
Patent Law—Substantially Equivalent Disclosure Sufficient to Satisfy Written Description Requirement for Non-Operative Features—*Nalpropion Pharmaceuticals, Inc. v. Actavis Laboratories FL, Inc.*, 934 F.3d 1344 (Fed. Cir. 2019).

The statutes governing patents, 35 U.S.C. §§ 1-390, require all patents to include a specification containing a written description of the claimed invention.¹ The U.S. Court of Appeals for the Federal Circuit (CAFC) has construed this requirement to include a sub-condition mandating the written description of the claimed invention adequately convey to a person of ordinary skill in the art (POSITA) that the patent’s inventors had possession of the claimed invention on the filing date of the patent application.² In *Nalpropion Pharmaceuticals, Inc. v. Actavis Laboratories FL, Inc.*,³ the CAFC considered whether a “substantially equivalent” disclosure was sufficient to convey such possession to a POSITA.⁴ The court held such disclosure adequate for that purpose when only supporting a *characteristic* of a step of the method recited in the specified claim, and not any operative steps of that method.⁵ The CAFC reasoned that, while

1. See 35 U.S.C. § 112 (2006), amended by Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 4(c), § 112, 125 Stat. 284, 296 (2011) (specifying written description requirement). The version of 35 U.S.C. § 112 in force before the Leahy-Smith America Invents Act (AIA) governs patents applied for prior to September 16, 2012. See Leahy-Smith America Invents Act sec. 4(e) (providing effective date for amendments to § 112). Because the application that matured into the patent discussed in this Case Comment was filed prior to September 16, 2012, the version of § 112 in force prior to the AIA applies. See U.S. Patent No. 8,916,195, at [22] (filed June 4, 2007). The changes to § 112 upon enactment of the AIA are not expected to substantively alter the written description requirement. See 1 DONALD S. CHISUM, CHISUM ON PATENTS § 2 (Matthew Bender, 3d ed. 2013) (asserting changes to § 112 unreflective of underlying legal principles).

2. See *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (articulating test for written description requirement). Congress has delegated exclusive jurisdiction over appeals relating to patents to the CAFC. See 28 U.S.C. § 1295(a)(1) (2018). Therefore, the CAFC’s decisions on patent law matters are binding on all U.S. district courts. See 8 DONALD S. CHISUM, CHISUM ON PATENTS § 21.02[5][b][iii] (Matthew Bender 2020) (describing reliance of district courts on CAFC precedents).

3. 934 F.3d 1344 (Fed. Cir. 2019).

4. See *id.* at 1351 (holding substantially equivalent disclosure may provide written description support for non-operative claim features). The U.S. District Court for the District of Delaware (Delaware District Court) deemed the disclosure at issue—the testing method employed to generate the data forming the basis for the claimed naltrexone dissolution profile—“substantially equivalent” to the testing method recited in the claim for assessing the naltrexone dissolution profile on the basis of expert testimony that a POSITA would consider these two testing methods to be substantially equivalent. See *id.* at 1350 (describing why disclosure deemed substantially equivalent). The CAFC accepted this factual finding. See *id.* (declining to disturb Delaware District Court’s finding).

5. See *id.* (holding dissolution profile non-operative because it relates only to measuring in vitro parameters). The term “operative steps” refers to the steps in a method claim that must be performed to infringe that claim. See *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005) (providing conditions for infringement of method claims). By contrast, non-operative features are elements recited in method claims that are not the operative steps. See 934 F.3d at 1350 (contrasting dissolution profile measurement with operative claim steps).

substantially equivalent disclosure is not typically enough to satisfy the written description requirement, it should be sufficient for claim features other than operative claim steps when the factfinder has determined such substantial equivalence exists, and there is no challenge to the sufficiency of the associated operative claim steps' written description.⁶

On June 4, 2007, Orexigen Therapeutics (Orexigen), Nalpropion Pharmaceuticals' (Nalpropion) predecessor in interest of the patents at issue, filed a patent application directed to oral doses of sustained-release naltrexone—a medication suitable for treating conditions ranging from substance dependence to excess weight.⁷ The application included examples describing the preparation of naltrexone oral doses, their dissolution profiles as measured by the USP Apparatus 1 Basket Method (Basket Method), and their efficacy for treating human patients.⁸ The application also included a statement that in vitro release rates described are those determined by the USP Apparatus 2 Paddle Method at 100 rotations per minute in a dissolution medium of water at 37° C (Paddle Method).⁹ On December 23, 2014, the patent application matured into a patent.¹⁰ The issued patent included claims reciting in vitro dissolution profiles having ranges of naltrexone release as determined by the Paddle Method.¹¹ Data obtained using the Basket Method supports these claims.¹²

Litigation arose when Orexigen learned that Actavis had filed an Abbreviated

6. See 934 F.3d at 1350-51 (advocating for flexibly and sensibly interpreting precedent).

7. See U.S. Patent No. 8,916,195, at [54] (filed June 4, 2007) (providing title of "sustained release formulation of naltrexone"); *id.* col. 1 ll. 45-49 (providing chemical formula of naltrexone and describing its known uses). At the time that Orexigen filed the application that matured into U.S. Patent No. 8,916,195 ('195 Patent), naltrexone was known for its use in treating alcohol and opioid dependence. See *id.* col. 1 ll. 45-49. Naltrexone was also known to cause weight loss. See *id.* col. 3 ll. 8-11 (referring to known prior art describing using naltrexone to promote weight loss). The '195 Patent's inventors believed they had invented a new method of reducing adverse effects associated with the administration of naltrexone in combination with other medications. See *id.* col. 3 ll. 15-29 (describing motivation for invention and invention itself).

8. See *id.* col. 5 ll. 22-23 (stating various embodiments of invention directed to oral dosage form comprising sustained-release naltrexone); *id.* col. 16 ll. 7-8, col. 30 ll. 6-29 (describing experiments related to sustained-release naltrexone's preparation, disintegration, dissolution, and use in patients); see also 934 F.3d at 1348 (stating data in application obtained by Basket Method). As used in the '195 Patent, the dissolution profile of a compound in a particular environment is the rate at which that compound is released when exposed to that environment. See '195 Patent figs.1 & 2, col. 4 ll. 25-29, col. 18 ll. 16-33 (describing and providing plots depicting dissolution profiles).

9. See '195 Patent col. 6 ll. 45-55 (equating "release rate" with in vitro release rate measured by Paddle Method). Actavis Laboratories FL (Actavis) asserted that using the Paddle Method to measure the release rate of a naltrexone oral dose would yield a different result than the Basket Method. See 934 F.3d at 1349-50 (summarizing Actavis's argument). The Delaware District Court did not find Actavis's arguments on this issue persuasive and the CAFC declined to disturb this factual finding. See *id.* at 1351 (describing Delaware District Court's weighing of expert testimony and CAFC's refusal to disturb findings).

10. '195 Patent, at [45] (providing patent issuance date).

11. See *id.* col. 30 ll. 6-29, col. 31 l. 5-col. 32 l. 3 (reciting Paddle Method-determined in vitro dissolution profiles).

12. See *id.* col. 18 ll. 26-28 (providing Basket Method-determined in vitro dissolution profiles). Another example in the '195 Patent describes assessing the dissolution of naltrexone tablets, but does not state the measurement technique employed. See *id.* col. 20 tbl.10.

New Drug Application (ANDA) seeking regulatory approval to sell a generic version of one of Orexigen's products.¹³ Because the patent directed to oral doses of naltrexone exhibiting sustained-release behavior covered this product, Orexigen had a cause of action under 35 U.S.C. § 271(e)(2)(A) for patent infringement.¹⁴ In response to Orexigen's infringement contentions, Actavis argued that the asserted claim was invalid due to a lack of written description support; namely, that the application did not convey to a POSITA that the inventors had possession of the claim's subject matter on the application's filing date.¹⁵ Specifically, Actavis argued that this claim includes dissolution ranges that do not have adequate written description support because the inventors obtained the data allegedly providing such support with a technique different than that recited in the claim.¹⁶

When assessing the validity of the asserted claim, the Delaware District Court found that it was valid because Actavis had failed to prove by clear and convincing evidence that the claim lacked sufficient written description support.¹⁷ The court credited expert testimony, which stated '195 Patent's

13. See *Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc.*, 282 F. Supp. 3d 793, 797 (D. Del. 2017) (providing procedural history), *aff'd in part, rev'd in part sub nom.* 934 F.3d 1344.

14. See 35 U.S.C. § 271(e)(2)(A) (2018) (stating applications submitted under section 505(j) for drug claimed in patent infringes said patent). Section 505(j) of the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 355(j), describes the procedures and requirements for submitting an ANDA application. See 21 U.S.C. § 355(j) (2018). Orexigen brought the patent infringement claim in the Delaware District Court. See *Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc.*, 282 F. Supp. 3d 793, 797 (D. Del. 2017) (stating Orexigen initiated patent infringement litigation), *aff'd in part, rev'd in part sub nom.* 934 F.3d 1344. Orexigen also alleged Actavis infringed two other patents: U.S. Patent No. 7,462,626 (filed Feb. 17, 2006) and U.S. Patent No. 7,375,111 (filed Apr. 21, 2004). See *id.* (listing patents asserted against Actavis). The district court found both of these patents valid and infringed. See *id.* at 818. The CAFC disagreed, holding that these two patents were both obvious, and therefore invalid. See 934 F.3d at 1356.

15. See *Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc.*, 282 F. Supp. 3d 793, 800-01 (D. Del. 2017) (describing Actavis's written description contentions), *aff'd in part, rev'd in part sub nom.* 934 F.3d 1344. After issuance, patents are presumed valid unless a party shows otherwise by clear and convincing evidence. See 35 U.S.C. § 282(a) (stating patent claims presumed valid and party asserting invalidity bears burden of proof); see also *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011) (holding defendant must establish patent invalidity by clear and convincing evidence). Nevertheless, invalidity is an affirmative defense to patent infringement. See 35 U.S.C. § 282(b)(2)-(3) (providing invalidity defenses); see also *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1563-64 (Fed. Cir. 1988) (allowing judiciary to find for alleged infringer raising invalidity defense); *Cornwall v. U.S. Constr. Mfg., Inc.*, 800 F.2d 250, 252 (Fed. Cir. 1986) (holding invalidity affirmative defense).

16. See *Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc.*, 282 F. Supp. 3d 793, 800-03 (D. Del. 2017) (describing Actavis's logic regarding lack of written description for claim 11 of '195 Patent), *aff'd in part, rev'd in part sub nom.* 934 F.3d 1344. Actavis also argued that the asserted claim recited ranges lacking written description support for a variety of other reasons. See *id.* (summarizing Actavis's arguments). These reasons included the selection of some ranges from a boilerplate paragraph, the selection of some ranges from data allegedly randomly picked from a table, and the lack of a demonstration by the inventors that they possessed the entirety of the claimed range. See *id.* (listing Actavis's contentions). None of these theories persuaded the district court or the CAFC. See 934 F.3d at 1349-51 (affirming district court's findings); *Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc.*, 282 F. Supp. 3d 793, 801 (D. Del. 2017) (crediting expert testimony stating Orexigen possessed claimed invention despite these drawbacks), *aff'd in part, rev'd in part sub nom.* 934 F.3d 1344.

17. See *Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc.*, 282 F. Supp. 3d 793, 801-03 (D. Del. 2017)

specification conveyed to a POSITA that its inventors had possession of the claimed invention.¹⁸ The Delaware District Court also found that the differences between the Basket Method and the Paddle Method were immaterial to this determination.¹⁹ The CAFC agreed and held that the *in vitro* dissolution profile as determined by the Paddle Method is not an operative claim step, and thus is adequately supported by the substantially equivalent disclosure of *in vitro* dissolution profiles obtained by the Basket Method.²⁰

Beginning with the Patent Act of 1790, each statute describing the preconditions for obtaining a patent has required inventors to provide a written description of the claimed invention.²¹ Since at least 1967, the appellate courts having jurisdiction over patent matters have interpreted this requirement to mean that the inventors must show they invented the subject matter of the patent's claims.²² In 1973, the Court of Customs and Patent Appeals (CCPA) further

(finding Actavis did not prove lack of written description by clear and convincing evidence), *aff'd in part, rev'd in part sub nom.* 934 F.3d 1344.

18. See *Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc.*, 282 F. Supp. 3d 793, 802 (D. Del. 2017) (crediting expert testimony explaining POSITA would believe inventors possessed claimed invention), *aff'd in part, rev'd in part sub nom.* 934 F.3d 1344.

19. See *Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc.*, 282 F. Supp. 3d 793, 802 (D. Del. 2017) (finding difference in measurement technique unimportant when specification shows possession of invention), *aff'd in part, rev'd in part sub nom.* 934 F.3d 1344. The district court found that description of a naltrexone oral dose having a dissolution profile within the claimed range was sufficient to show possession of the entire invention. See *id.* (comparing experimental data to claimed range).

20. See 934 F.3d at 1351 (allowing equivalent disclosure to satisfy written description requirement for claimed dissolution parameters).

21. See Act of Apr. 10, 1790, ch. 7, § 2, 1 Stat. 109, 110-11 (repealed 1793) (requiring patentee to deliver specification describing invention to Secretary of State); *In re Barker*, 559 F.2d 588, 592-93 (C.C.P.A. 1977) (tracing written description requirement from Patent Act of 1790 to date of decision). Since at least 1822, the judiciary has interpreted the purpose of the written description requirement as restricting inventors for claiming more than they invented. See *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 430 (1822) (explaining written description prevents inventor from obtaining patent broader than invention); *In re Barker*, 559 F.2d 588, 592-93, 592 n.4 (C.C.P.A. 1977) (discussing Supreme Court interpretation of written description requirement). The U.S. Constitution provides Congress with the authority to legislate regarding patents. See U.S. CONST. art. I, § 8, cl. 8 (establishing congressional power to promote progress of science and useful arts by granting patents).

22. See *In re Ruschig*, 379 F.2d 990, 995-96 (C.C.P.A. 1967) (holding inventors must show invention of claimed subject matter to satisfy written description requirement). Since *Ruschig*, further CCPA decisions followed its holding and ruled that the written description requirement mandates evidence of the invention of the claimed subject matter by the inventors. See *In re Wertheim*, 541 F.2d 257, 263 (C.C.P.A. 1976) (stating § 112 inquiry encompasses whether specification shows inventors invented claimed subject matter). In 1967, the CCPA provided a parallel mode of judicial review to the U.S. District Court for the District of Columbia. See 4 CHISUM, *supra* note 2, § 11.06[3][c][iv][B] (describing relationship between these courts). Although CCPA decisions were not binding on the U.S. District Court for the District of Columbia, they were often given deference. See *Plastic Contact Lens Co. v. Gottschalk*, 484 F.2d 837, 839 (D.C. Cir. 1973) (giving "great weight" to CCPA decisions); *Kollsman v. Ladd*, 226 F. Supp. 186, 188 (D.D.C. 1964) (stressing importance of respecting CCPA decisions to promote sound, uniform body of patent law); *Gen. Tire & Rubber Co. v. Watson*, 184 F. Supp. 344, 350 (D.D.C. 1960) (stating decisions from CCPA should receive "great respect"). Today, the CAFC has exclusive appellate jurisdiction over actions involving patent matters. See 4 CHISUM, *supra* note 2, § 11.06[3][e] (describing CAFC's formation); see also 28 U.S.C. § 1295(a)(1) (2018) (describing CAFC's jurisdiction and powers). The CAFC has adopted the CCPA's decisions as binding precedent. See 4 CHISUM, *supra* note 2, § 11.06[3][e][vi] (stating CAFC considers predecessor courts' holdings binding precedent). Accordingly, the

interpreted this requirement to also mean that the inventors must show they had possession of the claimed subject matter on the filing date of the application.²³ In the years since, the CAFC has explicitly expanded the written description requirement to encompass more than a mere statement of the claimed subject matter for certain types of inventions.²⁴ The CAFC has indicated that the extent of what must be included in the patent to satisfy the written description requirement varies depending on the predictability of the art in which the invention is made.²⁵ For inventions in unpredictable arts, the written description requirement can necessitate a description of one or more of the chemical, physical, and structural properties of claimed features of the invention.²⁶

Prior to 2010, there was judicial and scholarly criticism of the CAFC's evolving interpretation of the written description requirement, with critics alleging it was too stringent and becoming increasingly conflated with the enablement requirement.²⁷ In response, in *Ariad Pharmaceuticals, Inc. v. Eli*

CAFC has also held that evidence showing inventors actually invented the claimed subject matter is necessary to establish written description support. See *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (clarifying written description standard); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (requiring application to inform POSITA inventors invented claimed subject matter); *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989) (mandating application to allow POSITA to recognize inventors' invention of claimed subject matter).

23. See *In re Smith*, 481 F.2d 910, 915 (C.C.P.A. 1973) (explaining § 112 requires showing inventors had possession of invention). Later CAFC cases have also articulated a possession requirement. See *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (providing possession requirement); *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985) (holding trial court properly identified possession test for written description sufficiency); *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983) (articulating possession test for written description compliance). This aspect of the written description requirement provides a check on inventors who attempt to claim more than what they have invented. See Oskar Liivak, *Overclaiming Is Criminal*, 49 ARIZ. ST. L.J. 1417, 1431-32 (2017) (arguing written description requirement should prevent overclaiming if properly applied); see also *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 430 (1822) (describing Supreme Court's articulation of written description requirement).

24. See *Regents of the Univ. of Cal. v. Eli Lilly & Co. (Eli Lilly)*, 119 F.3d 1559, 1567 (Fed. Cir. 1997) (holding naming complementary DNA and constructive example insufficient without describing structural or physical characteristics); *Fiers v. Revel*, 984 F.2d 1164, 1171-72 (Fed. Cir. 1993) (holding reference to DNA and method for isolating it inadequate written description). But see *Falkner v. Inglis*, 448 F.3d 1357, 1367 (Fed. Cir. 2006) (finding no per se rule indicating gene or sequence recitation must support macromolecular sequence claims).

25. See *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005) (stating written description inquiry performed in view of predictability of art in area of invention).

26. See *supra* note 24 and accompanying text (summarizing written description requirement jurisprudence in unpredictable arts).

27. See *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1308 (Fed. Cir. 2004) (Rader, J., dissenting) (arguing *Eli Lilly* and subsequent written description cases created confusion); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 982 (Fed. Cir. 2002) (Rader, J., dissenting) (arguing *Eli Lilly* upset settled expectations); Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 127-28 (2006) (summarizing controversy surrounding written description requirement). Some scholars took strong positions that the evolution of written description jurisprudence after *Eli Lilly* was an undesirable departure from precedent that introduced confusion into the law. See Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 633 (1998) (asserting then-current interpretation of written description requirement abrogated precedent); Stephen J. Burdick, Note, *Moba v. Diamond Automation, Inc.: Questioning the Separate Written Description Requirement*, 19 BERKELEY

Lilly & Co., the CAFC clarified that the written description requirement is stand-alone and separate from the enablement requirement.²⁸ The CAFC also held that whether a patent has satisfied the written description requirement should be assessed by performing a factual inquiry into the specification to determine if the inventors had possession of the claimed invention.²⁹ The CAFC explained that this inquiry should be performed in light of a POSITA's level of skill at the time the application was filed, and may be satisfied by constructive reduction to practice, actual reduction to practice, or experimental data showing possession.³⁰

The CAFC and the CCPA have allowed a wide variety of disclosure types to satisfy the written description requirement as long as the relevant disclosure conveys the required possession of the claimed invention to a POSITA.³¹ For

TECH. L.J. 133, 144-48 (2004) (asserting *Eli Lilly* restriction requirement redundant with enablement requirement, unnecessary, and source of problems); Guang Ming Whitley, Comment, *A Patent Doctrine Without Bounds: The "Extended" Written Description Requirement*, 71 U. CHI. L. REV. 617, 626-30 (2004) (criticizing various courts for promoting confusion, questioning validity of issued patents, and allowing excessive discretion). The enablement requirement is a requirement that the patent describe how to make and use the claimed invention in sufficient detail such that a POSITA could do so. See generally 3 CHISUM, *supra* note 2, § 7.03 (defining enablement requirement).

28. See *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc) (holding inquiry into whether written description requirement satisfied separate from inquiry into enablement requirement satisfaction). The court supported this conclusion by parsing the grammar of § 112 and holding that deference to Supreme Court precedent and stare decisis compels separate requirements. See *id.* at 1343-48. This decision was not universally well-received by legal academics. See Andres Sawicki, *The Central Claiming Renaissance*, 103 CORNELL L. REV. 645, 719-20 (2018) (advocating for written description inquiry to focus on whether inventor distinguished work from prior art); Allen K. Yu, *The En Banc Federal Circuit's Written Description Requirement: Time for the Supreme Court to Reverse Again?*, 33 CARDOZO L. REV. 895, 897-99 (2012) (criticizing *Ariad* for upholding unpredictable, inconsistent, and senseless doctrine). *Ariad* exemplifies the CAFC's use of en banc review to clarify its interpretation of disputed points of patent law. See FED. R. APP. P. 35(a) (allowing en banc review when necessary to promote uniformity and for exceptionally important proceedings); see also *In re Kemps*, 97 F.3d 1427, 1431 n.5 (Fed. Cir. 1996) (stating en banc hearings appropriate for overruling precedent), *abrogated by In re Gartside*, 203 F.3d 1305 (Fed. Cir. 2000); *S. Corp. v. United States*, 690 F.2d 1368, 1370 & n.2 (Fed. Cir. 1982) (holding CAFC may resolve conflicting precedents en banc).

29. See *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (stating appropriate test requires objective inquiry into specification to assess what inventors possessed). The CAFC further stated that, because the relevant inquiry is factual, it will vary depending on the invention and the art. See *id.* (recognizing written description inquiry differs with context). A patent's specification is the portion of the patent that describes the invention. See 1 CHISUM, *supra* note 2, § GL1 (defining specification).

30. See *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351-52 (Fed. Cir. 2010) (en banc) (holding written description inquiry analyzed from POSITA's perspective and summarizing disclosures satisfying written description requirement). The *Ariad* court also clarified that possession of the claimed invention by the inventors is not sufficient to satisfy the written description requirement without an associated showing of such possession in the specification. See *id.* at 1352 (requiring specification demonstrate possession of invention). Actual reduction to practice requires that inventors produce a working embodiment of the invention; conversely, inventors may accomplish constructive reduction to practice by filing a patent application describing the claimed invention. See 3A CHISUM, *supra* note 2, § 10.06 (describing necessary actions for actual and constructive reduction to practice). The concept of constructive reduction to practice predates *Ariad*. See *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (stating requirements for actual and constructive reduction to practice); *Great N. Corp. v. Davis Core & Pad Co.*, 782 F.2d 159, 165 (Fed. Cir. 1986) (requiring working embodiment of invention to establish actual reduction to practice); *In re Glass*, 492 F.2d 1228, 1232 (C.C.P.A. 1974) (explaining filing date equivalent to date of constructive reduction to practice).

31. See *Eiselstein v. Frank*, 52 F.3d 1035, 1039 (Fed. Cir. 1995) (declaring specification need not use exact

example, these courts have held that the written description requirement may be satisfied by language in a specification that is different from the language in the claim that it supports.³² Additionally, these courts have held that portions of a patent that inherently, but not explicitly, describe a claim feature may satisfy the written description requirement for that claim feature.³³ Portions of the patent that merely make obvious the claimed features, however, have not satisfied the written description requirement.³⁴

In *Nalpropion Pharmaceuticals, Inc. v. Actavis Laboratories FL, Inc.*, the CAFC held disclosure that is substantially equivalent to a claim feature may provide adequate written description support if the claim feature is not an operative claim step.³⁵ First, the majority credited the Delaware District Court's factual finding that the substantially equivalent disclosure at issue would convey

words in claim to appropriately support claim); *In re Wright*, 866 F.2d 422, 425 (Fed. Cir. 1989) (stating adequate written description for features of essence in disclosure but not explicitly described); *Flynn v. Eardley*, 479 F.2d 1393, 1395 (C.C.P.A. 1973) (holding naming claimed compound not required if specification includes description leading towards claimed compound). In some matters, the CAFC has held drawings sufficient to provide written description support for the claims. See *Q.I. Press Controls, B.V. v. Lee*, 752 F.3d 1371, 1380 (Fed. Cir. 2014) (holding feature supported if depicted in figures); *Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1322 (Fed. Cir. 2002) (holding drawings sufficient to provide written description support); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1564 (Fed. Cir. 1991) (holding drawings alone may provide sufficient written description support). The tradition of employing a fairly flexible standard to assess the adequacy of written description support dates back to the CCPA, which has allowed description of a species to provide written description support for the genus of which it is a part. See *In re Smythe*, 480 F.2d 1376, 1383 (C.C.P.A. 1973) (holding species may provide written description support for genus when species makes genus predictable). When courts allow a species to provide support for a genus, they may give strong weight to expert testimony regarding how the patent application would be understood by a POSITA. See *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 866 (Fed. Cir. 1993) (crediting expert testimony stating drawing conveys possession of claimed invention to POSITA).

32. See *supra* note 31 and accompanying text (summarizing disclosure types sufficient to establish written description support).

33. See *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1309 (Fed. Cir. 2015) (holding claim not invalid for reciting property inherent in described formulation); *Spine Sols., Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1313 (Fed. Cir. 2010) (holding written description support for feature not explicitly disclosed but necessarily present); *Standard Oil Co. v. Montedison, S.p.A.*, 664 F.2d 356, 367 (3d Cir. 1981) (holding properties recited in claim adequately supported by explicitly-described polymer inherently having them). Establishing written description by inherency, however, is challenging. See *Chen v. Bouchard*, 347 F.3d 1299, 1307 (Fed. Cir. 2003) (finding no written description support for inherent compounds not recognized at time of filing); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998) (requiring missing description to necessarily exist in specification).

34. See *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (holding applicant entitled to filing date only for subject matter actually disclosed); see also *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008) (quoting *Lockwood* standard); *In re Huston*, 308 F.3d 1267, 1277 (Fed. Cir. 2002) (applying *Lockwood* standard). A patent application that does not evidence any contemplation of a feature cannot provide written description support for that feature, but it still may render it obvious to a POSITA. See *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1379 (Fed. Cir. 2009) (holding compatibility of claimed subject matter with disclosure insufficient to establish written description); *Lucent Techs., Inc. v. Gateway, Inc.*, 543 F.3d 710, 719 (Fed. Cir. 2008) (distinguishing obviousness from possession). A patent application having this property may thus preclude anyone from patenting the relevant feature. See 35 U.S.C. § 103 (2018) (precluding patents to obvious inventions).

35. 934 F.3d at 1351 (describing holding).

possession of the relevant non-operative claim feature to a POSITA.³⁶ The majority then acknowledged that, although substantially equivalent disclosure is typically insufficient to satisfy the written description requirement, the written description requirement for non-operative claim features should be assessed in a flexible and sensible manner.³⁷

The dissent in *Nalpropion* criticized the majority's reasoning as overturning long-standing written description jurisprudence, laying out two supposed errors in the majority's analysis.³⁸ According to the dissent, the first error is that, when analyzing the asserted claim, the majority improperly differentiated between the dissolution profile as measured by the Paddle Method—a claim feature allegedly supported by substantially equivalent description—and its operative steps.³⁹ The dissent argued that this dissolution profile, even though non-operative, limits the scope of the asserted claim, and thus should be analyzed in the same manner as its other features.⁴⁰ The dissent further asserted that the majority erred by improperly allowing disclosure that merely makes a claim feature obvious to provide written description support for it.⁴¹

As both the majority and the dissent agree, the holding in *Nalpropion* breaks new ground by applying a looser standard to determine whether the information in a patent application establishes written description support for the claimed invention.⁴² In its holding, the majority explicitly indicated that its decision was

36. See *id.* at 1350-51 (refusing to disturb district court's factual findings). The CAFC held that the lower court's factual findings, although disagreed with by Actavis, were supported by the record and so the CAFC could not disturb them even if it would have found differently if it were the factfinder. See *id.* at 1350.

37. See *id.* at 1351. The CAFC held that the claim feature at issue was not an operative claim step because it described an *effect* of performing the claimed method and was not itself a step in the claimed method. See *id.* at 1350 (distinguishing operative claim steps from other claimed features).

38. See *id.* at 1356 (Prost, C.J., dissenting) (summarizing dissent's position).

39. See 934 F.3d at 1357 (Prost, C.J., dissenting) (describing why Paddle Method should receive treatment like operative claim steps). The dissent believed that the method used to determine the dissolution profile should be understood to be limiting because *Nalpropion's* predecessor in interest argued that dissolution profiles measured by other test methods would not inherently be the same as those measured by the claimed test method. See *id.* (citing to prosecution history of '195 Patent). The dissent also noted that both parties to the litigation agreed that the relevant claim feature should be understood to be limiting. See *id.* (noting express agreement of Actavis with proposition). After coming to this conclusion, the dissent asserted that the written description inquiry for the claimed dissolution profile should proceed according to precedent. See *id.* at 1357-58 (asserting majority opinion articulated new rule at odds with prior precedent). Limiting claim features are those that restrict the subject matter encompassed by the claim. See *In re Paulsen*, 30 F.3d 1475, 1479 (Fed. Cir. 1994) (distinguishing limiting features from non-limiting purposes and intended uses); *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) (stating claim's limiting features restrict its scope).

40. See *supra* note 39 (describing dissent's logic).

41. See 934 F.3d at 1358 (Prost, C.J., dissenting) (advocating for *Lockwood* analysis). Allowing disclosure that makes a claim feature obvious to provide written description for it abrogates well-settled precedent. See *supra* note 34 (describing prior CAFC cases limiting claims to subject matter actually disclosed in specification). Prior to this decision, subject matter made obvious by a patent, but not disclosed in its specification, was unpatentable by anyone. See *supra* note 34 (describing obviousness bar).

42. See 934 F.3d at 1351 (applying flexible and sensible interpretation to facts); *id.* at 1356 (Prost, C.J., dissenting) (asserting majority's opinion not in accordance with precedent).

a “flexible, sensible interpretation” of the written description requirement and not one that was “rigid.”⁴³ Although there are advantages associated with its reasoning, the majority fails to appreciate that its new rule weakens the protections that 35 U.S.C. § 112 affords to the public, thereby preventing inventors, and subsequently patent holders, from removing technology from the public domain that they did not invent.⁴⁴ The dissent correctly characterized the majority opinion as a “new rule” added to the CAFC’s “long-standing written description jurisprudence” that is not in accordance with precedent.⁴⁵ The dissent also appropriately appreciates that the holding allows patent holders to claim subject matter in excess of that to which they, or their predecessors in interest, limited themselves to during patent prosecution before the U.S. Patent Office.⁴⁶ Therefore, it is readily apparent that, if not overturned, this decision will change the way that written description support is assessed in future litigation—in a manner that allows patent holders too much latitude to assert claims that extend beyond what the inventors actually invented.⁴⁷

New and stricter interpretations of old patent statutes typically introduce uncertainty into the validity of earlier-issued patents.⁴⁸ Here, however, the majority opinion expands the types of disclosure that may be used to provide written description support, making it more difficult for entities to challenge patents as invalid for lacking such support.⁴⁹ Because issued patents are presumed valid, this decision would superficially appear to have relatively minor effects on already-issued patents.⁵⁰ The majority’s opinion will likely, however, undesirably upset the expectation of entities that infringe patents, which would be invalid under prior written description jurisprudence, with the plan to assert invalidity as an affirmative defense if necessary.⁵¹

Further, the CAFC’s holding in this case will disadvantageously introduce uncertainty into the interpretation of 35 U.S.C. § 112 going forward because the CAFC has not clearly articulated how flexible its new standard is, nor clarified

43. See *id.* at 1351 (majority opinion) (affirming district court’s conclusion because “[r]igidity should yield to flexible, sensible interpretation”).

44. See *supra* notes 22-23 and accompanying text (discussing how § 112 imposes restraints on inventors).

45. See 934 F.3d at 1356-58 (Prost, C.J., dissenting) (asserting majority opinion departs from prior written description jurisprudence).

46. See *id.* at 1357 (pointing out Orexigen’s conduct before U.S. Patent Office shows claimed measurement technique’s limiting role).

47. See *id.* at 1357-58 (discussing novelty of standard for assessing written description provided by majority opinion); *supra* notes 42-43, 45 and accompanying text (addressing majority opinion upsets precedent).

48. See *supra* note 27 (describing uncertainty in written description case law after *Eli Lilly*).

49. See 934 F.3d at 1351 (allowing substantially equivalent disclosure to satisfy written description requirement).

50. See *supra* note 15 (discussing presumption of validity); *supra* text accompanying note 49 (describing majority opinion’s friendliness to patent owners).

51. See *supra* note 15 (providing presumption of validity and affirmative defense of invalidity); *supra* notes 42-43, 49 and accompanying text (highlighting majority opinion’s weakening of written description requirement).

the limits of the factual situations to which it will apply such a standard.⁵² For instance, uncertainty lingers as to what types of disclosure district courts may consider “substantially equivalent” to the features claimed, and what types of factual records the CAFC will consider sufficient to decline to disturb such findings.⁵³ It is also unclear how expansively the CAFC will apply its new rule of employing “flexible, sensible interpretation” of settled patent law in place of “rigid” adherence to accepted standards.⁵⁴ For these reasons, the likelihood remains that further litigation, time, and effort on the part of patent holders and patent infringers will be necessary to clarify the CAFC’s new approach to written description and stare decisis.⁵⁵

In *Nalpropion Pharmaceuticals, Inc. v. Actavis Laboratories FL, Inc.*, the CAFC established a new, more flexible standard for assessing written description support. This novel standard allows patent owners to establish written description support for non-operative claim features by showing that they are supported by “substantially equivalent” disclosure. While allowing such support is unlikely to upset the settled expectations of patent holders, it is likely to upset the existing expectations of entities who infringe patents with questionable written description support and assert the affirmative defense of invalidity. It is also likely to introduce uncertainty into the standards the CAFC uses to assess the issued patents’ validity. The magnitude of this uncertainty and the ability of entities to attack patents’ validity for lacking adequate written description support will likely not be clarified until further decisions explaining the majority’s logic are issued. In the interim, patentees and patent infringers will have little guidance assessing their relative bargaining positions, making expensive litigation more likely and settlements highly disincentivized.

Charlotte Stewart-Sloan

52. See *supra* note 27 (describing number of cases required to clarify written description standard after *Eli Lilly*); see also 934 F.3d at 1351 (stating holding employs “flexible” and “sensible” standard instead of yielding to rigid prior law); *id.* at 1356 (Prost, C.J., dissenting) (highlighting inconsistency with prior jurisprudence).

53. See 934 F.3d at 1357-58 (Prost, C.J., dissenting) (asserting majority mistakenly refused to consider limiting clause’s written description support). The dissent also disputed the equivalence of the Paddle Method with the Basket Method. *Id.* at 1358-59. It is possible that, like the CAFC’s interpretation of the written description requirement after *Eli Lilly*, the law regarding substantially equivalent disclosure may remain in flux until the CAFC issues an en banc opinion providing a definitive statement of how this new standard should be applied. See *supra* note 28 (discussing use of en banc review to clarify or overturn precedent).

54. See 934 F.3d at 1351; *id.* at 1356-59 (Prost, C.J., dissenting) (pointing out differences in perspectives of majority and dissent).

55. See *supra* note 54 and accompanying text (describing new lack of clarity in written description law).