 991, 995–96 (“While we have no doubt a person so motivated would be enabled by the specification to make it . . . the question is . . . whether the specification discloses the compound . . . as something appellants actually invented.”).

107. See *id.* at 992, 994; 3 CHISUM, *supra* note 69, § 7.04[1][a][i].

motivational “blaze marks,” analogizing finding the correct synthesis pathway for producing the claimed chemical to following a hidden trail through the woods, where markings on trees can point the way.¹⁰⁸

The CCPA continued to reaffirm the existence of a written description requirement until 1982,¹⁰⁹ when it was succeeded by the Federal Circuit.¹¹⁰ Although the Federal Circuit continued to recognize a distinct written description requirement,¹¹¹ the use of seemingly contradictory language in a subset of decisions led the court, in 1991, to again affirm that the written description requirement existed separately from enablement.¹¹² In *Vas-Cath Inc. v. Mahurkar*,¹¹³ the Federal Circuit clarified that the first paragraph of § 112 contains two requirements, with each focused on a different party: first, enablement is intended to convey the ability to make and use the invention to a skilled practitioner of the art; second, the written description requires the applicant to demonstrate their possession of the invention, as defined by the claims, at the time of filing.¹¹⁴

According to the USPTO’s Manual of Patent Examining Procedure (MPEP), the written description may convey possession “expressly, implicitly, or inherently.”¹¹⁵ Express disclosure can be sufficient, even if the exact words are not used.¹¹⁶ Implicit disclosure refers to “inferences” that a PHOSITA “would reasonably be expected to draw.”¹¹⁷ Lastly, inherent disclosure occurs when the absent information is “necessarily present in the thing described,” not merely possible or probable, and when a PHOSITA would recognize its necessary presence.¹¹⁸

Most recently, in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*,¹¹⁹ the Federal Circuit addressed, en banc, the existence of the separate written description and again reaffirmed its existence.¹²⁰ The court relied on

108. See *Ruschig*, 379 F.2d at 994–95 (“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 like the case here—to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.”).

109. See, e.g., *In re Barker*, 559 F.2d 588, 593 (C.C.P.A. 1977); *In re Smith*, 481 F.2d 910, 914 (C.C.P.A. 1973); see also 3 CHISUM, *supra* note 69, § 7.04[1][a][ii]–[iv].

110. See Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, § 127, 96 Stat. 25, 37 (codified at 28 U.S.C. § 1295); *About the Court*, U.S. CT. APPEALS FED. CIR. (Aug. 18, 2023 5:20 PM), <https://cafc.uscourts.gov/home/the-court/about-the-court> [<https://perma.cc/534F-Y3GL>]; *infra* Part I.C.

111. See, e.g., *In re Wilder*, 736 F.2d 1516, 1520 (Fed. Cir. 1984) (“The description requirement is found in 35 U.S.C. § 112 and is separate from the enablement requirement of that provision.”).

112. See *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562–63 (Fed. Cir. 1991).

113. 935 F.2d 1555 (Fed. Cir. 1991).

114. See *id.* at 1563–64.

115. MPEP § 2163(II)(3)(b) (9th ed. Rev. 10, June 2020).

116. See *id.*

117. *Id.* § 2144.01 (quoting *In re Preda*, 401 F.2d 825, 826 (C.C.P.A. 1968)).

118. See MPEP § 2163.07(a) (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)).

119. 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

120. See *id.* at 1340.

Supreme Court precedent distinguishing the written description requirement from enablement, as well as prior Federal Circuit decisions, such as *Vas-Cath*.¹²¹ In addition to affirming prior Federal Circuit rulings applying the written description requirement to original, unamended claims,¹²² the *Ariad* court also acknowledged that the standard for demonstrating “possession” has not been adequately set forth.¹²³ The majority recognized that the sufficiency of the written description is a factual question that is highly context-dependent; the analysis can vary based on how broad the claims are, whether the technological field is predictable or unpredictable, and whether the technology is new or established.¹²⁴ Because of that variability, the court chose to provide a few “broad principles” rather than more concrete guidance.¹²⁵ Firstly, constructive reduction to practice—which entails providing enough detail in the written description to enable a PHOSITA to make and use the invention, as well as an explanation of the utility of the invention—can be sufficient.¹²⁶ However, even actual reduction to practice—meaning that an embodiment of the invention is physically produced and tested—is not sufficient if it is not described in the specification.¹²⁷ Moreover, although a claim need not be repeated verbatim in the written description, all limitations—even those that would be considered obvious¹²⁸—must be present in the description.¹²⁹

121. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002); *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 59 (1938); *Ariad*, 598 F.3d at 1345–46, 1351 (citing *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 14 (1853)); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562–63 (Fed. Cir. 1991)).

122. See *Ariad*, 598 F.3d at 1350–51 (discussing *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568–69 (Fed. Cir. 1997) with support from *Fiers v. Revel*, 984 F.2d 1164, 1170 (Fed. Cir. 1993) and *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002)). The original claims submitted when a patent application is filed may be amended during patent prosecution. See *infra* Part I.B.2. The CCPA considered original claims, as part of the specification, to intrinsically satisfy the written description requirement and viewed the written description requirement as necessitating a showing of possession of the invention only with reference to claims that were amended at a later date. See *Ariad* at 1370–71 (Linn, J., dissenting). In the three cases cited in *Ariad*—*Fiers v. Revel*, *Enzo Biochem, Inc. v. Gen-Probe Inc.*, and *Regents of the University of California v. Eli Lilly & Co.*—the original claims at issue were genus claims. See *id.* at 1350 (majority opinion); see also Dmitry Karshedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. 1, 13 (2021). Genus claims are beyond the scope of this Note.

123. See *Ariad*, 598 F.3d at 1351.

124. See *id.*

125. See *id.* at 1352.

126. See *Yasuko Kawai v. Metlesics*, 480 F.2d 880, 886 (C.C.P.A. 1973).

127. See *In re Omeprazole Pat. Litig.*, 536 F.3d 1361, 1373 (Fed. Cir. 2008).

128. See 35 U.S.C. § 103. Some examples of obvious limitation are ones that involve a known method or simple substitution or would be obvious for a PHOSITA to try. See MPEP § 2141 (9th ed. Rev. 10, June 2020).

129. See *Ariad*, 598 F.3d at 1352; see also *Lizardtech, Inc. v. Earth Res. Mapping, Inc.*, 433 F.3d 1373, 1379 (Fed. Cir. 2006) (Rader, J., dissenting) (noting that the Federal Circuit “has searched for a proper standard for its revised and evolving written description doctrine” (citing *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005))).

B. *The Written Description During Patent Prosecution*

The patent prosecution process is the give and take between the applicant for a patent and an examiner from the USPTO.¹³⁰ This process takes, on average, between two and two-and-a-half years¹³¹ and occurs primarily through the exchange of written documents between the applicant and the patent examiner, though verbal negotiations can be important to the process.¹³² Roughly 60 percent of patent applications are determined to be eligible for a patent.¹³³

This section considers the written description as it progresses through patent prosecution. Part I.B.1 describes the process of drafting the specification, and Part I.B.2 discusses the role of the written description in responding to challenges from the USPTO.

1. Drafting the Written Description

The first step for an inventor seeking a patent is to file an application, which must include a specification and—unless the application is provisional—at least one claim to establish a filing date.¹³⁴ The filing date is important because it determines which publications can be used to challenge the patentability of an invention.¹³⁵

When drafting a patent application, the common wisdom is to begin with the claims because they are considered the most important part of the patent.¹³⁶ In prosecuting the patent, it is the claims that are carefully evaluated by the USPTO examiner for requirements such as novelty and

130. *Responding to Office Actions*, U.S. PAT. & TRADEMARK OFF. (Aug. 24, 2018, 2:16 PM), <https://www.uspto.gov/trademarks/maintain/responding-office-actions> [https://perma.cc/589N-8662].

131. *Patents Pendency Data*, U.S. PAT. & TRADEMARK OFF. (Nov. 17, 2014, 9:53 PM), <https://www.uspto.gov/dashboard/patents/pendency.html> [https://perma.cc/P7RB-EPD9] (reporting an average of 25.3 months from the filing date until final disposition of the application, not including requests for continued examination, and 29 months when including such requests).

132. R. CARL MOY, *1 MOY'S WALKER ON PATENTS* § 3:37 (4th ed. 2020).

133. *Patents Production, Unexamined Inventory and Filings Data June 2023*, U.S. PAT. & TRADEMARK OFF. (Nov. 17, 2014, 9:53 PM), <https://www.uspto.gov/dashboard/patents/production-unexamined-filing.html> [https://perma.cc/4B5D-NL72] (63 percent, averaging data from June 2021 through June 2023).

134. See 35 U.S.C. §§ 111(a), 112(a), 113; MPEP § 201.01 (9th ed. Rev. 10, June 2020); *Nonprovisional (Utility) Patent Application Filing Guide: Application Requirements*, U.S. PAT. & TRADEMARK OFF. (Jan. 31, 2018 11:25 AM), <https://www.uspto.gov/patents/basics/types-patent-applications/nonprovisional-utility-patent#heading-4> [https://perma.cc/Y3YT-6XL9]. A provisional application may be filed without claims to reserve a filing date; the applicant then has one year to convert the provisional application to a nonprovisional application. See 35 U.S.C. § 111(b)(2); *Nonprovisional (Utility) Patent Application Filing Guide: Introduction*, U.S. PAT. & TRADEMARK OFF. (Jan. 31, 2018, 11:25 AM), <https://www.uspto.gov/patents/basics/types-patent-applications/nonprovisional-utility-patent#heading-1> [https://perma.cc/3A4H-XR6G].

135. See 35 U.S.C. §§ 102–103; MPEP § 2120.

136. See SHELDON, *supra* note 62, § 8:1.1.

nonobviousness.¹³⁷ And in defending a patent against infringement, it is the claims that are construed and then compared to the potentially infringing product or process to assess infringement.¹³⁸ Further, in drafting the specification, the claims can serve as a guide for what information must be included in the written description¹³⁹ to ensure compliance with the written description, enablement, and best mode requirements of § 112(a).¹⁴⁰

A patent application is assigned its filing date upon submission to the USPTO.¹⁴¹ However, a patent application may claim an earlier effective filing date if its claims are supported in an earlier application.¹⁴² Effective filing date is discussed in more detail in the next section.

2. Written Description and Effective Filing Date

Most patent applications, including roughly 80 percent of those that will eventually receive an allowance, will be rejected after the first examination.¹⁴³ The majority of these rejections will be for obviousness (30 percent) or lack of novelty (21 percent).¹⁴⁴ A patent practitioner can either respond directly to the allegations of obviousness or lack of novelty, or they can attempt to sidestep the issue by amending the claims.¹⁴⁵ Alternatively, if the inventor has filed a series of applications, the claim may be eligible for an effective filing date that predates the publications being used to challenge the application.¹⁴⁶

The preferred strategy when facing a rejection due to earlier publications is to argue that those publications, when interpreted correctly, do not support either obviousness or lack of novelty.¹⁴⁷ This is preferred because amending a claim often requires adding a limitation that reduces the scope of the claim,

137. *See id.*; 35 U.S.C. §§ 102–103; MPEP § 2103(I)(C), (V). A claim is novel when it is not anticipated entirely by an earlier publication. *See* 35 U.S.C. § 102; MPEP § 2131. A claim is obvious if it is anticipated by a combination of one or more earlier publications, known methods in the field, or the ordinary level of creativity of a PHOSITA. *See* 35 U.S.C. § 103; MPEP § 2141(II)(2)(C), (III).

138. *See* 3 CHISUM, *supra* note 69, § 18.01.

139. *See* SHELDON, *supra* note 62, § 8:1.3.

140. *See* 35 U.S.C. § 112(a); MPEP § 2103(IV)(B).

141. *See* 35 U.S.C. § 111(a)(4).

142. *See* MPEP § 211.

143. *See* Chad Giles, *How Often Do Patent Applications Get Rejected?*, BIGPATENTDATA (May 16, 2019), <https://bigpatentdata.com/2019/05/how-often-do-patent-applications-get-rejected/> [<https://perma.cc/AB97-NCWN>] (analyzing data from 2009–2019).

144. *See* Tim Hellmann, *The Most Common Rejections: 102, 103, and 112(b)*, JURISTAT (Dec. 23, 2019), <https://blog.juristat.com/most-common-rejections> [<https://perma.cc/J7LF-FRBR>] (analyzing data from 2014–2018).

145. *See* 1 MOY, *supra* note 132, § 3:18.

146. *See* MPEP § 2152.01.

147. *See* 1 MOY, *supra* note 132, §§ 3:19–:20; PRAC. L. INTELL. PROP. & TECH., USPTO PATENT OFFICE ACTION RESPONSES: AMENDMENTS, Westlaw W-018-3491 (database updated 2023) (“Patent counsel should always attempt to respond to the examiner’s rejection . . . [w]ithout claim amendments.”).

lessening the patent's value.¹⁴⁸ Such amendments can also be used during litigation as evidence that the patentee agreed to a narrower construction of the claim.¹⁴⁹ Further, new matter cannot be added at this stage; therefore, when making an amendment, it is important that the change be supported in the written description as filed, otherwise the claim will be invalid for lack of written description.¹⁵⁰

Another option for avoiding publications that predate the application is to claim an earlier effective filing date. It is common practice for inventors to file a series of applications that benefit from the disclosure of information in an older parent application.¹⁵¹ A filing date is assigned to each application upon submission of a specification to the USPTO.¹⁵² However, if an application is filed as a continuation application—with reference to the parent application while the parent application is still pending—and the claims in the continuation application are supported in the specification of the parent application under § 112, then the claims are entitled to the parent application's filing date as their effective filing date.¹⁵³

Although amending claims or linking back to an earlier-filed specification may help a patent applicant avoid rejections based on earlier publications, these strategies are not without risk. When the written description is not written with a particular claim in mind, there is a chance that the claim will be invalidated for lack of written description during infringement litigation.¹⁵⁴

Although the Supreme Court has confirmed the existence of a separate written description requirement,¹⁵⁵ the Court has not taken up the issue frequently, allowing the Federal Circuit to sort out the details with regard to satisfying the requirement.¹⁵⁶ The origins and purpose of the Federal Circuit will be explored in the next section.

148. See PRAC. L. INTELL. PROP. & TECH, *supra* note 147; SHELDON, *supra* note 62, § 8:1.2 (“[T]he resulting narrow claim is more likely to be valid, but it is also likely that the claim will be too narrow to exclude competitors . . .”).

149. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002).

150. See MPEP § 2163(I)(B).

151. See 1 MOY, *supra* note 132, § 3:44.

152. See *supra* note 134 and accompanying text.

153. See 35 U.S.C. § 100(i); 37 C.F.R. § 1.78 (2022); MPEP § 211.

154. See Dennis Crouch, *Written Description's Shifting Focus to the Accused Embodiment*, PATENTLY-O (May 23, 2017), <https://patentlyo.com/patent/2017/05/descriptions-shifting-embodiment.html> [<https://perma.cc/VBK2-TTH3>] (“[T]he scope of the claimed invention can change significantly during prosecution through the amendment process. . . . During infringement litigation, however, a claimed invention lacking sufficient description in the specification will be found invalid and unenforceable.”).

155. See *supra* Part I.A.3.

156. See MPEP § 2163 (stating that the USPTO guidelines for evaluating the written description rely on Federal Circuit case law, as well that of its predecessor court, the CCPA).

C. Patent Law Uniformity: The Federal Circuit

The Federal Circuit is unique among the circuit courts in that its jurisdiction arises solely from subject matter rather than from territory.¹⁵⁷ As the successor to the CCPA, the Federal Circuit has exclusive jurisdiction over appeals from USPTO decisions, as well as infringement appeals from the district courts.¹⁵⁸

Placing all patent decisions under the Federal Circuit's jurisdiction was part of an attempt to reduce conflict among court decisions.¹⁵⁹ With regard to patents particularly, the committee that proposed the new court hoped that greater uniformity and predictability in patent law would spur an increase in research and development, which had lagged during the 1970s recession.¹⁶⁰ Further, because all appeals on particular subjects would pass through the same circuit court, there was an expectation that the burden on the Supreme Court to settle circuit splits would be reduced.¹⁶¹

Not all scholars believe that the Federal Circuit's exclusive jurisdiction over patents has led to desirable results. One concern is a lack of adaptability to new technologies and current thought, as well as an inability to change course when necessary.¹⁶² Although the problems of too many voices, inexperience with patent cases, and forum shopping have not gone unrecognized, some argue that allowing at least two circuits to hear patent appeals would inject needed debate and innovation.¹⁶³ This would also assist the Supreme Court by indicating which issues are in most need of the Court's input.¹⁶⁴ An alternative suggestion is for the Federal Circuit to relax its "prior-panel rule," which currently makes the decisions of prior Federal Circuit panels binding on later ones unless the decision is overturned en banc.¹⁶⁵

157. See S. Jay Plager & Lynne E. Pettigrew, *Rethinking Patent Law's Uniformity Principle: A Response to Nard and Duffy*, 101 NW. U. L. REV. 1735, 1735 (2007); Daniel J. Meador, *Origin of the Federal Circuit: A Personal Account*, 41 AM. U. L. REV. 581, 581 (1992).

158. See Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, § 127, 96 Stat. 25, 37 (codified at 28 U.S.C. § 1295) (establishing the Federal Circuit); Jason Rantanen, *The Landscape of Modern Patent Appeals*, 67 AM. U. L. REV. 985, 991 (2018) (describing the subject matter jurisdiction of the Federal Circuit); Pauline Newman, *Origins of the Federal Circuit: The Role of Industry*, 11 FED. CIR. BAR J. 541, 541 (2001); Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619, 1624 (2007).

159. See Meador, *supra* note 157, at 588–89.

160. See Newman, *supra* note 158, at 541–42.

161. See S. Jay Plager, *The United States Courts of Appeals, the Federal Circuit, and the Non-regional Subject Matter Concept: Reflections on the Search for a Model*, 39 AM. U. L. REV. 853, 855 (1990).

162. See Nard & Duffy, *supra* note 158, at 1620–21, 1621 n.7; Daniel Kazhdan, *The Federal Circuit Should Be More Tolerant of Intra-circuit Splits*, 26 FED. CIR. BAR J. 105, 105 (2016).

163. See Nard & Duffy, *supra* note 158, at 1623–25.

164. See *id.* at 1624.

165. See Kazhdan, *supra* note 162, at 138, 146.

Another common criticism of the Federal Circuit is that its rulings are highly panel dependent, meaning that decisions are difficult to predict and depend on which three judges form the panel for a given case.¹⁶⁶ Empirically, the existence of panel dependency is an open question, with a variety of studies coming to opposite conclusions.¹⁶⁷ Although there is some evidence that Federal Circuit judges are seeing more eye to eye than they did a decade ago,¹⁶⁸ swapping one judge out for another can make the difference between a patent being found valid or invalid, as was recently seen in *Novartis III*.¹⁶⁹ The *Novartis* case is explored in more detail in Part II.

II. RECENT CONCERNS ABOUT SATISFYING THE WRITTEN DESCRIPTION REQUIREMENT

Two cases recently before the Federal Circuit, *Biogen International GmbH v. Mylan Pharmaceuticals Inc.*¹⁷⁰ (*Biogen II*) and *Novartis Pharmaceuticals Corp. v. Accord Healthcare, Inc.*¹⁷¹ (*Novartis II*), sparked disagreement among Federal Circuit judges over the amount of disclosure necessary to satisfy the written description requirement.¹⁷² These decisions also raised concerns that the standard for complying with § 112(a) is now more stringent and unpredictable.¹⁷³ Part II.A of this Note discusses the *Biogen* case, Part II.B discusses the *Novartis* case, and Part II.C explores patent practitioners' reactions to both cases.

166. See Nard & Duffy, *supra* note 158, at 1627.

167. See *id.* at 1627 n.38 (collecting studies).

168. See Rantanen, *supra* note 158, at 989 & n.15, 1027 fig.14 (noting that although the rate of unanimous opinions dropped from 2004 to 2013, reaching a low around 60 percent, the rate has since rebounded to around 80 percent).

169. See 38 F.4th 1013 (Fed. Cir. 2022), *reh'g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom.* Novartis Pharms. Corp. v. HEC Pharm Co., 143 S. Ct. 1748 (2023); see also Chris Holman, *Federal Circuit Flips "Negative Claim Limitation" Decision After Change in Panel Composition*, PATENTLY-O (June 23, 2022), <https://patentlyo.com/patent/2022/06/negative-limitation-composition.html> [<https://perma.cc/BG37-VVFJ>].

170. 18 F.4th 1333 (Fed. Cir. 2021), *reh'g denied*, 28 F.4th 1194 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 112 (2022).

171. 21 F.4th 1362 (Fed. Cir. 2022), *vacated*, 38 F.4th 1013 (Fed. Cir. 2022), *and reh'g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom.* Novartis Pharms. Corp. v. HEC Pharm Co., 143 S. Ct. 1748 (2023).

172. See *Biogen III*, 28 F.4th 1194, 1196 (Fed. Cir. 2022) (Lourie, J., dissenting); *Novartis III*, 38 F.4th 1013, 1021 (Fed. Cir. 2022) (Linn, J., dissenting), *reh'g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom.* Novartis Pharms. Corp. v. HEC Pharm Co., 143 S. Ct. 1748 (2023).

173. See *Biogen III*, 28 F.4th at 1196 (Lourie, J., dissenting) (“[T]he court has contributed to the muddying of the written description requirement.”); *Novartis III*, 38 F.4th at 1020–21 (Linn, J., dissenting) (“The majority . . . applies a heightened written description standard.”); see also, e.g., Jonathan B. Fitzgerald, *Heightened Standards for Satisfying Written Description in Pharma Patents*, BIOPROCESS ONLINE (July 27, 2022), <https://www.bioprocessonline.com/doc/heightened-standards-for-satisfying-written-description-in-pharma-patents-0001> [<https://perma.cc/C87Z-4ZUK>]; David Taylor, *Opinion Summary – Novartis Pharmaceuticals v. Accord Healthcare Inc.*, FEDCIRCUITBLOG (July 1, 2022), <https://fedcircuitblog.com/2022/07/01/opinion-summary-novartis-pharmaceuticals-v-accord-healthcare-inc/> [<https://perma.cc/8RFU-MG3A>].

A. Biogen: *The Missing Link*

Biogen markets a small molecule, dimethyl fumarate (DMF), under the brand name Tecfidera[®] for the treatment of RRMS.¹⁷⁴ Litigation over the patents protecting Tecfidera[®] began when Mylan Pharmaceuticals filed an Abbreviated New Drug Application (ANDA), seeking FDA approval for a generic version of Tecfidera[®] under the Hatch-Waxman Act.¹⁷⁵ Biogen responded with an infringement lawsuit regarding U.S. Patent No. 8,399,514 (the ‘514 Patent), which claims protection for a 480 mg/day dosage of DMF.¹⁷⁶ Although the dosage was mentioned in the written description, the Federal Circuit found that the written description requirement was not met.¹⁷⁷

Part II.A.1 describes the background of the patent, and Part II.A.2 compares the court’s reasoning with the dissenting opinions.

1. The Tecfidera[®] Patent

The written description of the ‘514 Patent originated with the filing of a provisional application in 2007, prior to the start of the Tecfidera[®] Phase III trials.¹⁷⁸ The original application, entitled “Nfr2 Screening Assays and Related Methods and Compositions,” described methods for identifying and evaluating potential treatments for neurological diseases, such as MS, as well as treating such diseases with compounds similar to DMF.¹⁷⁹ A selection of effective dosage ranges were listed.¹⁸⁰

The Phase III clinical studies demonstrated unexpectedly promising results for a dosage (480 mg/day) not investigated during the Phase II study, and Biogen moved to patent the dosage.¹⁸¹ Initially, Biogen filed a new

174. See *Biogen II*, 18 F.4th at 1337.

175. See *Biogen Int’l GmbH v. Mylan Pharms. Inc. (Biogen I)*, No. 17-CV-116, 2020 U.S. Dist. LEXIS 107743, at *2 (N.D.W. Va. June 18, 2020), *aff’d*, 18 F.4th 1333 (Fed. Cir. 2021), *and reh’g denied*, 28 F.4th 1194 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 112 (2022); *supra* notes 13–15 and accompanying text.

176. *Biogen I*, 2020 U.S. Dist. LEXIS 107743, at *3, *13–14; U.S. Patent No. 8,399,514 (filed Feb. 13, 2012).

177. See *Biogen II*, 18 F.4th at 1346.

178. *Biogen I*, 2020 U.S. Dist. LEXIS 107743, at *9. Phase III trials, the final trial stage prior to FDA approval, have, among the preapproval studies, the largest enrollment and longest duration, with the purpose of evaluating the effectiveness of the treatment and monitoring for long-term and rare side effects. See *Step 3: Clinical Research*, U.S. FDA (Jan. 4, 2018), <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research> [<https://perma.cc/X6ZK-L2EE>]. The two Phase III trials for Tecfidera[®], DEFINE and CONFIRM, were both designed as two-year-long clinical studies to evaluate the effectiveness of two different dosages of dimethyl fumarate, 240 mg three times a day (720 mg/day) and twice a day (480 mg/day), with the latter study also comparing effectiveness against a drug already in use to treat RRMS. See Robert J. Fox, *BG00012—A Novel Oral Therapy in Development for the Treatment of Multiple Sclerosis*, 3 EUR. NEUROLOGICAL REV. 99, 101 (2008).

179. See U.S. Provisional Patent Application No. 60/888,921 (filed Feb. 8, 2007).

180. See *id.* at para. 0116; ‘514 Patent col. 18 ll. 58–62 (“For example, an effective dose of DMF or MMR to be administered to a subject orally can be from about 0.1 g to 1 g per pay [sic], 200 mg to about 800 mg per day (e.g., from about 240 mg to about 720 mg per day; or from about 480 mg to about 720 mg per day; or about 720 mg per day).”).

181. See *Biogen I*, 2020 U.S. Dist. LEXIS 107743, at *6–7, *11–12.

provisional application that described the Phase III data.¹⁸² They also amended U.S. Patent Application 12/526,296 (the ‘296 Application), the then-current incarnation of the original 2007 application, changing the title to “Treatment for Multiple Sclerosis,” adding the designer of the clinical trials as an inventor, and replacing the original claims with new claims reflecting the Phase III results.¹⁸³ Ultimately, a continuation of the ‘296 Application, claiming priority back to the original 2007 application because it contained the same written description,¹⁸⁴ was accepted and became the ‘514 Patent.¹⁸⁵ The application filed after the Phase III results were obtained was stalled in prosecution; it was unable to overcome a § 102 novelty rejection¹⁸⁶ that cited a 2008 publication describing Biogen’s own Phase III study,¹⁸⁷ and thus the application was eventually abandoned.¹⁸⁸

2. Insufficient Written Description: Lost in the Woods

Biogen brought its infringement suit against Mylan Pharmaceuticals in the U.S. District Court for the Northern District of West Virginia.¹⁸⁹ The district court found that the specification of the ‘514 Patent failed to demonstrate, under the requirements of § 112(a), that Biogen had possession of the invention—the 480 mg/day therapeutically effective dosage of DMF—at the time of filing.¹⁹⁰

Looking to the specification, the court noted that the 480 mg/day dosage is “[s]trikingly . . . mentioned only once,”¹⁹¹ as an endpoint of a dosage range—“about 480 mg to about 720 mg per day”—listed among several other ranges, all described as doses that could be “an effective amount” of “DMF or [monomethyl fumarate]” for treating “neurological diseases.”¹⁹² The court also observed that MS is mentioned as only one of roughly three dozen neurological diseases that could be so treated.¹⁹³

Biogen argued that the above details were all contained within one method described in the specification, Method 4, and that method provided a “link” between MS, DMF, and 480 mg/per day as a therapeutically effective

182. *See id.* at *11–12; *see also* U.S. Provisional Patent Application No. 61/490,572 (filed May 26, 2011) (became U.S. Patent Application No. 14/119,373 (filed Feb. 18, 2014)).

183. *See Biogen I*, 2020 U.S. Dist. LEXIS 107743, at *6, *12.

184. *See* U.S. Patent Application No. 13/372,426 (filed Feb. 13, 2012).

185. *See Biogen I*, 2020 U.S. Dist. LEXIS 107743, at *13.

186. *See* 35 U.S.C. § 102(a)(1) (stating that an inventor cannot be granted a patent if “the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention”).

187. *See* File Wrapper, U.S. Patent Application No. 14/119,373 Non-Final Rejection (Sept. 29, 2015) (rejecting claims under 35 U.S.C. § 102 in light of Fox, *supra* note 178).

188. *See Biogen I*, 2020 U.S. Dist. LEXIS 107743, at *13.

189. *See id.* at *2.

190. *See id.* at *20–21.

191. *See id.* at *27.

192. *See* U.S. Patent No. 8,399,514 col. 16 l. 39, col. 18 l. 52, col. 18 ll. 58–62 (filed Feb. 13, 2012); *supra* note 180 (quoting the list of dosage ranges from the ‘514 Patent).

193. *See Biogen I*, 2020 U.S. Dist. LEXIS 107743, at *24–25 (referencing U.S. Patent No. 8,399,514 col. 16 ll. 39–65 (filed Feb. 13, 2012)).

dosage.¹⁹⁴ However, due to the long list of neurological disorders and potential dosages, the court saw no such link.¹⁹⁵ With so many trees to search among, the court wished to see evidence of *In re Ruschig*-style “blaze marks” to point the way.¹⁹⁶

Using language supplied by the defendant, the court described Biogen’s claims as “selectively plucking specific words from the specification” and determined that this was not sufficient to provide written description support for possession of the invention.¹⁹⁷ In its analysis, the district court drew on Federal Circuit precedent¹⁹⁸ stating that simply repeating language from the specification verbatim in the claims is not always enough to “put others on notice of the scope . . . and demonstrate possession of that invention.”¹⁹⁹ The court further noted that claims must be assessed as “an integrated whole rather than as a collection of independent limitations.”²⁰⁰

The court supported its finding of lack of possession with detailed consideration of the inventors’ testimony and the prosecution timeline, determining that a PHOSITA could not have concluded from reading the specification that 480 mg/day of DMF would have effectively treated MS.²⁰¹ In particular, it noted that the ‘514 Patent overcame a § 103 obviousness challenge²⁰² before the Patent Trial and Appeals Board by emphasizing that the success of the 480 mg/day dosage was unexpected prior to the Phase III trial.²⁰³ Since the Phase III trial did not begin until after the original 2007 application was filed, the results of that trial could not have been possessed by the inventor at the time of the filing.²⁰⁴

The Federal Circuit affirmed the district court’s holding, agreeing that—at the time the original parent application was filed, prior to the start of the Phase III trials—a PHOSITA would not have understood from the specification that 480 mg/day of DMF would be “therapeutically effective” in treating MS.²⁰⁵ Commenting on the testimony of the inventor who had designed the clinical trials, the court stated that it was irrelevant that the inventor had “conceived the idea” of using 480 mg/day of DMF several years prior because “a patent cannot be awarded for mere theoretical research

194. *See id.* at *26.

195. *See id.*

196. *See id.* (citing *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1348 (Fed. Cir. 2010) (en banc)); *supra* note 108 and accompanying text.

197. *See Biogen I*, 2020 U.S. Dist. LEXIS 107743, at *18, *33.

198. *See id.* at *33.

199. *See Nuvo Pharms. (Ir.) Designated Activity Co. v. Dr. Reddy’s Lab’ys Inc.*, 923 F.3d 1368, 1380 (Fed. Cir. 2019) (citing *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968–69 (Fed. Cir. 2002)).

200. *See Novozymes A/S v. DuPont Nutrition Bioscis. APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013).

201. *See Biogen I*, 2020 U.S. Dist. LEXIS 107743, at *34–41.

202. *See* 35 U.S.C. § 103.

203. *See Biogen I*, 2020 U.S. Dist. LEXIS 107743, at *40; *Mylan Pharms. Inc. v. Biogen MA Inc.*, No. IPR2018-01403, 2020 WL 582736, at *15 (P.T.A.B. Feb. 5, 2020).

204. *See Biogen I*, 2020 U.S. Dist. LEXIS 107743, at *9, *36–39.

205. *See Biogen II*, 18 F.4th 1333, 1344 (Fed. Cir. 2021), *reh’g denied*, 28 F.4th 1194 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 112 (2022).

without more.”²⁰⁶ Biogen’s petition for a rehearing and its subsequent petition for certiorari were denied.²⁰⁷

The Federal Circuit’s decisions to first affirm the district court and then to deny a rehearing both sparked dissenting opinions, revealing disagreement within the court. In dissenting to the ruling to affirm, Judge Kathleen M. O’Malley took issue with the majority’s interpretation of *Nuvo Pharmaceuticals (Ireland) Designated Activity Co. v. Dr. Reddy’s Laboratories Inc.*²⁰⁸ and its application of “‘blaze marks’ precedent.”²⁰⁹ Meanwhile, in dissenting to the denial of rehearing en banc, Judge Alan David Lourie, joined by Chief Judge Kimberly A. Moore and Judge Pauline Newman, found four points of error. In addition to agreeing with Judge O’Malley’s analysis of *Nuvo*, they also criticized the district court and the Federal Circuit majority for “blurring the lines between written description and enablement” and for not containing their analysis to the “four corners of the specification.”²¹⁰

Regarding *Nuvo*, Judge O’Malley explained that the written description and claims of the patent at issue contradicted each other.²¹¹ The claims at issue in *Nuvo* described the formulation of an uncoated acid inhibitor, present in an amount defined by its ability to raise pH.²¹² Meanwhile, the written description disclosed a known issue: that the uncoated acid inhibitor was prone to destruction when exposed to stomach acid, and therefore it could not function to raise pH.²¹³ Because the written description failed to propose a work-around for this issue, a PHOSITA reading the specification would not expect the invention to work.²¹⁴ The *Biogen* majority, alternatively, did not find a contradiction within the specification; instead, the majority asked if the PHOSITA expected the claimed DMF dosage to be clinically effective based on earlier published research, when it should have been asking if the written description demonstrated possession of a therapeutically effective

206. *See id.* (citing *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc)).

207. *Biogen III*, 28 F.4th 1194, 1195 (Fed. Cir. 2022) (denying panel rehearing and rehearing en banc), *cert. denied*, 143 S. Ct. 112 (2022); *Biogen Int’l GmbH v. Mylan Pharms. Inc. (Biogen IV)*, 143 S. Ct. 112 (2022) (denying certiorari).

208. *Nuvo Pharms. (Ir.) Designated Activity Co. v. Dr. Reddy’s Lab’ys Inc.*, 923 F.3d 1368 (Fed. Cir. 2019).

209. *See Biogen II*, 18 F.4th at 1349, 1350 (O’Malley, J., dissenting).

210. *See Biogen III*, 28 F.4th at 1195, 1199–201, 1202 (Lourie, J., dissenting). Judge O’Malley participated in considering the petition for panel rehearing but retired before the decision on the petition for rehearing en banc. *See id.* at 1195 n.1 (majority opinion).

211. *See Biogen II*, 18 F.4th at 1349.

212. *Nuvo*, 923 F.3d at 1372–73.

213. *Id.* at 1374.

214. *See Biogen II*, 18 F.4th at 1349; *Nuvo*, 923 F.3d at 1374–75.

dosage.²¹⁵ Therefore, Judge O’Malley concluded that the majority never properly analyzed the ‘514 Patent under § 112(a).²¹⁶

Agreeing with Judge O’Malley, Judge Lourie simply reemphasized that the Federal Circuit has not required proof of clinical results.²¹⁷ Rather, all that is required is that the PHOSITA understand from the specification that the dosage in question is claimed to be therapeutically effective; Judge Lourie found this so clearly stated in the ‘514 Patent that no room was left for interpretation.²¹⁸

Regarding the “blaze marks” analysis, Judge O’Malley did not agree that the precedent applied to the ‘514 Patent because there were not enough “trees” to get lost among.²¹⁹ In Judge O’Malley’s assessment, blaze marks were needed when a patent contained a “laundry list” of potential choices, and the list of DMF dosages in the ‘514 Patent was not long enough to qualify.²²⁰

Judge Lourie added to Judge O’Malley’s contention that blaze marks did not apply. Quoting from the Federal Circuit’s *Novartis II* decision, issued just two months prior and reversed upon rehearing three months later, Judge Lourie explained that blaze marks are not required “where the claimed species is expressly described in the specification,” as both MS and the 480 mg/day dosage were described.²²¹ The dissent also rejected the majority’s focus on the single mention of 480 mg/day, as well as the implication that a specification that discloses significantly more than what is claimed fails to satisfy the written description requirement.²²²

Judge Lourie’s dissent also called the district court to task for “import[ing]” enablement and best mode considerations into the written description requirement.²²³ By asking for proof that 480 mg/day was effective, rather than whether it was disclosed as being effective, the court

215. *See id.* at 1350. With respect to the ‘514 Patent, therapeutic efficacy is defined by DMF’s ability to upregulate Nrf2 expression or activate the Nrf2 pathway. *See id.* at 1347–48. Meanwhile, clinical efficacy would be the Phase III endpoints, such as rate of relapse. *See id.* at 1348; Fox, *supra* note 178.

216. *See Biogen II*, 18 F.4th at 1350.

217. *See Biogen III*, 28 F.4th 1194, 1200 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 112 (2022).

218. *See id.* (“The claims specify precisely the amount that they claim would be ‘therapeutically effective,’ namely, ‘480 mg per day.’ ‘514 patent col. 27 ll. 65–67. And the patent specification leaves nothing for the skilled artisan to deduce; it expressly states that 480 mg per day is an effective amount.”).

219. *See Biogen II*, 18 F.4th at 1351.

220. *See id.* at 1351–52.

221. *See Biogen III*, 28 F.4th at 1199 (quoting *Novartis II*, 21 F.4th 1362, 1370 (Fed. Cir. 2022), *vacated*, 38 F.4th 1013 (Fed. Cir. 2022), and *reh’g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom.* *Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023)); *infra* Part II.B.1.

222. *See Biogen III*, 28 F.4th at 1199–200 (“The panel majority opinion implies that a patent fails the written description requirement . . . when it contains too much disclosure beyond the claimed invention” and “a patentee must disclose the claimed subject matter more than once The en banc court should have intervened to correct these incorrect propositions.”).

223. *See id.* at 1201.

was investigating enablement, not disclosure; meanwhile, asking if a PHOSITA would understand that 480 mg/day was the “most effective” dosage was relevant to best mode.²²⁴ Further, Judge Lourie commented that there is no requirement that patents only claim the most effective method, regardless of the requirement being assessed.²²⁵

Lastly, the Lourie dissent noted that written description is supposed to be analyzed by “an objective inquiry into the four corners of the specification,” with extrinsic evidence available, as needed, for clarifying meaning.²²⁶ Instead, the district court used expert testimony and prosecution history to develop hypotheses about Biogen’s motivations and prosecution decisions, which, Judge Lourie stated, was irrelevant to assessing the written description requirement.²²⁷ Ultimately, as Judge Lourie put it, the *Biogen* decision was an “outlier” among written description cases that “contributed to the muddying of the written description requirement.”²²⁸

B. Novartis: *Silence Isn’t Sufficient*

Novartis, like Biogen,²²⁹ markets a drug for RRMS: Gilenya.²³⁰ The active ingredient of Gilenya is fingolimod, which is structurally similar to a naturally occurring lipid, sphingosine, and is believed to slow the progression of MS by inhibiting the formation of new blood vessels.²³¹ As with Biogen’s Tecfidera[®],²³² litigation over Gilenya began when a hopeful generic manufacturer, in this case HEC Pharm, filed an ANDA and Novartis sued for infringement in district court.²³³ This time, the limitation at issue was for the absence of a treatment step—a loading dose—which the Federal Circuit initially found valid but then invalidated on rehearing.²³⁴

Part II.B.1 describes the background of the patent, and Part II.B.2 contrasts the dueling opinions of the Federal Circuit over the course of the two hearings.

1. The Gilenya Patent

Though filed in 2014, U.S. Patent No. 9,187,405 (the ‘405 Patent) traces its priority back to a British patent filed in 2006, which possesses a written

224. *See id.* at 1200–01.

225. *See id.* at 1201.

226. *See id.* at 1202 (quoting *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)).

227. *See id.*

228. *See id.* at 1196.

229. *See supra* Part II.A.1.

230. *See Novartis II*, 21 F.4th 1362, 1365 (Fed. Cir. 2022), *vacated*, 38 F.4th 1013 (Fed. Cir. 2022), *and reh’g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom.* *Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023).

231. *See id.*; U.S. Patent No. 9,187,405 col. 1 ll. 5–12 (filed Apr. 21, 2014).

232. *See supra* Part II.A.1.

233. *Novartis II*, 21 F.4th at 1365–66.

234. *Novartis III*, 38 F.4th 1013, 1015 (Fed. Cir. 2022), *reh’g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom.* *Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023).

description that is substantially similar to that of the ‘405 Patent with respect to all the relevant details.²³⁵ The ‘405 Patent contains only six claims; the three independent claims are largely identical, all claiming the same 0.5 mg/day dosage and the lack of a loading dose.²³⁶ The ‘405 Patent’s prosecution history was fairly straightforward: Novartis was able to overcome an initial § 103 obviousness rejection²³⁷ by arguing that the previously published invention called specifically for a loading dose.²³⁸ Interestingly, the negative loading dose claim limitations that moved Novartis past the obviousness rejection were not present in the original claims as filed; they were added four months later, prior to receipt of the first nonfinal rejection.²³⁹

2. Insufficient Written Description: A Double Negative Is Not Proof Positive

HEC challenged two claimed limitations as lacking written description support: the 0.5 mg/day dosage and the absence of a loading dose.²⁴⁰ The U.S. District Court for the District of Delaware found in favor of Novartis, upholding the validity of the patent.²⁴¹

The Federal Circuit initially affirmed the district court on appeal in an opinion written by Judge O’Malley.²⁴² The 0.5 mg/day dosage was clearly present in the “Prophetic Trial,”²⁴³ which suggested testing three dosages—0.5 mg/day, 1.25 mg/day, and 2.5 mg/day—and additional support was provided by the dosage from animal trial data, as understood by a

235. See *Novartis II*, 21 F.4th at 1366; ‘405 Patent.

236. See ‘405 Patent col. 12 ll. 47–67, col. 13 ll. 1–9 (filed Apr. 21, 2014). A loading dose is a larger dose given prior to regular daily treatment in order to quickly increase the level of the therapeutic in the body. See *Novartis II*, 21 F.4th at 1366.

237. See 35 U.S.C. § 103; File Wrapper, U.S. Patent No. 9,187,405, Non-Final Rejection (Apr. 6, 2015) (rejecting all claims under § 103 as unpatentable over an academic review article describing Novartis’s Phase II and Phase III trials, in light of International Patent Application No. WO 2006/058316 (filed Nov. 28, 2005), an earlier patent assigned to Novartis for the same family of compounds—S1 P receptor modulators—but for a less specific application (e.g., “graft rejection or treating an autoimmune disorder”).

238. See File Wrapper, U.S. Patent No. 9,187,405, Applicant Arguments/Remarks Made in an Amendment (July 6, 2015).

239. See File Wrapper, U.S. Patent No. 9,187,405, Claims (Aug. 18, 2014); File Wrapper, U.S. Patent No. 9,187,405, Preliminary Amendment (Aug. 18, 2014); File Wrapper, U.S. Patent No. 9,187,405, Non-Final Rejection (Apr. 6, 2015).

240. See *Novartis II*, 21 F.4th at 1369.

241. See *Novartis Pharms. Corp. v. Accord Healthcare, Inc. (Novartis I)*, No. 18-1043, 2020 U.S. Dist. LEXIS 196939, at *13–14 (D. Del. Sept. 11, 2020), *aff’d*, 21 F.4th 1362 (Fed. Cir. 2022), and *vacated*, 38 F.4th 1013 (Fed. Cir. 2022), and *reh’g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom. Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023).

242. See *Novartis II*, 21 F.4th at 1365.

243. See MPEP § 608.01(p)(II) (9th ed. Rev. 10, June 2020) (“[P]rophetical examples (paper examples) . . . describe the manner and process of making an embodiment of the invention which has not actually been conducted.”).

PHOSITA.²⁴⁴ With the dosage mentioned explicitly, blaze marks were not needed.²⁴⁵ The Federal Circuit majority also found that the absent loading dose limitation was supported, rejecting what they characterized as HEC's attempt to "create a new heightened written description standard for negative limitations."²⁴⁶ The majority was satisfied with the district court's examination of the patent in light of expert testimony as to what a PHOSITA would have understood.²⁴⁷

Chief Judge Moore disagreed with the majority, finding a complete lack of written description support for the absent loading dose and stating that the majority's opinion would "dramatically" affect patent prosecution by allowing unsupported negative claim limitations to be added long after the first filing.²⁴⁸ Quoting MPEP § 2173.05(i), which states that "[t]he mere absence of a positive recitation is not a basis for an exclusion,"²⁴⁹ she succinctly reiterated: "silence alone is insufficient."²⁵⁰ Therefore, even if a PHOSITA understood the method described in the specification to not include a loading dose, such understanding was not enough to support adding a limitation excluding a loading dose in the claims.²⁵¹ Rather, the court explained, written description support can be found in a logical explanation for the exclusion, such as when the specification provides a list of disadvantages to its inclusion²⁵² or when several alternative features are described in the specification and only some are meant to be included in a claim.²⁵³

The majority responded to Chief Judge Moore's objections with MPEP § 2163, which allows claim limitations to be supported by "implicit" and "inherent" disclosure, as well as "express" disclosure.²⁵⁴ The majority understood "implicit" disclosure to mean the specification as understood when read by a PHOSITA.²⁵⁵

244. See *Novartis II*, 21 F.4th at 1369–70 (citing expert testimony that "a skilled artisan 'would understand that the inventors translated the lowest dose that had ever been seen as effective from their [rat] experiment (0.3 mg/kg once per week) to the 0.5 dose'").

245. See *id.* at 1370; *supra* note 221 and accompanying text.

246. *Novartis II*, 21 F.4th at 1373.

247. See *id.* at 1375.

248. See *id.* at 1377 (Moore, J., dissenting).

249. See MPEP § 2173.05(i) (9th ed. Rev. 10, June 2020) ("Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. [§] 112(a).").

250. See *Novartis II*, 21 F.4th at 1378.

251. See *id.* ("The knowledge of ordinary artisans may be used to inform what is actually in the specification, but not to teach limitations that are not in the specification, even if those limitations would be rendered obvious by the disclosure." (quoting *Rivera v. Int'l Trade Comm'n*, 857 F.3d 1315, 1322 (Fed. Cir. 2017))).

252. See *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012); *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1348 (Fed. Cir. 2016).

253. See *Novartis II*, 21 F.4th at 1378 & n.1 (Moore, C.J., dissenting).

254. See *id.* at 1374 (majority opinion); MPEP § 2163(I)(B) ("While there is no *in haec verba* requirement, newly added claims or claim limitations must be supported in the specification through express, implicit, or inherent disclosure.").

255. See *Novartis II*, 21 F.4th at 1374 ("What is critical is how a person of skill in the art would read the disclosure—not the exact words used.").

Following the Federal Circuit’s finding for Novartis, HEC petitioned for a panel rehearing, but before the panel could consider the request, Judge O’Malley retired.²⁵⁶ Chief Judge Moore and Judge Richard Linn were then joined by Judge Todd M. Hughes,²⁵⁷ who voted with Chief Judge Moore to grant a rehearing and reverse the original ruling, holding the ‘405 Patent was invalid due to an “inadequate written description” regarding the absent loading dose.²⁵⁸ Chief Judge Moore, this time writing for the majority, rejected the district court’s assumption that a patent is presumed to be complete “such that things not mentioned are necessarily excluded.”²⁵⁹ She restated that the written description must somehow convey to the PHOSITA that the inventor “intended the exclusion, such as a discussion of disadvantages or alternatives.”²⁶⁰ To allow otherwise would be to grant support to “every later-added negative limitation,” as long as the specification was silent.²⁶¹

Judge Linn, in dissent, wrote that the majority had created a “heightened standard of ‘necessary exclusion’” for negative claim limitations.²⁶² He noted that the Federal Circuit, in *Inphi Corp. v. Netlist, Inc.*,²⁶³ had previously rejected a heightened standard for negative claims.²⁶⁴ Although the Federal Circuit had found the “exclusion of alternatives” and “express recitation of (dis)advantages” sufficient to satisfy the written description requirement, they were not necessary.²⁶⁵ Further, the written description in *Inphi* was found to be inadequate because the negative limitation was inconsistent with the disclosure, not because it lacked a reason to exclude.²⁶⁶

The dissent also took issue with the majority’s contention that if the absence of a loading dose would have been clear to a PHOSITA, then there was no reason to add it to the claims.²⁶⁷ Judge Linn countered this by noting that the limitation was added to avoid an earlier publication and that Novartis “was doing no more than what applicants regularly do to secure allowance in making explicit that which was implicit prior to the amendment.”²⁶⁸

256. See Taylor, *supra* note 173; Holman, *supra* note 169.

257. See Taylor, *supra* note 173.

258. See *Novartis III*, 38 F.4th 1013, 1015 (Fed. Cir. 2022), *reh’g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom.* *Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023).

259. See *id.* at 1019 (stating that the “concept that a patent is presumed ‘complete’ infected the district court’s analysis”).

260. See *id.* at 1017; *supra* notes 252–53 and accompanying text.

261. See *Novartis III*, 38 F.4th at 1017.

262. See *id.* at 1021 (Linn, J., dissenting).

263. 805 F.3d 1350 (Fed. Cir. 2015).

264. See *Novartis III*, 38 F.4th at 1021 (citing *Inphi Corp. v. Netlist, Inc.*, 805 F.3d 1350, 1356 (Fed. Cir. 2015)).

265. See *Inphi*, 805 F.3d at 1356.

266. See *Novartis III*, 38 F.4th at 1022 (citing *In re Bimeda Rsch. & Dev. Ltd.*, 724 F.3d 1320, 1324 (Fed. Cir. 2013) (finding inconsistent with the written description a claim for treating bovine mastitis that excluded one specific anti-infective when the disclosure of the invention and all other claims described the invention as a mastitis treatment excluding all antibiotics or anti-infective agents).

267. See *id.* at 1024.

268. See *id.*

C. Patent Practitioners' Concerns After Biogen and Novartis

Following the Federal Circuit *Biogen* and *Novartis* decisions, industry groups, legal scholars, and other patent practitioners raised concerns about a muddled, and potentially heightened, standard for the written description requirement.²⁶⁹ Further, shortly after Novartis's petition for rehearing was denied, the USPTO published a request for comments on various initiatives for ensuring the reliability of patents, including a question regarding changes to practice to improve claim support in the written description.²⁷⁰

This section explores the concerns voiced about the present state of the written description requirement. Part II.C.1 explores the concerns of patent practitioners in response to *Biogen* and *Novartis*, and Part II.C.2 details the USPTO's suggestions for improving compliance with the written description requirement.

1. Response of Practitioners

In response to *Biogen* and *Novartis*, some patent practitioners have expressed concern that the written description standard has been heightened.²⁷¹ These practitioners worry that a more demanding standard will impact the ability to obtain and defend patents, which will in turn discourage innovation.²⁷²

Following *Biogen*, some industry and legal practitioners have suggested that proof that an invention works is now required to satisfy the written description standard.²⁷³ In particular, two industry groups, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO), jointly filed an amici curiae brief in support of Biogen's petition for certiorari,²⁷⁴ as did the Chemistry

269. See *infra* Part II.C.1.

270. See Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. 60130, 60133 (proposed Oct. 4, 2022).

271. See, e.g., Fitzgerald, *supra* note 173; Laura Smalley, *Federal Circuit Imposes Heightened Standard for Written Description Support of Negative Claim Limitations*, JD SUPRA (June 29, 2022), <https://www.jdsupra.com/legalnews/federal-circuit-imposes-heightened-6435686/> [<https://perma.cc/3SDS-HK8P>].

272. See, e.g., Brief of Amici Curiae Pharm. Rsch. & Mfrs. of Am. (PhRMA) & Biotech. Innovation Org. (BIO), in Support of Petitioners at 6, *Biogen Int'l GmbH v. Mylan Pharms. Inc.*, 18 F.4th 1333 (Fed. Cir. 2021) (No. 21-1567); Brief of Amici Curiae Intell. Prop. L. Professors in Support of Novartis Pharms. Corp.'s Petition for Panel & *En Banc* Rehearing at 7, *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013 (Fed. Cir. 2022) (No. 21-1070).

273. See Brief of Amici Curiae Pharm. Rsch. & Mfrs. of Am. (PhRMA) & Biotech. Innovation Org. (BIO), in Support of Petitioners, *supra* note 272, at 6; Brief of Amicus Curiae Chem. & L. Div. of Am. Chem. Soc'y in Support of Petitioners at 6, *Biogen Int'l GmbH.*, 18 F.4th 1333 (No. 21-1567).

274. Brief of Amici Curiae Pharm. Rsch. & Mfrs. of Am. (PhRMA) & Biotech. Innovation Org. (BIO), in Support of Petitioners, *supra* note 272. PhRMA represents roughly three dozen leading American pharmaceutical and biotechnology companies, and BIO represents over 1,000 international members, including industry leaders, start-ups, and universities. See *id.* at 1–2.

and the Law Division of the American Chemical Society.²⁷⁵ These three groups pointed out that the courts have consistently held that an invention need only be “scientifically plausible”²⁷⁶ and that “examples or an actual reduction to practice” are not required.²⁷⁷ Rather, it has been sufficient to describe the invention such that a PHOSITA can recognize the correspondence between the written description and the claims.²⁷⁸ In contrast, they argue, the *Biogen* court required the inclusion of evidence from the Tecfidera[®] clinical trials that demonstrated the effectiveness of the 480 mg/day dosage.²⁷⁹ This requirement, they believed, will stifle innovation by creating an impossible standard and by generating confusion about what must be included in the written description to ensure a valid patent.²⁸⁰

The inability to obtain patents due to an impossible standard would, according to PhRMA and BIO, dry up innovation.²⁸¹ The biopharmaceutical field requires incentivization to invent due to the large amount of time, money, and risk invested in the development of each new treatment.²⁸² The patent system incentivizes this gamble by ensuring a temporary monopoly for those few drugs that make it to market;²⁸³ the uncertainty of waiting until completion of clinical testing for the grant of a patent would disincentivize the pursuit of such research, as any clinical success would not be guaranteed protection.²⁸⁴ Further, because clinical trials often last multiple years²⁸⁵ and the FDA requires disclosure of clinical trials,²⁸⁶ this mandated disclosure would serve as a prior publication challenging the novelty of an

275. Brief of Amicus Curiae Chem. & L. Div. of Am. Chem. Soc’y in Support of Petitioners, *supra* note 273. The members represented by the Chemistry and the Law Division of the American Chemical Society are primarily patent attorneys. *See id.* at 1.

276. *See* Brief of Amici Curiae Pharm. Rsch. & Mfrs. of Am. (PhRMA) & Biotech. Innovation Org. (BIO), in Support of Petitioners, *supra* note 272, at 6.

277. *See* Brief of Amicus Curiae Chem. & L. Div. of Am. Chem. Soc’y in Support of Petitioners, *supra* note 273, at 5 (first citing MPEP § 2107.02 (9th ed. Rev. 10, June 2020) (brief incorrectly cites § 2017.02); then citing *Alcon Rsch. Ltd. v. Barr Lab’ys, Inc.*, 745 F.3d 1180, 1190 (Fed. Cir. 2014)).

278. *See id.* at 6.

279. *See* Brief of Amici Curiae Pharm. Rsch. & Mfrs. of Am. (PhRMA) & Biotech. Innovation Org. (BIO), in Support of Petitioners, *supra* note 272, at 5; Brief of Amicus Curiae Chem. & L. Div. of Am. Chem. Soc’y in Support of Petitioners, *supra* note 273, at 6.

280. *See* Brief of Amici Curiae Pharm. Rsch. & Mfrs. of Am. (PhRMA) & Biotech. Innovation Org. (BIO), in Support of Petitioners, *supra* note 272, at 6, 8; Brief of Amicus Curiae Chem. & L. Div. of Am. Chem. Soc’y in Support of Petitioners, *supra* note 273, at 7.

281. *See* Brief of Amici Curiae Pharm. Rsch. & Mfrs. of Am. (PhRMA) & Biotech. Innovation Org. (BIO), in Support of Petitioners, *supra* note 272, at 2–3.

282. *See id.* at 6–7, 10; Brief of Amici Curiae Intell. Prop. L. Professors in Support of Novartis Pharms. Corp.’s Petition for Panel & *En Banc* Rehearing, *supra* note 272, at 7.

283. *See supra* Part I.A.1.

284. *See* Brief of Amici Curiae Pharm. Rsch. & Mfrs. of Am. (PhRMA) & Biotech. Innovation Org. (BIO), in Support of Petitioners, *supra* note 272, at 10.

285. *See, e.g., supra* note 178.

286. *See* Brief of Amici Curiae Pharm. Rsch. & Mfrs. of Am. (PhRMA) & Biotech. Innovation Org. (BIO), in Support of Petitioners, *supra* note 272, at 8–9, 9 n.9.

application,²⁸⁷ making obtaining a patent for FDA-approved treatments impossible.²⁸⁸

PhRMA and BIO also expressed concern that the general public may be negatively impacted if clinical trial data were to be required for sufficient written description.²⁸⁹ The patent bargain benefits society by encouraging inventors to share their discoveries so that other inventors might benefit from the knowledge and so that the invention becomes available for use by the general public once the period of exclusivity ends.²⁹⁰ Requiring clinical evidence to be collected prior to seeking a patent would delay patent filing.²⁹¹ As a result, there would be a delay in the disclosure of useful knowledge and the exclusivity period, which is counted from the filing date,²⁹² would be extended, postponing the availability of less expensive generic versions of drugs.²⁹³

In discussing practitioner confusion about the written description standard, groups representing both the biopharmaceutical industry and legal professionals warned that a shifting standard also risks reducing innovation.²⁹⁴ The New England Legal Foundation, agreeing with Judge Lourie's assessment that the *Biogen* majority conflated various patentability requirements,²⁹⁵ noted that this muddiness is problematic, reducing trust in

287. *See id.* at 9. Only disclosures made by the inventor less than a year prior to the effective filing date of a patent pose no challenge to an application; older disclosures can be used to support a rejection of an application due to lack of novelty or obviousness. 35 U.S.C. §§ 102(b)(1), 103; *see also supra* notes 186–87 and accompanying text; *supra* note 237.

288. *See* Brief of *Amici Curiae* Pharm. Rsch. & Mfrs. of Am. (PhRMA) & Biotech. Innovation Org. (BIO), in Support of Petitioners, *supra* note 272, at 8–9.

289. *See id.* at 9.

290. *See supra* Part I.A.1.

291. *See* Brief of *Amici Curiae* Pharm. Rsch. & Mfrs. of Am. (PhRMA) & Biotech. Innovation Org. (BIO), in Support of Petitioners, *supra* note 272, at 9.

292. *See* 35 U.S.C. § 154(a)(2).

293. *See* Brief of *Amici Curiae* Pharm. Rsch. & Mfrs. of Am. (PhRMA) & Biotech. Innovation Org. (BIO), in Support of Petitioners, *supra* note 272, at 9–10, 9 n.10. Although PhRMA and BIO wrote here in support of brand-name innovator Biogen, the biopharmaceutical industry is not clearly divided between drug innovators and generic manufacturers. For example, Novartis's generic division, Sandoz, was the second-largest generics producer (by sales) in 2021, and many large pharmaceutical and biotech companies are involved in the manufacture of generics. *See* Kevin Dunleavy, Zoey Becker, Fraiser Kansteiner, Angus Liu & Eric Sagonowsky, *The Top 10 Generic Drug Makers by 2021 Revenue*, FIERCE PHARMA (July 18, 2022, 3:00 AM), <https://www.fiercepharma.com/pharma/top-10-generic-drugmakers-2021-revenue> [https://perma.cc/324J-R7CQ]; Tracy Staton, *Amgen Joins Big Pharma's Branded Generics Club with \$700M Deal*, FIERCE PHARMA (Apr. 25, 2012, 11:08 AM), <https://www.fiercepharma.com/m-a/amgen-joins-big-pharma-s-branded-generics-club-700m-deal> [https://perma.cc/NV8Q-3GWQ].

294. *See* Brief of *Amici Curiae* Pharm. Rsch. & Mfrs. of Am. (PhRMA) & Biotech. Innovation Org. (BIO), in Support of Petitioners, *supra* note 272, at 6; Brief of *Amicus Curiae* Chem. & L. Div. of Am. Chem. Soc'y in Support of Petitioners, *supra* note 273, at 4; Brief of *Amicus Curiae* New Eng. Legal Found. in Support of Petitioners at 8, *Biogen Int'l GmbH v. Mylan Pharms. Inc. (Biogen II)*, 18 F.4th 1333 (Fed. Cir. 2021) (No. 21-1567).

295. *See supra* notes 223–25 and accompanying text. In addition to enablement and best mode, the New England Legal Foundation's brief also states that the *Biogen III* decision considers nonobviousness and utility as part of its written description assessment. *See* Brief of *Amicus Curiae* New Eng. Legal Found. in Support of Petitioners, *supra* note 294, at 9–10.

the patent system.²⁹⁶ Patent practitioners rely on the USPTO's guidelines in the MPEP²⁹⁷ and the guidance of prior court precedent when drafting and litigating patents.²⁹⁸ Uncertainty about the ability to obtain and defend patents could have a negative impact on business and innovation because patent holders will be less able to both trust in patent protection already granted and predict which inventions will be protectable in the future.²⁹⁹ A lack of predictability makes both business planning and obtaining investment capital more difficult.³⁰⁰

Response to the Federal Circuit's *Novartis* rehearing³⁰¹ evoked similar concerns about a new written description standard that, by diverging from precedent, potentially endangers the validity of many granted patents.³⁰² In addition to concerns over the negative impact on innovation, practitioners are worried that the holding will change how patent applications must be drafted and prosecuted.³⁰³

Prior to *Novartis*, the Federal Circuit did not require that a patent written description include information well-known to the relevant PHOSITA, and in fact encouraged applicants to omit such information.³⁰⁴ However, some practitioners understand the *Novartis III* decision to hold that when a written description is silent as to a particular claim limitation, PHOSITA testimony that the limitation is well-known in the art cannot provide the requisite support.³⁰⁵ Instead, the specification would have to be drafted to include "every detail . . . even if those details were already well-known in the art."³⁰⁶

Some practitioners are also concerned that *Novartis III* eliminates the negative claim limitation as an important, and previously encouraged, patent prosecution tool for avoiding earlier disclosures.³⁰⁷ It is common for the first draft of a patent to contain broad claims, with the hope of securing the most

296. See Brief of Amicus Curiae New Eng. Legal Found. in Support of Petitioners, *supra* note 294, at 8, 10.

297. See Brief of Amicus Curiae Chem. & L. Div. of Am. Chem. Soc'y in Support of Petitioners, *supra* note 273, at 6 ("[P]ractitioners rely on the United States Patent and Trademark Office as the authoritative interpreter of the Patent Law as set forth in the MPEP.").

298. See Brief of Amicus Curiae New Eng. Legal Found. in Support of Petitioners, *supra* note 294, at 13.

299. See Brief of Amici Curiae Pharm. Rsch. & Mfrs. of Am. (PhRMA) & Biotech. Innovation Org. (BIO), in Support of Petitioners, *supra* note 272, at 2; Brief of Amicus Curiae New Eng. Legal Found. in Support of Petitioners, *supra* note 294, at 13.

300. See Brief of Amici Curiae Pharm. Rsch. & Mfrs. of Am. (PhRMA) & Biotech. Innovation Org. (BIO), in Support of Petitioners, *supra* note 272, at 2.

301. *Novartis III*, 38 F.4th 1013 (Fed. Cir. 2022), *reh'g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom.* *Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023).

302. See Brief of Amici Curiae Intell. Prop. L. Professors in Support of *Novartis Pharms. Corp.*'s Petition for Panel & *En Banc* Rehearing, *supra* note 272, at 2, 4, 7.

303. See *id.* at 4, 10.

304. See *id.* at 10.

305. See *id.* at 1–2. The amici believe that the inability to rely on testimony applies to positive limitations as well as negative ones. See *id.* at 2.

306. See *id.* at 6.

307. See *id.* at 4–5.

protection possible.³⁰⁸ This is particularly true in the biopharmaceutical industry, where patents are often filed early in development and are therefore written broadly in anticipation of a variety of potential outcomes.³⁰⁹ Negative claim limitations can then be added later to narrow the invention to its proper scope.³¹⁰ Some practitioners fear that without recourse to negative limitations, it will be harder to successfully overcome novelty and obviousness rejections in all fields.³¹¹

Because of the various *Biogen* and *Novartis* decisions, as well as other recent written description decisions,³¹² practitioners appear to be following written description developments closely.³¹³ Some practitioners see these rulings as simply emphasizing the proper practice of carefully drafting written descriptions to support all possible claims following a robust search of existing publications.³¹⁴ Meanwhile, patent holders are bracing for further challenges, whereas those with motivation to challenge patents may increasingly take advantage of this successful new method of attack.³¹⁵

Lastly, some commentators have used these cases as an opportunity to critique the Federal Circuit. Writing in support of *Novartis*, several law professors described the *Novartis* decision as “fuel[ing] the perception of the Federal Circuit as an overactive and unpredictable court.”³¹⁶ Another commentator saw *Biogen* as part of the Federal Circuit’s “slow, disquieting tendency to have [its opinions] spread from the doctrinal boundaries to encompass more and more circumstances that, in past precedent would have been inconceivable.”³¹⁷

308. See SHELDON, *supra* note 62, § 8:5.1.

309. See Brief of *Amici Curiae* Intell. Prop. L. Professors in Support of *Novartis* Pharms. Corp.’s Petition for Panel & *En Banc* Rehearing, *supra* note 272, at 6.

310. See *id.* at 4.

311. See *id.* at 6.

312. See *Indivior UK Ltd. v. Dr. Reddy’s Lab’s S.A.*, 18 F.4th 1323, 1329, 1332 (Fed. Cir. 2021) (invalidating several claims involving ranges because, although the ranges could be calculated from information in the specification, they were not explicitly recited); *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1342 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022) (invalidating claims to DNA encoding a broad group of engineered proteins due to insufficient disclosure of representative examples), *cert. denied*, 143 S. Ct. 402 (2022).

313. See Handler, *supra* note 33.

314. See, e.g., Dustin Luetzgen, *Negative Claim Elements and the Importance of Complete Patent Disclosures: How Novartis Lost a \$2.8 Billion Drug to Generic Drug Makers*, WILSON SONSINI (June 29, 2022), <https://www.wsgr.com/en/insights/negative-claim-elements-and-the-importance-of-complete-patent-disclosures-how-Novartis-lost-a-dollar28-billion-drug-to-generic-drug-makers.html> [<https://perma.cc/UC5L-E9BH>].

315. See Handler, *supra* note 33; Luke T. Shannon & Andrew M. Solomon, *Silence Is Not Golden - Federal Circuit Invalidates Method of Treatment Patent for Lack of Written Description*, NAT’L L. REV. (June 24, 2022), <https://www.natlawreview.com/article/silence-not-golden-federal-circuit-invalidates-method-treatment-patent-lack-written> [<https://perma.cc/8P7U-CFE5>].

316. See Brief of *Amici Curiae* Intell. Prop. L. Professors in Support of *Novartis* Pharms. Corp.’s Petition for Panel & *En Banc* Rehearing, *supra* note 272, at 9 (collecting articles).

317. Kevin E. Noonan, *Biogen Int’l GmbH v. Mylan Pharmaceuticals Inc. (Fed. Cir. 2021)*, PATENT DOCS (Dec. 1, 2021), <https://www.patentdocs.org/2021/12/Biogen-intl-gmbh-v-mylan-pharmaceuticals-inc-fed-cir-2021.html> [<https://perma.cc/7ZR5-VTR9>].

2. USPTO Request for Public Comment

In October 2022, the USPTO published a list of questions regarding “initiatives to ensure robust and reliable patents” in response to a 2021 Executive Order issued by President Biden.³¹⁸ The Executive Order, entitled “Promoting Competition in the American Economy,”³¹⁹ broadly focused on reducing the control of a few large players in a variety of sectors, including prescription drugs, for the benefit of workers, consumers, and small businesses.³²⁰ The stated goals of the USPTO’s proposed initiatives are to improve the reliability of patents for all technologies and, with respect to the biopharmaceutical industry, to strike the proper balance between incentivizing the development of new drugs and not overly delaying the availability of cost-saving generics.³²¹

One of the initiatives proposed by the USPTO is aimed at improving claim support in patents.³²² Currently, the MPEP states that patent applicants “should show support in the original disclosure for the new or amended claims.”³²³ The second question presented for public comment asks how “claim support and/or continuation practice” should be changed to make patents more reliable.³²⁴ The first three parts of question two ask whether there should be a requirement “to explain or identify” what part of the written description specifically supports each claim or claim limitation.³²⁵ This new requirement could be applied to claims presented in an initial filing, claims at the time of amendment during the prosecution process, and claims for which an applicant seeks the benefit of an earlier filing date.³²⁶ For the latter, support would have to be identified in the relevant earlier application.³²⁷ Another option for this new procedure would be to require “express or inherent support . . . for negative claim limitations,”³²⁸ thereby removing the option for “implicit” support.³²⁹ A further suggestion would amend the “or” to “and” in the requirement that claims “must find clear support or antecedent basis in the description” to clarify that “clear support” is not optional.³³⁰

318. See Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. 60130, 601330–31 (proposed Oct. 4, 2022).

319. Exec. Order No. 14,036, 86 Fed. Reg. 36987 (July 14, 2021).

320. See *id.* at 36987–88.

321. See Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. at 60130–31.

322. See *id.* at 60132.

323. See *id.* (citing MPEP § 2163(II)(A) (9th ed. Rev. 10, June 2020)).

324. See *id.* at 60133.

325. See *id.*

326. See *id.* at 60132.

327. See *id.*

328. See *id.* at 60133.

329. See *supra* note 254 and accompanying text.

330. See 37 C.F.R. § 1.75(d)(1) (2022); Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. at 60132. A claim lacks antecedent basis if an element in the claim is absent completely from the written description, if the description is inconsistent, if the language used to describe the element is inaccurate, or if there is ambiguity as to which element in the description is being referred to by the claim. See SHELDON, *supra* note 62, § 8:6.3[B]. An additional suggestion relates to more detailed

The potential impact of the USPTO's initiatives for improving compliance with the written description requirement is further addressed in Part III.

III. CLARIFYING THE WRITTEN DESCRIPTION REQUIREMENT

Following *Biogen* and *Novartis*, patent practitioners are uncertain about what may be required to satisfy the written description requirement going forward.³³¹ Ultimately, unless the Supreme Court decides to take up the issue,³³² it is up to the Federal Circuit to provide much-needed guidance.³³³ Part III.A analyzes the *Biogen* and *Novartis* opinions to better understand what the Federal Circuit is looking for in the written description. Part III.B proposes that the Federal Circuit should redefine the written description standard by providing a target for practitioners to shoot for rather than providing a handful of potentially useful arrows.

A. The Role of the Written Description Requirement

In analyzing the *Biogen* and *Novartis* opinions, it is clear that the Federal Circuit sees the written description requirement as playing a necessary role in producing valid patents.³³⁴ Below, Part III.A.1 considers the need for the written description requirement. Part III.A.2 analyzes what *Biogen* and *Novartis* reveal about the role that the written description requirement plays in the eyes of the Federal Circuit. Finally, Part III.A.3 considers how patent practitioners can adapt to the new landscape.

1. The Need for a Separate Written Description Requirement

As noted by the Federal Circuit in *Ariad Pharmaceuticals*,³³⁵ the written description requirement “often rise[s] and fall[s] together” with the enablement requirement.³³⁶ Further, the patent statute’s plain language does not clearly indicate that there is a separate written description requirement.³³⁷ Therefore, even though the written description requirement has been repeatedly reinforced by the courts,³³⁸ some still question whether it is necessary.³³⁹

support of genus, *see supra* note 122, and Markush (list of options) claims, *see* MPEP § 803.02 (9th ed. Rev. 10, June 2020), which are beyond the scope of this Note. *See* Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. at 60132.

331. Handler, *supra* note 33.

332. *See supra* note 26 and accompanying text.

333. *See infra* Part III.A.3.

334. *See infra* Part III.A.1.

335. 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

336. *Id.* at 1352.

337. *See* Sterne, *supra* note 96, at 232.

338. *See Ariad*, 598 F.3d at 1345–47 (summarizing Supreme Court precedent); 3 CHISUM, *supra* note 69, § 7.04[1][e][vi] & nn.116–17.1 (collecting Federal Circuit cases ruling on the written description requirement).

339. *See* Dennis Crouch, *An Enabling Written Description*, PATENTLY-O (Nov. 7, 2022), <https://patentlyo.com/patent/2022/11/enabling-written-description.html> [<https://perma.cc/H5LT-VQR2>].

If the written description is doing real work as a separate requirement, there should be cases in which the fates of enablement and written description are not entangled. *Biogen* and *Novartis* are two such cases: although both addressed sufficiency of the written description, neither raised the issue of insufficient enablement.³⁴⁰ Presumably this was because a lack-of-enablement argument faced difficulties in both cases. Such a difficulty can easily be seen in *Novartis*, in which the claim limitation at issue was the absence of a loading dose.³⁴¹ Given that the limitation was a restraint from taking an action, there was nothing to enable but inaction.

Meanwhile in *Biogen*, the limitation at issue was the 480 mg/day dosage.³⁴² The written description listed four increasingly narrow dosage ranges, with 480 mg/day appearing as the lower endpoint for the narrowest range.³⁴³ Seven total dosages were mentioned as range endpoints, with only 720 mg/day stated more than once.³⁴⁴ As the objection was not related to how to make and administer a 480 mg/day dosage, but simply to the specific dosage claimed, an enablement challenge would probably have to be premised on undue experimentation.³⁴⁵ Perhaps, given that *Biogen* had tested five treatment regimens across their Phase II and Phase III studies,³⁴⁶ the parties challenging the patent would not have expected seven variable dosages to be far enough outside of standard practice to qualify as undue experimentation.³⁴⁷

Assuming that the patents at issue in both *Biogen* and *Novartis* were properly enabled, the Federal Circuit is indeed likely looking for something more beyond enablement when assessing the written description. The Federal Circuit said as much in *Vas-Cath*: “[t]he purpose of the ‘written description’ requirement is broader than” enablement—the written description must demonstrate, at the time of the original filing date, “possession of the invention” to “those skilled in the art.”³⁴⁸

Although this standard for sufficiency of written description has been reiterated many times,³⁴⁹ there is no concrete explanation or list of criteria defining what beyond enablement must be disclosed to establish

340. See *Novartis II*, 21 F.4th 1362, 1368 n.5 (Fed. Cir. 2022) (noting enablement was not at issue), *vacated*, 38 F.4th 1013 (Fed. Cir. 2022), *and reh’g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom.* *Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023); *Biogen I*, No. 17-CV-116, 2020 U.S. Dist. LEXIS 107743, at *18 (N.D.W. Va. June 18, 2020) (addressing only written description), *aff’d*, 18 F.4th 1333 (Fed. Cir. 2021), *and reh’g denied*, 28 F.4th 1194 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 112 (2022).

341. *Novartis III*, 38 F.4th 1013, 1015 (Fed. Cir. 2022), *reh’g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom.* *Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023).

342. *Biogen II*, 18 F.4th 1333, 1342 (Fed. Cir. 2021), *reh’g denied*, 28 F.4th 1194 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 112 (2022).

343. See *supra* note 180.

344. See *id.*

345. See *supra* notes 81–82 and accompanying text.

346. See *Fox*, *supra* note 178, at 100–01.

347. See *supra* text accompanying note 83.

348. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991).

349. See MPEP § 2163.02 (9th ed. Rev. 10, June 2020).

“possession.”³⁵⁰ The next section attempts to identify what that “something more” was in *Biogen* and *Novartis*.

2. The Impact of *Biogen* and *Novartis* on the Written Description Requirement

In the various decisions in both *Biogen* and *Novartis*, dissenting opinions criticized the majority for departing from Federal Circuit precedent and creating a more demanding standard for the written description requirement.³⁵¹ Although it is not clear that all the concerns of the dissenters will prove to be founded, it is likely that patent practitioners will adjust disclosure practices in light of the decisions.³⁵²

In *Biogen I* and *Biogen II*, both the district court and the Federal Circuit highlighted the fact that the claim limitation in question, the 480 mg/day dosage, was mentioned only once within the specification.³⁵³ The Federal Circuit called it a “significant fact that cuts against Biogen’s case.”³⁵⁴ It is unclear if the Federal Circuit would have found the single mention as significant if another dosage, 720 mg/day, had not been mentioned multiple times, including independently (as opposed to an endpoint of a range of dosages).³⁵⁵ However, as the *Biogen III* dissent noted, the court has previously stated that the presence of unclaimed disclosures does not weigh against written description support of claimed matter.³⁵⁶ Therefore, reading any change to the written description requirement as narrowly as possible, *Biogen* seems to demand the repetition of key claim limitations, which has not been required before.³⁵⁷

This repetition issue is part of a larger discussion about Biogen’s failure to “link” the specific dosage to the claim that it is a “therapeutically effective amount.”³⁵⁸ Although the Federal Circuit found a sufficient link between

350. See *supra* notes 124–29 and accompanying text.

351. See *supra* Parts II.A.2, II.B.2.

352. See, e.g., Handler, *supra* note 33; Shannon & Solomon, *supra* note 315.

353. See *Biogen II*, 18 F.4th 1333, 1343 (Fed. Cir. 2021), *reh’g denied*, 28 F.4th 1194 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 112 (2022); *Biogen I*, No. 17-CV-116, 2020 U.S. Dist. LEXIS 107743, at *27 (N.D.W. Va. June 18, 2020), *aff’d*, 18 F.4th 1333 (Fed. Cir. 2021), and *reh’g denied*, 28 F.4th 1194 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 112 (2022); *supra* note 191 and accompanying text.

354. See *Biogen II*, 18 F.4th at 1343.

355. See *id.* (The court found the single mention “significant . . . particularly because it appears at the end of one range among a series of ranges, including DMF concentrations of 100–1,000, 200–800, 240–720, and 480–720 mg/day. . . . in stark contrast to DMF720,” which appears in two ranges in addition to being “referenced independently”; however, the court later stated that the single reference was crucial because it “was part of a wide DMF-dosage range and not listed as an independent therapeutically efficacious dose” without reference to 720 mg/day as a benchmark).

356. See *Biogen III*, 28 F.4th 1194, 1199 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 112 (2022) (Lourie, J. dissenting).

357. See *id.* at 1200.

358. See *Biogen I*, 2020 U.S. Dist. LEXIS 107743, at *26–27.

MS and DMF, the court desired “something more”³⁵⁹ to connect both the disease and the drug to the 480 mg/day dosage.³⁶⁰

If Judge Lourie is correct in reading a requirement for clinical data into the majority opinion, this would indeed be a significant change to precedent;³⁶¹ however, it is not clear that this is what the majority intended to convey. The majority notes that the patent application was filed prior to commencement of the Phase III study that demonstrated the efficacy of 480 mg/day.³⁶² It also critiques the original patent specification because the included basic research results did not provide support for particular human dosages.³⁶³ This is not a clear call for Phase III data; an alternative interpretation is that the lack of support in the original specification cannot be rescued by the eventual results of the Phase III study. Rather, the court appears to be suggesting that, given testimony that Biogen had access to data suggesting the use of the 480 mg/day dosage as far back as 2003,³⁶⁴ it is this data, not the Phase III study, that could have provided the necessary connection to the 480 mg/day dosage.³⁶⁵

Therefore, reading *Biogen* conservatively, the “something more”³⁶⁶ that the Federal Circuit was looking for was probably not clinical data, but rather the same supporting data that convinced Biogen to include 480 mg/day in their Phase III trials. Given that the original patent application was filed just over a month before the Phase III trials started,³⁶⁷ it is reasonable to assume that the inclusion of such data in the patent application was possible. However, even though *Biogen* may not stand for as dramatic a change as requiring clinical efficacy data, it could still lead practitioners to change their habits. Going forward, patent prosecutors may be hesitant to simply list alternative methods or ingredients without justification for their inclusion and assume that the written description requirement will be satisfied.³⁶⁸

In *Novartis III*, there is a consensus between the majority and the dissent: the negative no-loading dose claim limitation is not mentioned explicitly in the specification.³⁶⁹ There is disagreement, however, over the role of the PHOSITA in interpreting that silence.³⁷⁰ The dissent would allow for a PHOSITA to read the specification’s silence as implicitly disclosing the

359. See *supra* Part III.A.1.

360. See *Biogen II*, 18 F.4th at 1343.

361. See *Biogen III*, 28 F.4th at 1200 (Lourie, J., dissenting).

362. See *Biogen II*, 18 F.4th at 1344.

363. See *id.*

364. See *Biogen I*, 2020 U.S. Dist. LEXIS 107743, at *5–6.

365. See *Biogen II*, 18 F.4th at 1344.

366. See *supra* Part III.A.1.

367. See *Biogen I*, 2020 U.S. Dist. LEXIS 107743, at *9–10 (The ‘514 Patent traces its priority to the application filed February 8, 2007, and the DEFINE trial began March 14, 2007).

368. See Handler, *supra* note 33.

369. See *Novartis III*, 38 F.4th 1013, 1017 (Fed. Cir. 2022), *reh’g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom.* *Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023); *id.* at 1021 (Linn, J., dissenting).

370. See *id.* at 1017 (majority opinion); *id.* at 1023 (Linn, J. dissenting).

negative limitation.³⁷¹ In contrast, the majority would not find such PHOSITA testimony sufficient; rather, the limitation must be inherent, and therefore “always . . . understood” by PHOSITAs “as being necessarily excluded” by silence.³⁷² Otherwise, the majority believes, there should be “something more”: a reason supporting the presence of the negative limitation should be provided in the specification, such as disadvantages for not excluding the element or a discussion of alternative options.³⁷³

The *Novartis III* majority insists that its “necessarily excluded” standard does not heighten the requirement for negative limitations,³⁷⁴ and patent practitioners have not disagreed.³⁷⁵ However, it must be expected that at least some patent drafters have relied on the inclusion of “implicit” in the MPEP’s language;³⁷⁶ even if it is not a heightening of the Federal Circuit’s standard, it is still a shift in available guidance. Regardless, practitioners have recognized that the *Novartis III* ruling further paints a target on written description as an attractive pathway to patent invalidation.³⁷⁷ Particularly given the Federal Circuit’s disapproval of implicit support,³⁷⁸ the onus is now on practitioners to perform even more careful searches of previously disclosed technology in order to identify elements that may need to be excluded.³⁷⁹ In a sense, this is a taller order than the diligence the *Biogen* holding encourages; rather than disclosing more of what the inventor understands about an invention, the drafter must discover what the inventor does not know that they do not know and proactively shield against it.³⁸⁰

3. USPTO Proposals and Patent Practitioner Best Practice

Though the USPTO’s current consideration of policy changes³⁸¹ is in response to an executive order predating *Biogen* and *Novartis*,³⁸² it appears that these recent rulings have had an influence. In particular, one of the

371. *See id.* at 1023 (Linn, J., dissenting).

372. *Id.* at 1017–18 (majority opinion).

373. *See id.* at 1016.

374. *See id.* at 1019–20.

375. *See, e.g.,* Andrew Alexander, *Silence Doesn’t Support Negative Claim Limitations*, JDSUPRA (July 22, 2022), <https://www.jdsupra.com/legalnews/silence-doesn-t-support-negative-claim-8929876> [<https://perma.cc/6AFE-VGPG>] (“[T]he Federal Circuit’s decision is probably not novel . . .”).

376. *See* MPEP § 2163(I)(B) (9th ed. Rev. 10, June 2020).

377. *See* Alexander, *supra* note 375; Shannon & Solomon, *supra* note 315.

378. *See Novartis III*, 38 F.4th at 1017 n.2.

379. *See* Shannon & Solomon, *supra* note 315; Jonathan B. Fitzgerald & Jaime D. Choi, *Reexamining Negative Limitations After Novartis Patent Ruling*, LAW360 (Sept. 26, 2022, 6:02 PM), <https://www.law360.com/articles/1534169> [<https://perma.cc/5JFQ-EURK>].

380. *See* Courtenay C. Brinckerhoff, *Federal Circuit Reconsiders Written Description Support for Negative Limitation*, FOLEY (July 12, 2022), <https://www.foley.com/en/insights/publications/2022/07/federal-circuit-description-negative-limitation> [<https://perma.cc/KW3T-Z9NV>] (“[A] need for a negative claim limitation often does not arise until the application is undergoing prosecution. For example, an unexpected prior art publication may be cited that requires an element the invention does not.”).

381. *See supra* Part II.C.2.

382. *See supra* notes 318–19 and accompanying text.

proposals suggests that applicants should show “express or inherent support . . . for negative claim limitations,”³⁸³ conspicuously omitting the option for “implicit” written description support currently present in the USPTO’s guidance.³⁸⁴ This is a clear response to the majority’s rejection of “implicit” support in the Novartis rehearing.³⁸⁵

Patent practitioners, concerned about a shifting written description standard, should not look to the USPTO proposals as a source of clarity. In *Novartis III*, the Federal Circuit gave weight only to its own precedent,³⁸⁶ irrespective of USPTO guidance,³⁸⁷ and the USPTO now intends to adjust its guidance accordingly.³⁸⁸ Similarly, any new policies implemented after the notice and comment period will still be subject to the Federal Circuit’s interpretation.

Regardless of whether the USPTO’s suggested requirements for more formal identification of claim support are implemented, some practitioners already regard drawing clear ties between the written description and the claims as “best practice.”³⁸⁹ Moreover, practitioners, concerned about the increasing use of written description to invalidate patents,³⁹⁰ are primed to take more care in providing claim support.³⁹¹ Although identifying support for claims and claim amendments in response to a USPTO rejection is already standard practice,³⁹² it is unclear how this practice would look if original claims must be linked to specific text of the written description. The simplest implementation would probably be to annotate each claim with references to the relevant lines or paragraphs in the specification.

The benefit of explicitly linking claims to the written description for the patent office is obvious: it would be a time-saving practice for patent examiners.³⁹³ However, there are potential negative consequences for the applicant. Most clearly, providing greater clarification would be “burdensome and generally unnecessary” for patent drafters,³⁹⁴ but it may

383. See Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. 60130, 601331 (proposed Oct. 4, 2022).

384. See MPEP § 2163(I)(B) (9th ed. Rev. 10, June 2020); *supra* note 254.

385. See *Novartis III*, 38 F.4th 1013, 1017 n.2 (Fed. Cir. 2022), *reh’g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom.* *Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023).

386. See *id.*

387. See *id.* at 1023 & n.1 (Linn, J. dissenting).

388. See Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. at 60131.

389. See Letter from Robert A. Armitage to The Hon. Katherine K. Vidal, Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights 9 (Oct. 16, 2022), https://downloads.regulations.gov/PTO-P-2022-0025-0006/attachment_1.pdf [<https://perma.cc/6BFW-QGK3>].

390. See Handler, *supra* note 33; Shannon & Solomon, *supra* note 315.

391. See Luetgen, *supra* note 314.

392. See 1 MOY, *supra* note 132, § 3:19.

393. See Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. at 60132.

394. See Alec Pronk, *The Final Word: Who Weighed In After the Second Extension of USPTO’s Robust and Reliable Patents RFC*, IPWATCHDOG (March 22, 2023, 12:15 PM), <https://ipwatchdog.com/2023/03/22/final-word-weighed-second-extension-usptos-robust->

also impact the range of strategies available when defending against validity challenges. Presumably, the burden of showing insufficient written description will remain with the examiner.³⁹⁵ But, given the court's willingness to delve into the details of prosecution history,³⁹⁶ if failure to cite potentially relevant sections of the specification during prosecution weighs against the credibility of making such a link during litigation, patent litigators may lose flexibility while defending validity.

However, as stated above, any changes to USPTO requirements for the written description will be subordinate to the Federal Circuit's assessment of sufficiency, which remains unpredictable.³⁹⁷

B. A More Predictable Written Description Test Is Needed

Judge Randall R. Rader once described the Federal Circuit's written description requirement standard as “[b]ring your specifications to the Federal Circuit and we will tell you if they contain sufficient descriptions.”³⁹⁸ Although the “broad principles” approach³⁹⁹ may have been workable in the past, the apparent uptick in the use of written description to defend against infringement litigation⁴⁰⁰ suggests that the time has come for a more reliable standard.

The current standard requires that the written description demonstrate that the inventor was “in possession of the invention” at the time of filing⁴⁰¹ or, alternatively, that the inventor “invented the subject matter now claimed.”⁴⁰² This requirement looks for “something more” beyond enablement⁴⁰³ and is not necessarily satisfied by a basic description of the limitation.⁴⁰⁴

Looking to the *Biogen* and *Novartis* decisions for that “something more,” a parallel emerges: the desire of the Federal Circuit to see the logic supporting a claim limitation spelled out in the disclosure.⁴⁰⁵ Essentially, the

reliable-patents-rfc/id=158176/ [https://perma.cc/4QDQ-WM5B] (quoting INT'L FED'N OF INTELL. PROP. ATT'YS, RESPONSE TO REQUESTS FOR COMMENTS ON USPTO INITIATIVES TO ENSURE THE ROBUSTNESS AND RELIABILITY OF PATENT RIGHTS 2 (2023), https://downloads.regulations.gov/PTO-P-2022-0025-0210/attachment_1.pdf [https://perma.cc/7ZB2-6QET]).

395. See MPEP § 2163(II)(A) (9th ed. Rev. 10, June 2020).

396. See *Biogen Int'l GmbH v. Mylan Pharms. Inc. (Biogen III)*, 28 F.4th 1194, 1200–01 (Fed. Cir. 2022) (Lourie, J. dissenting), *cert. denied*, 143 S. Ct. 112 (2022).

397. See *Handler*, *supra* note 33; Noonan, *supra* note 317.

398. See *Lizardtech, Inc. v. Earth Res. Mapping, Inc.*, 433 F.3d 1373, 1379 (Fed. Cir. 2006) (Rader, J., dissenting).

399. See *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc).

400. See *Handler*, *supra* note 33; *Shannon & Solomon*, *supra* note 315; Noonan, *supra* note 317.

401. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1564 (Fed. Cir. 1991).

402. *In re Barker*, 559 F.2d 588, 593 (C.C.P.A. 1977).

403. See *supra* Part III.A.1.

404. See Noonan, *supra* note 317 (noting that *Biogen II* represented the first time that describing a claim limitation in the exact words used in the claim was found to be insufficient support).

405. See *Biogen II*, 18 F.4th 1333, 1343 (Fed. Cir. 2021), *reh'g denied*, 28 F.4th 1194 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 112 (2022).

court is asking for insight into how the inventor developed the invention. This is more than mere description,⁴⁰⁶ but it does not overlap with enablement, as it does not explain “how to make or use”⁴⁰⁷ the invention. However, it does require the inventor to demonstrate an understanding of the technology beyond a recitation of jargon that could then be implemented by any PHOSITA; in other words, it demonstrates possession by mapping the path to the invention. Therefore, one possible way to formulate a test for sufficiency, at least in the unpredictable arts,⁴⁰⁸ is to ask whether the written description adequately describes to a PHOSITA how the inventor progressed from the prior-known technology to the novel limitations now being claimed. This test would not alter the written description standard from where it stands following *Biogen* and *Novartis*. Yet, it would finally provide a coherent definition of “possession” that gives patent drafters a concrete goal for which to aim, as well as providing patent holders and litigators with a more reliable measure by which to assess patent validity.

Had such a test existed, it would have been clear that both Biogen’s ‘514 Patent⁴⁰⁹ and Novartis’s ‘405 Patent⁴¹⁰ were invalid.⁴¹¹ The ‘514 Patent specification stated the 420 mg/day dosage of DMF but omitted the data that led to its inclusion in the Phase III study,⁴¹² and the ‘405 Patent specification was entirely silent regarding the lack of a loading dose, providing no supporting data leading to the limitation.⁴¹³ Not only would the test have made it clearer to the parties, as well as the court, that necessary disclosure was missing, but the absent information would actually be of value to the patent bargain. An explanation of the logic of an invention, in addition to demonstrating the understanding of the inventor, would place useful knowledge in the hands of those seeking to learn from and advance the invention. Simply requiring that a limitation be repeated more than once⁴¹⁴ offers no such benefit.

This Note does not intend to suggest that only one written description test is necessary. Both the Biogen⁴¹⁵ and Novartis patents⁴¹⁶ contained claims “drawn to a single embodiment,”⁴¹⁷ as opposed to genus claims,⁴¹⁸ and both

406. *Description*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/description> [https://perma.cc/G29Z-29DV] (last visited Nov. 3, 2023) (“a statement or account giving the characteristics of someone or something”).

407. MPEP § 2164 (9th ed. Rev. 10, June 2020).

408. *See* MPEP § 2163(II)(A)(3)(i) (9th ed. Rev. 10, June 2020) (noting that more evidence was required to satisfy the written description requirement for inventions in the unpredictable arts, i.e., experimental sciences).

409. *See* U.S. Patent No. 8,399,514 (filed Feb. 13, 2012); *supra* Part II.A.1.

410. *See* U.S. Patent No. 9,187,405 (filed Apr. 21, 2014); *supra* Part II.B.1.

411. *See supra* Part III.A.2.

412. *See supra* notes 364–65 and accompanying text.

413. *See* ‘405 Patent.

414. *See supra* note 191 and accompanying text.

415. *See* U.S. Patent No. 8,399,514 col. 27 ll. 59–67, col. 28 ll. 58–67, col. 29 ll. 1–29, col. 30 ll. 1–28 (filed Feb. 13, 2012).

416. *See* ‘405 Patent col. 12 ll. 49–67, col. 13 ll. 1–9.

417. *See* MPEP § 2163(II)(A)(3)(a)(i) (9th ed. Rev. 10, June 2020).

418. *See id.* § 2163(II)(A)(3)(a)(ii); *see also supra* note 122.

were focused on dosage claims for RRMS pharmaceuticals,⁴¹⁹ a very small corner of the field of technology covered by patents. As the Federal Circuit has stated, the written description test must vary based on the particular technology in question.⁴²⁰ But the way to address this variability is not to offer a list of possible ways patent applicants could potentially satisfy the written description requirement without guidance as to the height of the goalpost.⁴²¹ Lists without explanation now fail to satisfy the written description requirement;⁴²² direction for satisfying the written description requirement should be more than a list as well. Therefore, to improve predictability in written description decisions, this Note proposes that the court, in assessing written description, articulate the “something more”⁴²³ that is necessary to satisfy the test—not as a nebulous concept like “possession of the invention,”⁴²⁴ but as a concrete goal attainable through written disclosure and beneficial to the relevant technological field. This improved predictability would address the concerns of patent practitioners and those who rely on the patent system.⁴²⁵

CONCLUSION

Patents serve an important role in incentivizing the development of new technologies, such as new medical treatments for devastating diseases like MS. However, without a proper balance between inventor rights and responsibilities, the public may bear the burdens rather than the benefits from such inventions, such as delayed availability of cost-saving generic drugs. The written description requirement should play a role in this proper balance by ensuring that patents are only granted to true inventors. However, the standard for satisfying the written description requirement has long been nebulous, asking inventors to demonstrate their “possession” of the claimed invention but failing to provide concrete guidance as to what level of disclosure is sufficient.

As the recent cases *Biogen* and *Novartis* have demonstrated, the written description requirement is becoming an increasingly favored target for those challenging patent validity during infringement litigation. The outcomes of these cases have been difficult to predict because the definition of “possession” of the invention is not clear. This Note proposes that the Federal Circuit develop goal-focused tests for written description sufficiency

419. See *Novartis III*, 38 F.4th 1013, 1015 (Fed. Cir. 2022), *reh'g denied*, No. 2021-1070 (Fed. Cir. Sept. 20, 2022), *cert. denied sub nom.* *Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023); *Biogen II*, 18 F.4th 1333, 1335 (Fed. Cir. 2021), *reh'g denied*, 28 F.4th 1194 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 112 (2022).

420. See *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

421. See *id.* at 1351–52 (listing factors for generic claims and presenting several “broad principles”); *supra* notes 126–29 and accompanying text.

422. See *Handler*, *supra* note 33.

423. See *supra* Part III.A.1.

424. See *supra* Part I.A.3; see also *Ariad*, 598 F.3d at 1351 (“The term ‘possession,’ however, has never been very enlightening.”).

425. See *supra* Part II.C.1.

so that patent practitioners better understand what information must be disclosed for an inventor to merit patent protection. This would enable true inventors to obtain valid patents while protecting the public from those who would seek to claim what they did not invent.