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Double Patenting: Follow-on Pharmaceutical Patents that Suppress Competition

Douglas L. Rogers*

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ABSTRACT

Prices for pharmaceutical products over the last 10 years have skyrocketed, increasing far more rapidly than the general cost of living. This article argues there should be greater competition for the production of follow-on drugs through the strengthening of the double patenting prohibition: preventing extending exclusive rights beyond the original patent term by dressing up part of that invention as a new one. This prohibition against the same party holding two patents covering the same composition announced by the Supreme Court in the 1800's has been weakened by lower federal courts to (1) only considering the claims and not the rest of the specification in determining if the same invention is being claimed by the inventor in two patents and (2) only applying the prohibition when the earlier patent did not satisfy the technical meaning of "prior art" within §102 of the Patent Act. The rulings weakening the double patenting doctrine have disregarded that the "invention" of a genus patent is not determined only by the claims, but also by the embodiments disclosed in the specification, and under Supreme Court and Federal Circuit precedent it must be presumed that the party with a genus patent has invented the full scope of the genus. These weakening rulings have also disregarded that the double patenting doctrine arises from §101 of the patent statutes, rather than §§102 and 103, which the Federal Circuit models its double patenting test on, often incorrectly concluding there is no double patenting. §§102 and 103 serve different purposes than §101. This article argues that when the same inventor holds a genus patent for a pharmaceutical product, it should be estopped from obtaining a patent on a species within the scope of the genus, whether or not the genus patent constitutes prior art. Applying this strengthened double patenting doctrine would increase competition for the development of follow-on pharmaceutical products.

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¶1 1850: Samuel Morse “could not take out a subsequent patent for a portion of his first invention [the telegraph], and thereby extend his monopoly beyond the period limited by law.”¹

¶2 1894: “[N]o patent can issue for an invention actually covered by a former patent, especially to the same patentee, although the terms of the claims may differ.”²

¹ O’Reilly v. Morse, 56 U.S. 62, 114 (1853).

² Miller v. Eagle Mfg. Co., 151 U.S. 186, 198 (1894).

INTRODUCTION

People who decry the rising prices of their medicines probably do not recognize one cause of that rise—a relatively obscure patent law doctrine called double patenting. The double patenting doctrine, which actually prohibits double patenting, should promote competition for improvements but has often failed. In a series of rulings, the Federal Circuit has weakened the double patenting doctrine and removed it from its historical Supreme Court roots. This has allowed pharmaceutical companies to obtain second patents for compositions covered by their earlier patents and to extend their exclusive rights in the applicable composition beyond the term permitted for a single patent. The Supreme Court can and should reinvigorate the double patenting doctrine as a *prohibition* on such second patents. This reinvigorated double patenting prohibition will promote innovation and competition for pharmaceuticals by third parties and limit price gouging resulting from unjustified extensions of patent rights.

To put this in patent law terms, pharmaceutical companies have been obtaining broad U.S. patents that cover all compositions containing common elements, a genus, that sometimes includes millions of compositions.³ As a result, patentees have acquired what the U.S. Supreme Court has characterized as a right to “cripple competition”⁴ because a genus patent gives the holder (a “First Inventor” and the patent a “First Patent”) the right to exclude for 20 years any other company from making, using, selling or offering to sell any of those millions of embodiments (a “First Invention”).⁵ These patents (1) hinder others from determining which species within the genus have the most promising medical

³ JANICE M. MUELLER, PATENT LAW 176 (Wolters Kluwer 4th ed. 2012) (“A genus is a grouping or category made up of multiple species that share some characteristic”); *see, e.g.*, *Sanofi-Synthelabo v. Apotex, Inc.*, 492 F. Supp. 2d 353, 362–63 (S.D.N.Y. 2007), *aff’d*, 550 F.3d 107 (Fed. Cir. 2009) (the genus ‘596 patent covered several million compounds); *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1286 (Fed. Cir. 2012) (the genus ‘416 patent “teaches a broad genus encompassing ‘approximately nine trillion compounds.’”).

⁴ *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2230 (2013) (“Patent holders have a ‘lawful right to exclude others from the market’ . . . ; thus a patent ‘conveys the right to cripple competition.’”) (quoting *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1310 (2012)).

⁵ 35 U.S.C. § 154(a) (post-AIA). Currently the patent term is measured from the earliest effective filing date of the patent application. *Id.* Due to the length of time a patent application takes to process, the average term of a utility patent from the date of its grant is “usually about 17 years.” Mueller, *supra* note 3, at 21. Under the Patent Act of 1861, the term of a patent was 17 years from the date of issuance of the patent. *See* Act of March 2, 1861, ch. 88, § 16, 12 Stat. 246, 249 (1861). As a result of the Uruguay Round Amendments Act (URAA) becoming effective on June 8, 1995, the term of a patent was changed from 17 years from the date of issuance to 20 years from the earliest effective U.S. filing date. Emily A. Evans & Jill A. Jacobson, *Double Patenting Recapitulated*, 87 J. PAT. & TRADEMARK OFF. SOC’Y 625, 626 (2005). However, the expiration dates of patents issuing from related patent applications can still differ. *See, e.g.*, Dennis Crouch, *Does Obviousness Type Double Patenting Survive the AIA?*, PATENTLY-O (Sept. 23, 2014), <http://patentlyo.com/patent/2014/09/obviousness-patenting-survive.html> [https://perma.cc/3MED-A9QG] (“First, the term of a patent may be adjusted or extended due to a variety of factors with the result that family member applications may have different expiry dates. The second source of potential term-separation comes from the statutory definitions of prior art that excludes certain prior applicant disclosures from the scope of prior art.”). The term of a patent is also subject to a number of extensions, discussed in Part IIB *infra*.

properties⁶ and (2) prevent others from selling such species in competition with the patentee.⁷ The First Inventor commonly subsequently obtains a patent for a narrower composition for a promising commercial product (a “Follow-On Patent” or “Follow-On Product”) within the scope of the genus.⁸ This second patent can give the patentee exclusive rights to that narrower composition extending longer into the future than the genus patent did and giving the patentee the ability to keep prices above the marginal cost of production of that invention.⁹

¶5 For instance, Otsuka Pharmaceutical Co., Ltd. received a patent in 1988 covering approximately nine trillion antipsychotic compounds that included aripiprazole and subsequently obtained a patent expressly claiming aripiprazole, which allowed Otsuka to extend its exclusive rights in aripiprazole from March 29, 2005 to April 2015.¹⁰ In 2001, AbbVie Inc. received a patent for a broad method of treating rheumatoid arthritis with methotrexate and an antibody, and in 2010 it received a patent for a narrower method—within the scope of the original patent—of treating arthritis with methotrexate and an antibody, allowing AbbVie to extend its exclusive rights to the narrower method from 2012 to 2018.¹¹ A recent study showed that such subsequent patents added 6.3 to 7.4 years of patent life to the original patent.¹²

⁶ A “species claim” is a claim theoretically “covering only a single entity.” Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141, 1168 (2008). However, in fact, all species claims cover more than one embodiment, where “essentially all patent claims—not just those defining chemical and biotechnological inventions—are genus claims.” *Id.* at 1169. As a result, the term species and genus are relative terms. *In re Sarett*, 327 F.2d 1005, 1014 (C.C.P.A. 1964). There is a common law experimental use exemption, but the Federal Circuit narrowly construed that exemption in *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002). Mueller, *supra* note 3, at 535–36; ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 846–47 (6th ed. 2013). In addition, 35 U.S.C. § 271(e)(1) provides that it is not an act of infringement to make a patented invention “solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs” However, the scope of this regulatory use exemption and the use of patented compositions as research tools is unsettled after *Merck KGaA v. Integra LifeSciences I Ltd.*, 545 U.S. 193, 202 (2005), in which the Supreme Court expressly declined to express an opinion on whether § 271(e)(1) “exempts from infringement the use of ‘research tools’ in the development of information for the regulatory process.” *Id.* at 205, n.7. There is “troubling evidence regarding delays or impediments to scientific research (with concerns appearing much more pronounced with respect to patented diagnostics) that result from patent licensing costs, licensing failures, or the chilling effects of uncertain potential liability.” Henrik Holzapfel and Joshua D. Sarnoff, *A Cross-Atlantic Dialog on Experimental Use and Research Tools*, 48 IDEA 122, 144 (2008).

⁷ See, e.g., *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740 (Fed. Cir. 2013).

⁸ See, e.g., Lisa L. Ouellette, *How Many Patents Does It Take To Make A Drug - Follow-On Pharmaceutical Patents And University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 301 (2010); and Michael Enzo Furrow, *Pharmaceutical Patent Life-Cycle Management After KSR v. Teleflex*, 63 FOOD & DRUG L.J. 275, 276 (2008). Terms other than “Follow-On” commonly used are “evergreening,” “secondary patents,” and “layering.” See, respectively, Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 348 (2007) [hereinafter Eisenberg]; N. Nicole Stakleff, *A Drug Life: The Chemistry Of Patent And Regulatory Exclusivity For Pharmaceuticals*, 16 FLA. COASTAL L. REV. 27, 54 (2014); Lara J. Glasgow, *Stretching The Limits Of Intellectual Property Rights: Has The Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227, 248 (2001).

⁹ Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 996 (1997).

¹⁰ See *infra* notes 431–51 and accompanying text.

¹¹ See *infra* notes 454–73 and accompanying text. Professor Love has pointed out that “in practice follow-on, or ‘secondary,’ pharmaceutical patents are often successfully challenged by generic drug

¶6 The high cost of patented pharmaceutical products has become a national issue,¹³ and from 2006 to 2013, the price of brand name drugs “climbed about three times faster than the rate of inflation.”¹⁴ Subsequently, the Mayo Clinic and over 100 prominent oncologists published criticism of the high prices of cancer drugs.¹⁵ They noted, “In the United States, the average price of new cancer drugs increased 5- to 10- fold over 15 years, to more than \$100,000 per year in 2012.”¹⁶ They argued for “[r]eforming the patent system to make it more difficult to prolong product exclusivity unnecessarily (patent ‘evergreening’).”¹⁷ Similarly, the Henry J. Kaiser Foundation reported that “most Americans feel that drug costs are unreasonable (72 percent).”¹⁸ The AARP Policy Institute said, “The gap between brand name drug price increases and the rate of general inflation has been growing wider over the past few years.”¹⁹

¶7 Yet higher prices have not resulted in increased innovation. Dr. Marcia Angell, M.D., the former Editor in Chief of *The New England Journal of Medicine*, wrote that

companies.” Brian J. Love, *Patent Duration*, in 2 RESEARCH HANDBOOK ON THE ECONOMICS OF INTELLECTUAL PROPERTY LAW (Peter S. Menell & David L. Schwartz eds., Edward Elgar Publishing, forthcoming 2016), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2642927 [https://perma.cc/8JE5-X5XN]. AbbVie’s species patent was successfully challenged on obviousness type double patenting (*infra* notes 454–73), but the success of some challengers does not comfort those challengers who were unsuccessful (e.g., *infra* notes 431–51 and accompanying text) or the patients who would have liked to obtain cheaper medicine.

¹² Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents*, PLOS ONE, <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0049470> [https://perma.cc/VG3A-VLQV]. This article addresses subsequent patents that fall within the scope of the original genus patents, not other combinations of patents, such as a composition patent and a subsequent patent for a method of using that composition and others discussed in the article by Kapczynski, Park and Sampat.

¹³ See, e.g., Stephanie Armour, *Lawmakers, Candidates Target High Drug Prices*, WALL ST. J. (Nov. 16, 2015), <http://www.wsj.com/articles/lawmakers-candidates-target-high-drug-prices-1447635567> [https://perma.cc/ZN4Y-JJZZ]. Some of the recent uproar about high prices for pharmaceutical products have not involved the price of patented drugs at all. See Andrew Pollack, *Martin Shkreli’s Latest Plan to Sharply Raise Drug Price Prompts Outcry* (Dec. 11, 2015), N. Y. TIMES, <http://www.nytimes.com/2015/12/12/business/martin-shkreli-latest-plan-to-sharply-raise-drug-price-prompts-outcry.html> [https://perma.cc/HRF7-ULZL].

¹⁴ Daniel J. Kevles, *Medicare, Medicaid, and Pharmaceuticals: The Price of Innovation*, 15 YALE J. HEALTH POL’Y, L. & ETHICS (2015). See also Serena Lipski, *Excessive Pricing And Pharmaceuticals: Why The Federal Patent Act Does Not Preempt State Regulation of Pharmaceutical Prices*, 39 U. TOL. L. REV. 913, 924 (2008) (“In the more than two decades that have passed since the Hatch-Waxman Act, there have been dramatic price increases in the cost of pharmaceutical drugs.”).

¹⁵ Andrew Pollack, *Drug Prices Soar, Prompting Calls for Justification*, N.Y. TIMES (July 23, 2015), <http://www.nytimes.com/2015/07/23/business/drug-companies-pushed-from-far-and-wide-to-explain-high-prices.html> [https://perma.cc/KM39-UJSU]; Mayo Clinic, *In Support of a Patient-Driven Initiative and Petition to Lower the High Price of Cancer Drugs*, [http://www.mayooclinicproceedings.org/article/S0025-6196\(15\)00430-9/fulltext](http://www.mayooclinicproceedings.org/article/S0025-6196(15)00430-9/fulltext) [https://perma.cc/Q647-6KX6] [hereinafter *Mayo Clinic*].

¹⁶ *Mayo Clinic*, *supra* note 15, at 2.

¹⁷ *Id.* at 2–3.

¹⁸ Kaiser Health Tracking Poll: August 2015, <http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015/> [https://perma.cc/K6Z8-L3MT] (last visited Sept. 24, 2015).

¹⁹ Stephen W. Schondelmeyer & Leigh Purvis, *Rx Price Watch Report, November 2014, Trends In Retail Prices Of Brand Name Prescription Drugs Widely Used By Older Americans, 2006 to 2013*, 16 (2014), <http://www.aarp.org/content/dam/aarp/ppi/2015/rx-price-watch-report-AARP-ppi-health-nov-14.pdf> [https://perma.cc/KA96-M4ST].

“the pharmaceutical industry is not especially innovative” and added that from 1998 through 2002, the Food and Drug Administration (FDA) approved 415 new drugs, but only 14 percent were “truly innovative.”²⁰ In 2012, the President’s Council of Advisors on Science and Technology said that “the pace of new therapeutic development has not kept up with the explosion in scientific knowledge” and observed, “The number of novel drugs has remained constant for several decades, even as R&D budgets have substantially increased.”²¹ In 2015 the FDA reported that “rising research and development (R&D) expenditures are not being matched by a proportionate discovery of innovative medicines.”²²

Dr. Martin Luther King Jr. said in a 1954 sermon that “if we are to make this a better world in which to live, we’ve got to go back. We’ve got to rediscover these precious values that we’ve left behind.”²³ This article argues that the Federal Circuit needs to rediscover the still-valid principles and values expressed in Supreme Court decisions in the 1800s that an inventor “could not take out a subsequent patent for a portion of his first invention, and thereby extend his monopoly beyond the period limited by law”²⁴ and that “no patent can issue for an invention actually covered by a former patent, especially to the same patentee, although the terms of the claims may differ.”²⁵ Similarly in 1896 in *Singer Mfg. Co. v. June Mfg. Co.*,²⁶ the Supreme Court said, “It is self-evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property. It is upon this condition that the patent is granted.”²⁷ These still-valid principles²⁸ reflect this country’s “historical antipathy to monopoly.”²⁹

²⁰ MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* (2004).

²¹ Exec. Office of the President, President’s Council of Advisors on Sci. & Tech., *Report to the President on Propelling Innovation in Drug Discovery, Development, and Evaluation* (Sept. 2012), <https://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-fda-final.pdf> [<https://perma.cc/B2SS-6BUJ>].

²² U.S. Food & Drug Admin., *Targeted Drug Development: Why Are Many Diseases Lagging Behind?*, 1 (July 2015), <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm454955.htm> [<https://perma.cc/TS9J-8UEN>]; cf. Joseph Walker, *Patients Struggle With High Drug Prices*, WALL ST. J. (Jan. 2, 2016), <http://www.wsj.com/articles/patients-struggle-with-high-drug-prices-1451557981> [<https://perma.cc/KGL9-TXMX>] (“The Food and Drug Administration approved 41 new drugs in 2014, the most in nearly two decades. The catch is their cost.”).

²³ Martin Luther King, Jr., *February 28, 1954: Rediscovering Lost Values*, KING INST. ENCYCL., http://kingencyclopedia.stanford.edu/encyclopedia/documentsentry/doc_rediscovering_lost_values/index.html [<https://perma.cc/2MDP-PE3X>].

²⁴ *O’Reilly v. Morse*, 56 U.S. at 114.

²⁵ *Miller v. Eagle Mfg. Co.*, 151 U.S. at 198.

²⁶ *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169 (1896).

²⁷ *Id.* at 185.

²⁸ See, e.g., *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293–94 (2012) [hereinafter *Mayo*] (relying on *Morse*); *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1372–73 (Fed. Cir. 2014) (relying on *Miller* and quoting *Singer* as reaffirming the prohibition on double patenting, “It is self-evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property. It is upon this condition that the patent is granted.”)

²⁹ *DeepSouth Packing Co. v. Laitrom Corp.*, 406 U.S. 518, 530 (1972).

¶9 This article argues that what the Federal Circuit calls the double patenting doctrine is an emaciated version of the balanced principles announced by the Supreme Court in the second half of the nineteenth century. Contrary to the current Federal Circuit standard, when an inventor or her employer³⁰ receives a genus patent for a pharmaceutical composition, that inventor and her employer should not then obtain a subsequent patent for a composition of matter within the scope of the genus. Such grant extends the period of exclusive right in the composition of matter beyond that authorized by statute and is inconsistent with the representation the applicant made when she acquired the genus patent—that she had invented all compositions of matter within the genus.³¹

¶10 In contrast, a third party who has not already received or applied for a patent for subject matter covered by the First Patent has not claimed to have invented the genus. The principles in *Morse*, *Miller* and *Singer* quoted above³² should not apply in the same way to a third party claiming subject matter within the scope of the First Patent granted to the First Inventor. There is no danger that the third party will extend exclusive rights (since he does not yet have any exclusive rights) beyond his existing patent term. The same principles also should not apply to the First Inventor if he applies for a patent covering subject matter not within the scope of his genus patent, because again there is no danger that he will extend exclusive rights he already has beyond the initial patent term.

¶11 Part II discusses the U.S. patent law foundations of balancing the grant of exclusive rights with promoting competition and the additional statutory benefits already provided to pharmaceutical manufacturers. Part II argues that overly broad genus patents and Follow-On Patents to the First Inventor tip the balance by restricting third-party competition for improvements.

¶12 Part III explains that the “invention” has never depended solely on what the skilled draftsman claimed,³³ but took into account the invention disclosed in the specification of the patent application. Part III points out that this concept of invention remains true today and that the written description requirement of § 112 limits the scope of a genus patent to no more than the embodiments of the invention disclosed in the specification and includes each embodiment covered by a patent claim. Although the recent decisions discussed in this part indicate that many broad genus patents that were granted in the past would—if submitted today—be held invalid, that does not resolve how courts should react to applications by an inventor for a patent on a species within the scope of a genus patent that was granted to that inventor in the past or will be granted in the future.

¶13 Part IV addresses that question and argues that the Federal Circuit has improperly limited double patenting by determining the inventions involved through comparison only of the patents’ claims and not of their specifications.³⁴ Part IV argues that courts

³⁰ Pharmaceutical companies typically have agreements with their research scientists to assign any inventions the scientists develop to the pharmaceutical companies. See *infra* note 336.

³¹ See 35 U.S.C. § 115; *infra* note 218 and accompanying text.

³² See *supra* notes 1, 2, 26–27 and accompanying text.

³³ On a number of occasions the Supreme Court has cautioned against allowing patent eligibility to depend on the draftsman’s art. *Alice Corp. Pty. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2359 (2014); *Mayo*; *Diamond v. Diehr*, 450 U.S. 175, 191–92 (1981); *Parker v. Flook*, 437 U.S. 584, 590 (1978).

³⁴ Technically, the claims are part of and are found at the end of the specification. See 35 U.S.C. § 112, ¶ 2 (pre-AIA); 35 U.S.C. § 112(b) (post-AIA); Oskar Liivak, *Finding Invention*, 40 FLA. ST. U. L.

should determine the “invention” in double patenting cases in the same way that “invention” is determined under § 112 and § 271(a): by determining the scope of embodiments of the claimed invention disclosed in the specification. It analyses inconsistent decisions by earlier courts and the Federal Circuit on double patenting under 35 U.S.C. § 101.³⁵ It argues that when a First Inventor³⁶ obtains a genus patent, since that patent is presumed valid under 35 U.S.C. § 282,³⁷ the First Inventor should not be able to obtain a subsequent patent on a species within the genus by arguing that the First Inventor had not really contemplated the scope of its genus invention at the time of the genus application.

¶14 Part V discusses the Leahy-Smith America Invents Act (AIA), which changes the definition of “prior art” for patents whose effective filing date is on or after March 16, 2013.³⁸ Part V points out that statutory exemptions from treating collaborative research as prior art—culminating with the passage of the AIA—increases the need for a strong double patenting prohibition as AIA litigation starts to predominate.³⁹

¶15 Part VI concludes that the double patenting prohibition urged in this article is an important tool for promoting competition in pharmaceutical products and consumer access to pharmaceutical products at reasonable prices. Part VI also suggests additional research is needed to determine whether this article’s arguments about double patenting should similarly apply to anticipation arguments under § 102 when the genus patent is prior art to a subsequent species patent to the same inventor.

REV. 57, 66 (2012) (“claim language is part of the specification”). For clarity, when this article refers to the specification, it means the part of the specification other than the claims.

³⁵ Compare *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280 (Fed. Cir. 2012) with *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F. 3d 1366 (Fed. Cir. 2014).

³⁶ See discussion *infra*, Part IVB3, on the required relationship between the holders of the two patents, or a patent and patent application, for the double patenting prohibition to apply.

³⁷ The presumption requires clear and convincing evidence to rebut. See *infra* note 217. Under the AIA there are methods to challenge the validity of granted patents in administrative proceedings that only require a preponderance of the evidence to succeed. See, e.g., 35 U.S.C. §§ 316(e) (*inter partes* review), 326(e) (post-grant proceedings).

³⁸ See § 3(n) of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codifying scattered sections of 35 U.S.C.) enacting and setting the date for new 35 U.S.C. §§ 100, 102 and 103 to apply generally to “any application for patent, and to any patent issuing thereon, that contains or contained at any time . . . a claim to a claimed invention that has an effective filing date . . . that is on or after” March 16, 2013. Mueller, *supra* note 3, at 208, 233. Mueller writes, “A most unfortunate aspect of the AIA is that Congress entirely rewrote key statutory provisions of the Patent Act without renumbering many of the statutory sections in Title 35, U.S.C.” *Id.* at 234. As a result, “U.S. Patent law will operate on a dual framework of pre- and post-AIA rules for at least 30 years following the AIA’s enactment.” *Id.* at 173–74. To avoid confusion, and following one of Mueller’s recommended practices when this article is referring to § 101, § 102 or § 103, it provides after the citation “(pre-AIA)” when it is referring to situations in which pre-AIA law is applicable and “(post-AIA)” when it is referring to situations in which the AIA is applicable. *Id.* at 235.

³⁹ Professor Crouch reported on September 14, 2015, “Although there are no several thousand AIA patents issued, there have been no court cases yet involving an AIA patent or patent application.” Dennis Crouch, *Implementing the AIA: First to File Patents*, PATENTLY-O (Sept. 14, 2015), <http://patentlyo.com/patent/2015/09/implementing-first-patents.html> [https://perma.cc/6MCM-G4E8].

I. PATENT LAW SHOULD PROMOTE COMPETITION AMONG INVENTORS FOR FOLLOW-ON PRODUCTS

A. Patent Law Balance

¶16 The U.S. Constitution authorizes Congress to pass patent statutes to promote the progress of the “useful arts,”⁴⁰ a reference to engineering, mechanics, and applied science.⁴¹ The Supreme Court has recognized that a patent is an “inducement . . . to bring forth new knowledge.”⁴² Scholars agree that patents provide a necessary incentive to invent, since otherwise “inventors would be unable to recoup . . . their research and development costs because third parties could simply copy the invention and compete with the inventor unencumbered by the need to recover fixed costs.”⁴³ However, the fact that patent protection may be necessary to give companies the incentives to invest hundreds of millions of dollars⁴⁴ does not determine the proper recipients or scope of the incentives.

¶17 In addition to providing incentives, “one of the purposes of the patent system is to encourage dissemination of information concerning discoveries and inventions,”⁴⁵ such as “disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired.”⁴⁶ The Supreme Court has explained, “The disclosure required by the Patent Act is ‘the *quid pro quo* of the right to exclude.’”⁴⁷ Scholars have pointed out that the *quid pro quo* theory is in tension with the incentive theory, since disclosures encourage competition for improvements and weaken the incentives for the First Inventor.⁴⁸ However, as discussed below, this tension reflects the need for patent law to reflect a balance between incentives, access to information, and competition.

⁴⁰ The U.S. Constitution provides that Congress shall have the power “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” U.S. Const. art. I, § 1, cl. 8 (capitalization in original). See EDWARD C. WALTERSCHEID, *TO PROMOTE THE PROGRESS OF USEFUL ARTS: AMERICAN PATENT LAW AND ADMINISTRATION*, 1793-1836 19 (1998).

⁴¹ CHRISTINA BOHANNAN & HERBERT HOVENKAMP, *CREATION WITHOUT RESTRAINT – PROMOTING LIBERTY AND RIVALRY IN INNOVATION* 120 (2012) [hereinafter *Bohannan/Hovenkamp*].

⁴² *Graham v. John Deere Company of Kansas City*, 383 U.S. 1, 9 (1966).

⁴³ CRAIG ALLEN NARD, *THE LAW OF PATENTS* 33 (3d ed. 2014).

⁴⁴ DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 3 (2009); see also WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 316 (2003) (“the strongest case for patents in something like their present form is said to be found in a subset of the drug industry.”); MICHELE BOLDRIN & DAVID K. LEVINE, *AGAINST INTELLECTUAL MONOPOLY* 212 (2010) [hereinafter *Boldrin/Levine*] (“the best case for the existence of patents is in the pharmaceutical industry”).

⁴⁵ *Brenner v. Manson*, 86 S. Ct. 1033, 1041 (1966).

⁴⁶ *Universal Oil Products Co. v. Globe Oil & Refining Co.*, 322 U.S. 471, 484 (1944).

⁴⁷ *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.* 534 U.S. 124, 142 (2001) (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974)).

⁴⁸ Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 133–34 (Winter 2006) (“The *quid pro quo* view of the patent system, therefore, contemplates at least a limited form of free-riding; the competitor may be able to use the patent disclosure to create the incremental innovation at a lower cost than discovering the invention independently.”); Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81 (2004).

¶18 The Supreme Court has cautioned that “in rewarding useful invention, the rights and welfare of the community must be fairly dealt with and effectually guarded.”⁴⁹ The Court has also recognized the “restrictive effect of the limited patent monopoly”⁵⁰ and has explained, “The inherent problem was to develop some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent.”⁵¹ The Supreme Court has concluded that patent “protection strikes a delicate balance between creating ‘incentives that lead to creation, invention, and discovery’ and ‘imped[ing] the flow of information that might permit, indeed spur, invention.’”⁵² Writing for a unanimous Court in 1989, Justice O’Connor said, “From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.”⁵³

¶19 Scholars have similarly discussed the importance of balance in patent law.⁵⁴ In their seminal article on patent scope, Professors Merges and Nelson pointed out that what constitutes an incentive for some, “such as extension of an initial patent to cover subsequently-developed versions of the invention,”⁵⁵ may have the opposite effect on others. They concluded, “When a broad patent is granted or expanded via the doctrine of equivalents, its scope diminishes incentives for others to stay in the invention game, compared again with a patent whose claims are trimmed more closely to the inventor’s actual results.”⁵⁶ Genus patent claims⁵⁷ are a choice of the patent applicant, and

⁴⁹ *Sears and Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964).

⁵⁰ *Graham*, 383 U.S. at 11.

⁵¹ *Id.*

⁵² *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013) (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012)).

⁵³ *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (striking down a Florida statute that prohibited the use of a direct molding process to duplicate unpatented boat hulls); *see also Goldstein v. California*, 412 U.S. 546, 569 (1973) (“Congress had balanced the need to encourage innovation and originality of invention against the need to insure competition in the sale of identical or substantially identical products.”).

⁵⁴ Not all scholars are in agreement. For instance, Professor Kitch, in his “prospect theory,” and other scholars have argued that “broad patent rights are beneficial because they encourage patent owners to explore, improve, and commercialize undeveloped areas of the inventive space fenced in by their claims.” Brian J. Love, *Interring the Pioneer Invention Doctrine*, 90 N.C. L. REV. 379, 412 (Jan. 2012) [hereinafter *Love/Interring*]. Professor Love explains, “Prospect theory thus suggests that innovation is optimally incentivized when a single entity is vested early on with broad patent rights that allow it to control an entire technological field.” *Id.* at 414. However, the prospect theory seems inconsistent with the Supreme Court decisions in *Morse* (see *infra* notes 146–53 and accompanying text); *Consolidated Electric* (see *infra* note 154–57 and accompanying text); *Schriber-Schroth* (see *infra* notes 158–61 and accompanying text); and with the Federal Circuit’s decision in *Ariad* (see *infra* notes 191–204 and accompanying text) tying the permitted scope of a claim to what the applicant disclosed in the specification. The Supreme Court has never adopted the prospect theory, and in *Brenner v. Manson*, 383 U.S. 519 (1991), the Court held that a patent “is not a reward for the search, but compensation for its successful conclusion.” *Id.* at 536.

⁵⁵ Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 843 (1990) [hereinafter *Merges/Nelson*].

⁵⁶ *Id.* at 916. The doctrine of equivalents is a judge-made doctrine intended to prevent defendants from avoiding a finding of infringement if they make only insubstantial changes in a patented product. Mueller, *supra* note 3, at 468–69; *see also infra* notes 232–39 and accompanying text. For a discussion of the impact varying applications of the doctrine of equivalents can have on competition for improvements,

applicants can write claims that increase or narrow the scope of the exclusionary rights for the prospective patent application and their effect on others.⁵⁸

¶20 In weighing that balance, Professor Lemley has argued that patent laws can be justified “only to the extent that they do on balance encourage enough creation and dissemination of new works to offset those costs.”⁵⁹ Professor Nichols has argued that “the social value of competition may outweigh the social value that can be achieved from a monopoly drug product alone.... We have a compelling social interest in promoting competition as well as innovation.”⁶⁰

¶21 The next section shows that Congress has provided—through statutes and grants—huge incentives for pharmaceutical inventions, including extending the term of patents for commercial products, so that already the “incentive to extend the patent life of brand name drugs is overwhelming.”⁶¹

B. *Additional Benefits to Pharmaceutical Manufacturers*⁶²

¶22 The Bayh-Dole Act of 1980 authorized universities to patent their discoveries resulting from federal funding, subject to certain rights of the Federal Government.⁶³ The Bayh-Dole Act provides, among other things, that it is the “policy and objective of the Congress. . . to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise.”⁶⁴ Professor Ouellette argues, “To justify granting these private patent rights for government-sponsored inventions, one cannot use the typical innovation incentive of patents, because academic researchers have been innovating long before the Bayh-Dole Act and are primarily motivated by a desire for prestige.”⁶⁵ She concludes, “Bayh-Dole patents typically are justified under commercialization theory—the idea that companies need exclusive patent rights to bring an invention to market.”⁶⁶

see Timothy R. Holbrook, *Equivalency and Patent Law's Possession Paradox*, 23 HARV. J.L. & TECH. 1, 39–45 (2009).

⁵⁷ *Supra* notes 3 and 6. This article uses genus and species in their relative senses, so when referring to a species in this article, that species could in fact be a genus to some other smaller set of species.

⁵⁸ See, e.g., *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373, 1381 (Fed. Cir. 2003) (“A skilled patent drafter, however, might fashion a claim to cover the metabolite in a way that avoids anticipation. For example, the metabolite may be claimed . . . as a pharmaceutical composition (e.g., with a pharmaceutically acceptable carrier). The patent drafter could also claim a method of administering the metabolite or the corresponding pharmaceutical composition.”).

⁵⁹ *Lemley/Economics*, *supra* note 9, at 997.

⁶⁰ Len M. Nichols, *What Price Should We Pay for Specialty Drugs*, Center for Health Policy Research and Ethics Issue Brief #3, 5 (May 15, 2015).

⁶¹ Lara J. Glasgow, *Stretching The Limits Of Intellectual Property Rights: Has The Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227, 232 (2001).

⁶² The three sets of benefits discussed here are not the exclusive ones. For instance, the 1983 Orphan Drug Act “includes certain tax incentives, clinical as well as R&D subsidies, fast-track approval, along with strong intellectual and marketing rights for products developed for treating rare conditions.”

MARIANA MAZZUCATO, *THE ENTREPRENEURIAL STATE* 82 (2014).

⁶³ 35 U.S.C. §§ 200–212.

⁶⁴ 35 U.S.C. § 200.

⁶⁵ Ouellette, *supra* note 8, at 307.

⁶⁶ *Id.* See also, Mark A. Lemley, *Are Universities Patent Trolls?*, 18 FORDHAM INTELL. PROP.

¶23 The Federal Government has also provided significant funding and tax incentives for pharmaceutical research. For instance, the National Institute of Health (NIH) has provided the biotech sector \$624 billion in research funding: “Through a system of nearly 50,000 competitive grants, the NIH supports more than 325,000 researchers at over 3,000 universities, medical schools, and other research institutions in every US state and throughout the world . . . traces of government support can also be seen in almost every single major biopharmaceutical product in the USA.”⁶⁷

¶24 In addition, through the adoption of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act),⁶⁸ the federal government took affirmative steps to further the commercialization of pharmaceutical products. Hatch-Waxman allows: (1) generic manufacturers to test but not market their generic products while the patents for the patented products are still in force, (2) generic manufacturers to rely on the safety/efficacy studies the manufacturer of the patented product had provided to the FDA,⁶⁹ and (3) manufacturers of new chemical entities five years of “data exclusivity” generally.⁷⁰

¶25 Under Hatch-Waxman, moreover, Congress has authorized the U.S. Patent and Trademark Office (USPTO) to administratively extend the term of a “patent which claims a product” if a number of conditions are satisfied.⁷¹ One condition is that the term of the patent must not have been previously extended under § 156(e)(1).⁷² As a result, “where a

MEDIA & ENT. L.J. 611, 621 (2008); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U.L. REV. 77, 97–98 (1999).

⁶⁷ Mazzucato, *supra* note 62, at 60–61; *see also* Brian J. Love, *Do University Patents Pay Off? Evidence from a Survey of University Inventors in Computer Science and Electrical Engineering*, 16 YALE J.L. & TECH., 285, 287, n.1 (2014) (“about two-thirds of university research funding comes from the federal government”); William Lazonick, & Oner Tulum, *US Biopharmaceutical Finance and the Sustainability of the Biotech Business Model*, 40 RES. POL’Y 8–12 (2011), <http://ssrn.com/abstract=2257932>.

⁶⁸ Pub. L. No. 98-417, 98 Stat. 1585 (1984). Professors Eisenberg and Crane have discussed in detail how the Hatch-Waxman Act intertwined the benefits of patent and FDA law and promoted the development of generic pharmaceuticals, while also giving benefits to patented pharmaceuticals. Rebecca S. Eisenberg & Daniel A. Crane, *Patent Punting: How FDA and Antitrust Courts Undermine the Hatch-Waxman Act to Avoid Dealing with Patents*, 21 MICH. TELECOMM. & TECH. L. REV. 197, 206–11 (2015). For additional discussions of the Hatch-Waxman Act, *see* Ouellette, *supra* note 8, at 304–06; and Furrow, *supra* note 8, at 284–87.

⁶⁹ MARTIN A. VOET, *THE GENERIC CHALLENGE, UNDERSTANDING PATENTS, FDA AND PHARMACEUTICAL LIFE-CYCLE MANAGEMENT* 111–12 (4th ed. 2013).

⁷⁰ *Id.* at 100; Vincent J. Roth, *Will FDA Data Exclusivity Make Biologic Patents Passé?*, 29 SANTA CLARA COMPUTER & HIGH TECH. L.J. 249, 261 (2013) (“Hatch-Wax provides a five year period of data exclusivity for new drugs.”); *see also* Brian J. Love, *Patent Duration*, in RESEARCH HANDBOOK ON THE ECONOMICS OF INTELLECTUAL PROPERTY LAW (Peter S. Menell & David L. Schwartz eds., forthcoming 2016) [hereinafter *Love/Duration*] <http://ssrn.com/abstract=2642927> (“for at least some new drugs, FDA approval occurs so long after patent filing that data exclusivity extends beyond the expiration of patent rights to the drug”).

⁷¹ 35 U.S.C. § 156(a). Patent term extension or restoration under § 156 bases the extension of the patent term on delays in the FDA regulatory process for approving a pharmaceutical product for marketing, whereas patent term adjustment under § 154 is based on delays of the USPTO in granting the initial patent. *See* Mueller, *supra* note 3, at 22–24.

⁷² 35 U.S.C. § 156(a)(2).

patent covers more than one drug product, the patent could not be extended for a second drug product if the patent had already been extended for a first drug product.⁷³ Another condition is that the product in question must have been subject to a regulatory review by the FDA before its commercial marketing or use.⁷⁴ The total extension can be no longer than five years, and the period of extension granted—together with the remaining term of the patent at the time of the extension—may not exceed fourteen years.⁷⁵

¶26 In short, the patent system and other federal laws provide significant, special incentives to the pharmaceutical industry not available to other industries. This is relevant background for considering whether there is the appropriate balance between First Inventors and other improvers for pharmaceutical products.⁷⁶ The next section addresses how the courts have treated patents for improvements by parties unrelated to the First Inventor (in contrast to improvements by the First Inventor or employer of the First Inventor) and how that treatment can affect competition.

C. Competition for Follow-on Products

¶27 Since 1793, Congress has authorized the granting of a patent to whoever invents⁷⁷ “any new and useful machine, manufacture and composition of matter⁷⁸ and “any improvement therein not before known or used”⁷⁹ There was no definition of

⁷³ Paul Burgess and John Lucas, *Which Generic Drug Would You Want To Use? The Federal Circuit's Interpretation Of 'Active Ingredient,' 'Active Moiety' And 'Approved Product'*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 11, 14 (2005).

⁷⁴ 35 U.S.C. § 156(a)(4).

⁷⁵ 35 U.S.C. § 156(g)(6)(b) and 156(c)(3). Since its adoption, “the PTO has extended the lives of over 600 drug patents by an average of about 3.5 years. . . . In rare instances – seven times since 1980 – Congress has also simply bypassed both mechanisms entirely by passing private laws that extend the life of particular patents. . . .” *Love/Duration*, 4. There has been significant controversy over whether the patent term extension provisions of Hatch-Waxman have been applied appropriately. *See, e.g.*, Kristin E. Behrendt, *The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest?*, 57 FOOD & DRUG L.J. 247 (2002); Paul Burgess & John Lucas, *Which Generic Drug Would You Want to Use? The Federal Circuit's Interpretation of 'Active Ingredient,' 'Active Moiety' and 'Approved Product'*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 11 (2005); Ann Kotze, *Reining in Patent Term Extensions for Related Pharmaceutical Products Post-Photocure and Ortho-McNeil*, 106 NW. U. L. REV. 1419 (2012).

⁷⁶ Some think that on balance the system of patents for pharmaceutical products is not useful. Boldrin/Levine, *supra* note 44, at 238 (“To argue that the system could be fixed by eliminating patents on pharmaceuticals would be foolish Far from encouraging great new health and life-saving products, the system instead produces too much innovation and expense of the wrong kind—me-too drugs to get around the other guy's patents.”)

⁷⁷ DONALD S. CHISUM, CHISUM ON PATENTS [hereinafter CHISUM], vol. 9 at app. 10-1. Section 101 provides that whoever “invents or discovers a new and useful . . .” but the Supreme Court has held mere discoveries are not patentable. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2110 (2013) (“groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry”).

⁷⁸ Under the Patent Act of 1790, the comparable words were “manufacture, engine, machine, or device” and the additional category of patentable subject matter was “art.” *See* CHISUM, *supra* note 77, at vol. 9, app. 9-1. “Art” was used instead of “process” until the Patent Act of 1952. *Id.* at vol. 9, app. 19-22.

⁷⁹ *Id.* at vol. 9, app. 10-1. Section 101 currently provides, “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

“improvement” in the 1793 statute, and still is no statutory definition of improvement.⁸⁰ However, since § 101 ends with the statement, “subject to the conditions and requirements of this title,” there is no implication in the statute that any inventor has a right to a patent for any improvement.

¶28 In one sense, all patents are for improvements over what existed in prior art, so “improvement” is really a relative term referring chronologically to what came after some other invention and was related to that earlier invention.⁸¹ Since “the patent grant is a right to *exclude*, not an affirmative right to practice an invention,” there is no necessary inconsistency between granting a patent to one inventor for a First Invention and then granting a different party a patent for an improvement to the First Invention.⁸² But if patents are granted for both, what are the relative rights of the two patent holders?

¶29 Professor Duffy suggested a policy basis for treating First Inventors differently than other individuals trying to improve on a First Invention.⁸³ He said that “the existence of the earlier patent affords the pioneer patentee a fairly strong incentive to develop improvements that increase the market for the technology.”⁸⁴ He added, “This “consideration tends to suggest that the patentability standard should perhaps be more stringent, because the reward of the second patent may be unnecessary to encourage the pioneering patentee to develop the improvement.”⁸⁵

¶30 An additional reason for differentiating between First Inventors and unrelated third party improvers in the grant of patents for further improvements is that the First Inventor has already submitted an oath to the USPTO under §115 that he has invented the genus, which includes all species within the genus. In *Odiorne v. Amesbury Nail Factory*,⁸⁶ Justice Story said, the first patent could be “an estoppel to any future patent for the same invention” by the same inventor.⁸⁷ In contrast, the unrelated third party improver has not submitted any such oath, so is not faced with an estoppel argument that he had already claimed he had invented the species within the genus.

¶31 Professors Bohannon and Hovenkamp noted that there are at least three ways to address the rights of a First Inventor and a third party who invented an improvement to a

⁸⁰ See CHISUM, *supra* note 77, at vol. 9, app. 9-1; § 100 (pre-AIA); § 100 (post-AIA).

⁸¹ Professor Collins writes, “Technological progress is a cumulative endeavor. The outputs of the work of earlier generations of inventors are inputs into the work of later generations of inventors.” Kevin Emerson Collins, *Getting into the ‘Spirit’ of Innovative Things: Looking to Complementary and Substitute Properties to Shape Patent Protection for Improvements*, 26 BERKELEY TECH. L.J. 1217, 1247 (Spring 2011) [hereinafter Collins]. Professor Merges suggested that technically the only improvement claims are claims drafted as “Jepson” claims, saying, “Strictly speaking, only a patent drafted in Jepson format is an improvement patent.” Robert P. Merges, *Brief Note on Blocking Patents and Reverse Equivalents: Biotechnology as an Example*, 73 J. PAT. & TRADEMARK OFF. SOC’Y, 878, 879, n.3 (1991) [hereinafter Merges/Blocking]. See also MPEP § 2929 III, § 608.01(m); 37 C.F.R. 1.75(e); and Merges/Duffy, *supra* note 6, at 32. However, Professor Merges and Duffy agree, “Improvements can also be drafted in the standard format.” *Id.*

⁸² Merges/Blocking, *supra* note 81, at 879, n.2 (1991).

⁸³ John F. Duffy, *A Timing Approach to Patentability*, 12 LEWIS & CLARK L. REV. 343 (2008).

⁸⁴ *Id.* at 365.

⁸⁵ *Id.* He cautioned, however, “The unique aspects of improvement patents seem sufficiently great as to demand more detailed treatment than can be accomplished in this article.” *Id.* at 366.

⁸⁶ 18 F. Cas. 578, 2 Mason 28 (Cir. Ct. D. Mass. 1819).

⁸⁷ *Id.* at 579.

First Invention (the “Improver”), and those ways affect competition differently.⁸⁸ First, giving the First Inventor exclusive control over all improvements “would completely undermine anyone else’s incentives to improve the patented technology. It would also reduce the *competitive* pressure on the patentee to improve.”⁸⁹ Second, giving the Improver exclusive rights to any improvement that independently met patentability requirements might initially give both the First Inventor and Improver “strong incentives to improve, but it might make the original patentee’s patent worthless if a market-shifting improvement were developed.”⁹⁰ Third, permitting “the patentee to enforce its patent claims and the improver to enforce any independently patentable claims in its own patent” would create the possibility of “‘blocking’ patent claims,”⁹¹ in which the earlier patent is called the “dominant” patent and the improvement patent is called the “subserving” patent.⁹²

¶32

The third alternative above “is closest to the position the law has adopted” with respect to inventions held by different parties and “may come closest to a proper allocation of the incentive to develop further technology as between the primary and subsequent inventors.”⁹³ Reflecting that balance of incentives and competition, § 2 of the Patent Act of 1793⁹⁴ provided: “any person, who shall have discovered an improvement in the principle of any machine . . . which shall have been patented, and shall have obtained a patent for such improvement, he shall not be at liberty to make, use or vend the original discovery, nor shall the first inventor be at liberty to use the improvement....”⁹⁵ This § 2 clearly referred to the First Inventor and Improver as different individuals. Congress repealed this § 2 in the Patent Act of 1836,⁹⁶ but since that repeal the Supreme Court issued three decisions⁹⁷ on blocking patents between unrelated parties, essentially perpetuating judicially the statutory balance adopted in § 2.

⁸⁸ Bohannon/Hovenkamp, *supra* note 41, at 69.

⁸⁹ *Id.* (emphasis in original).

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² Merges/Blocking, *supra* note 81, at 878–79, n.2 (1991).

⁹³ Bohannon/Hovenkamp, *supra* note 41, at 69–70.

⁹⁴ CHISUM, *supra* note 77, at vol. 9, app. 10. See also Charles W. Adams, *Allocating Patent Rights Between Earlier and Later Inventions*, 54 ST. LOUIS U.L.J. 55, 65, n.45 (Fall 2009) [hereinafter Adams].

⁹⁵ CHISUM, *supra* note 77, at vol. 9, app. 10-1 to 10-2.

⁹⁶ Act of Feb. 21, ch. 11, 2, 1 Stat. 318, 321, *repealed by* Act of July 4, 1836, ch. 357, § 20, 5 Stat. 117, 125. See CHISUM, *supra* note 77, at vol. 9, app. 11-21, § 21; Adams, *supra* note 94, at 66. While § 2 was still in effect, in *Evans v. Eaton*, 20 U.S. 356 (1822), the Supreme Court addressed a patent claim for an improvement Evans made in 1873 or 1874 to a machine used in the manufacture of flour called a Hopperboy. *Id.* at 357. Evans sued Eaton for infringement, and Eaton defended on the ground that the Hopperboy was in use prior to 1873, not on the ground of the existence of a blocking patent. *Evans v. Eaton*, 8 F.Cas. 856, 857–58 (Cir. Ct. D. Pa.). The Supreme Court said that a patent gives “any inventor of an improvement in the principle of any machine . . . an exclusive right to a patent for his improvement; but he is not to be at liberty to use the original discovery, not [sic] is the first inventor at liberty to use the improvement.” 20 U.S. at 429. The Court rejected the patent claim of Evans, because he was not entitled to a patent on the whole machine and he had not described his own improvement to only obtain a patent on the improvement. *Id.* at 430–32; see also Adams, *supra* note 94, at 65–66.

⁹⁷ Adams, *supra* note 94, at 67 (“Besides Cochrane and Cantrell, the Supreme Court has dealt with the subject of blocking patents in one other case—*Temco Electric Co. v. Apco Manufacturing Co.*”).

¶33 In 1876, in the first of the three cases, *Cochrane v. Deener*,⁹⁸ the defendants in a patent infringement suit defended in part on the existence of their own patents in the manufacture of flour,⁹⁹ but the Supreme Court dismissed that defense. The Court said that the only consequence of a blocking patent was “that each inventor is precluded from using inventions made and patented prior to his own, except by license from the owners thereof. His invention and his patent are equally entitled to protection from infringement, as if they were independent of any connection with them.”¹⁰⁰

¶34 The second decision, decided in 1886, *Cantrell v. Wallick*¹⁰¹ also did not involve the same party holding or applying for a patent on the First Invention and the Improvement. Instead, *Cantrell* involved a patent granted to Wallick for an improvement in an apparatus for enameling mouldings and a subsequent claim of infringement by Wallick against Cantrell.¹⁰² Robert Marcher had patented an earlier apparatus, and Cantrell defended on the ground that the Wallick patent was invalid because it embraced the Marcher patent.¹⁰³ The Court rejected that defense, saying, “Two patents may both be valid when the second is an improvement on the first, in which event, if the second includes the first, neither of the two patentees can lawfully use the invention of the other without the other’s consent.”¹⁰⁴

¶35 The third decision, *Temco Electric Motor Co. v. APCO Mfg. Co.*, decided in 1928, involved a patent held by Temco (the Thomson patent) for a shock absorber for an automobile¹⁰⁵ and an improved shock absorber made by Apco under a subsequent patent issued to Storrie.¹⁰⁶ Subsequent to its initial patent, Temco developed an improvement in the shock absorber and applied for a patent on that improvement, which led to an interference with the Storrie patent to determine who invented that improvement first.¹⁰⁷ Storrie, not Temco, was awarded the patent in the interference, so the Supreme Court did not address whether Temco could have been awarded a separate patent for the improvement to its earlier shock absorber.¹⁰⁸ The Supreme Court held, “It is well

⁹⁸ 94 U.S. 780 (1876).

⁹⁹ *Id.* at 782 and 786–87.

¹⁰⁰ *Id.* at 787 (emphasis added).

¹⁰¹ 6 S. Ct. 970 (1886).

¹⁰² *Id.* at 970–71.

¹⁰³ *Id.* at 972.

¹⁰⁴ *Id.* at 973. The Court added, “It is only the patentee of the original invention who has the right to complain of the use made of his invention.” *Id.*

¹⁰⁵ 48 S. Ct. 170 (1928).

¹⁰⁶ *Id.* at 171–72. Temco sued Apco for infringement, and Apco defended on the ground of the Storrie patent, but the Court rejected that defense. *Id.* at 173.

¹⁰⁷ *Id.* at 172. The Supreme Court described the differences between the claimed inventions of Temco and Apco as “the substitution of the radius link for the metal guide and casing and hanger” and added, “Except for the radius link, there is no difference in operation and result.” *Id.* Interferences were the pre-AIA procedure for determining which of two competing patent claims for the same invention were given priority and awarded the patent under the first to invent priority system in place in the United States before the application of the AIA. Mueller, *supra* note 3, at 223–25. The AIA “eliminated interferences . . . but added a new derivation proceeding.” *Id.* at 220.

¹⁰⁸ 48 S. Ct. at 172; *Apco Mfg. Co. v. Temco Electric Motor Co.*, 11 F.2d 109 (5th Cir 1926) (“in an interference proceeding in the Patent Office priority of the conception of the radius link as a part of a shock absorber adapted to the Ford car was awarded to one Storrie . . .”).

established that an improver cannot appropriate the basic patent of another, and that the improver without a license is an infringer, and may be sued as such.”¹⁰⁹

¶36

None of the three decisions discussed above turned on the same person holding both patents, and Professor Adams has identified at least three types of improvements that could lead to blocking patents between unrelated parties.¹¹⁰ The first is “where the improvement to a prior invention consists of the combination of a component with the prior invention.”¹¹¹ The second is if the First Inventor obtained a patent on composition XYZ, and the Improver subsequently obtained a patent for a new method of using composition XYZ.¹¹² The third “is when an inventor makes a broad claim to an entire class (or genus) of products after producing only a single member of the class (or species).”¹¹³ An example of this third type is *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*,¹¹⁴ which involved “genus claims encompassing the use of all substances that achieve the desired result of reducing the binding of NF- κ B to NF- κ B recognition sites.”¹¹⁵

¶37

This third type of a blocking patent – a broad genus patent – can block a significant amount of competition for improvements by third parties.¹¹⁶ For instance, in *Galderma Laboratories, L.P. v. Tolmar, Inc.*,¹¹⁷ the Shroot patents (held by Galderma)¹¹⁸ claimed “a general chemical formulation that ‘could result in hundreds, if not thousands of different compounds’ to treat a broad range of diseases,”¹¹⁹ and adapalene was within the range of alternatives of the Shroot patents.¹²⁰ The Federal Circuit observed that the “now expired Shroot patents blocked the market entry of 0.3% adapalene products until their expiration in 2010, long after Galderma invented 0.3% adapalene compositions of the asserted

¹⁰⁹ *Id.* at 173.

¹¹⁰ Adams, *supra* note 94, at 60–64. How to identify blocking patents as a practical matter is not always clear. See Ian Simmons, Patrick Lynch & Theodore H. Frank, ‘I Know It When I See It’: *Defining and Demonstrating ‘Blocking Patents’*, 16-SUM ANTITRUST 48 (2002) (“What if the second item of intellectual property theoretically can be practiced without the first, but practicing the second alone would not be commercially viable?”). Of course, if the two patents are held by the same party, then there is no blocking, because the holder of one can choose not to exclude itself from practicing the other invention.

¹¹¹ Adams, *supra* note 94, at 60.

¹¹² *Id.* at 61–62.

¹¹³ *Id.* at 63–64.

¹¹⁴ 598 F.3d 1336 (Fed. Cir. 2010), discussed in more detail in this article *infra* notes 191-204.

¹¹⁵ *Id.* at 1340–41.

¹¹⁶ Not only does the patent exclude any other person from making or selling the patented invention without permission, but, due to the narrow common law experimental use doctrine and limited statutory exemption under § 271(e), potential competitors are restricted in how they can experiment in trying to develop alternative products. *Supra* note 6.

¹¹⁷ Galderma Labs. L.P. v. Tolmar, Inc., 737 F.3d 731 (Fed. Cir. 2013).

¹¹⁸ See Br. of Pls.-Appellees, 2013 WL 1333337 at *13 (Fed. Cir.) (“The molecule adapalene was patented by Galderma in a series of patents (the ‘Shroot’ patents) that first issued in the late 1980s, including U.S. Patent Nos. 4,717,720 (A13024), 5,098,895 (A13036), and RE 34,440 These Shroot patents disclosed an enormous variety of different chemical compounds, different dosage forms, and different diseases that could be treated by the chemical compounds disclosed therein.”).

¹¹⁹ Galderma, 891 F. Supp. 2d at 603. In other cases, the genus patent has covered millions and even trillions of embodiments. See *supra* note 4.

¹²⁰ The Shroot patents disclosed “adapalene as the active ingredient, in concentrations of 0.001%, 0.1% and 1%” and concentrations “preferably between 0.01 and 1 weight percent.” Galderma, 737 F.3d at 735. See also Galderma, 891 F. Supp. 2d at 609.

claims. As such, no entity other than Galderma could have successfully brought . . . 0.3% to market prior to 2010.”¹²¹

¶38 Scholars generally have agreed that such broad patents restrict competition for improvements.¹²² Professors Bohannon and Hovenkamp state, “If IP law prevents competition by granting rights that are too broad, it discourages competitors from building on existing ideas, works, and inventions.”¹²³ They argue that people have “a reduced incentive [to innovate] as it becomes more costly to build on the ideas of others.”¹²⁴ Professor Love similarly argued that even in the pharmaceutical and biomedical industries, “broad pioneer rights are unlikely to spur additional innovation.”¹²⁵ He continued, “History further suggests that extending broad patent rights to early inventors in new fields will generally chill, if not entirely freeze, innovation for years at a time.”¹²⁶ Professor Merges and Professor Nelson argued that generally “where a few organizations controlled the development of a technology, technical advance appeared sluggish.”¹²⁷ They concluded, “Without extensively reducing the pioneer’s incentives, the law should attempt at the margin to favor a competitive environment for improvements, rather than an environment dominated by the pioneer firm.”¹²⁸

¶39 When a pharmaceutical company faces the argument that its Follow-On Patent constitutes improper double patenting, the company typically argues that the Follow-On Patent reflects a different invention than the First Invention and that the Follow-On Patent was not obvious at the time the company applied for a patent for the First Invention, disregarding the fact that the genus patent claimed the species disclosed by the Follow-On Patent.¹²⁹ This should be a difficult argument for the First Improver to make,

¹²¹ 737 F.3d at 740. *See also* Merck & Co. v. Teva Pharm. USA, Inc., 395 F.3d at 1377.

¹²² Professor Lemley has pointed out, “It is not enough to say that intellectual property law favors ‘creators’—for here we have creators on both sides of the equation, and the law must choose between them.” Lemley/*Economics*, *supra* note 9, at 998.

¹²³ Bohannon/Hovenkamp, *supra* note 41, at 273.

¹²⁴ *Id.* at 6.

¹²⁵ *Love/Interring*, *supra* note 54, at 446.

¹²⁶ *Id.* at 457.

¹²⁷ Merges, *supra* note 55, at 908.

¹²⁸ *Id.* Innovations exhibiting “extraordinary technological advances” have often been referred to as “pioneer inventions.” Love, *supra* note 54, at 381–82. This article does not use the term “pioneer,” because the dividing line between a pioneer and another improvement is not always clear. Instead, this article uses “First Invention” as a term to signify that the invention was invented before a subsequent invention, with the subsequent invention being an improvement. Historically, when a court found that a patent was a “pioneer,” it “customarily reward[ed] the inventor with a broad range of equivalents, thereby permitting her to claim ownership of technology lying substantially beyond the literal scope of her claims.” *Id.* at 389. However, the Federal Circuit has issued decisions on pioneer patents that seem to at least be in tension. *Cf.* Cohesive Tech., Inc. v. Waters Corp., 543 F.3d 1351, 1371 (Fed. Cir. 2008) (“pioneering inventions often, by their very nature, result in broader application of the doctrine of equivalents”); Texas Instruments, Inc. v. U.S. Int’l Trade Comm’n, 846 F.2d 1369, 1370 (Fed. Cir. 1988) (“even its ‘pioneer’ status does not change the way infringement is determined”). *See also* Joshua D. Sarnoff, *The Doctrine of Equivalents and Claiming the Future after Festo*, 14 FED. CIR. BAR J. 403 (2004). Since this article focuses on subsequent species claims within the literal scope of an earlier genus claim, there is no need to consider to what extent a pioneer patent should be given any leeway in determining equivalents. *But see* Love, *supra* note 54, at 379 (“the pioneer doctrine should now be excised from patent law once and for all.”).

¹²⁹ *See, e.g.*, Otsuka Pharm. Co., Ltd. v. Sandoz, Inc., 678 F.3d 1280, 1290–91 (Fed. Cir. 2012); *infra* notes 431–51 and accompanying text.

in light of its oath or declaration that it had invented the genus¹³⁰ and in light of the Federal Circuit’s decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*¹³¹ that an applicant can only obtain a patent for a genus when he had possessed the full scope of the invention at the time of the application.¹³²

¶40 Since what “invention” a patent covers is essential to applying the *Miller* principle that “no patent can issue for an invention actually covered by a former patent,”¹³³ the next section examines the meaning of “invention” and the disclosure requirements for a genus patent.

II. A PATENTEE SHOULD BE BOUND BY ITS OATH

A. *Invention Claimed Cannot Exceed Disclosures in Specification*

¶41 Ever since the first U.S. patent statute, an applicant for a patent has had to describe his invention. Section 2 of that 1790 act provided that the inventor must submit “in writing . . . a description, accompanied with drafts or models . . . of the thing or things, by him or them invented or discovered . . . to distinguish the invention or discovery from other things before known and used. . . .”¹³⁴ Under the early patent statutes, “Patent claims were unknown,” and “the jury would determine infringement by determining whether the defendant’s machines . . . were ‘substantially, in their principles and mode of operation, like’ . . . the invention described in the patent specification. . . .”¹³⁵ The patent application described the preferred embodiment of the invention, which was “understood to encompass all equivalents.”¹³⁶ Scholars label this practice of claiming as “central claiming.”¹³⁷

¶42 After 1822, the U.S. gradually¹³⁸ switched from central claiming to “peripheral claiming.”¹³⁹ In 1836, Congress required that the applicant for a patent “particularly

¹³⁰ *Supra* note 31 and accompanying text; *infra* note 218 and accompanying text.

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

¹³² *Infra* notes 191–204 and accompanying text.

¹³³ *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894).

¹³⁴ Section 2 of Patent Act of 1790, ch. 7, 1 Stat. 109–112 (April 10, 1790); CHISUM, *supra* note 77, at vol. 9, app. 9–1.

¹³⁵ John F. Duffy, *The Festo Decision and the Return of the Supreme Court to the Bar of Patents*, 2002 SUP. CT. REV. 273, 308 n.108, 309 (2002) (quoting *Odiorne v. Winkley*, 18 F. Cas. 581, 582 (C.C.D. Mass. 1814)).

¹³⁶ Mueller, *supra* note 3, at 78.

¹³⁷ *Id.* at 78; Love, *supra* note 54, at 389–91. For a detailed history of the transition from central claiming and the patenting of “principles” to a system of peripheral claiming, see Joshua D. Sarnoff, *The Historic and Modern Doctrines of Equivalents and Claiming the Future, Part I (1790–1870)*, 87 J. PAT. & TRADEMARK OFFICE SOC’Y 371, 387–408 (2005).

¹³⁸ Jeanne C. Fromer, *Claiming Intellectual Property*, 76 U. CHI. L. REV. 719, 734 (2009). It was only a general, gradual switch because the courts have continued to apply the doctrine of equivalents to patent claims, and the doctrine of equivalents is a vestige of central claiming. *Id.* at 735–38. Also, with means plus function claims, the claims do not provide the outer limits. *Id.* at 738. See also Dan L. Burk & Mark A. Lemley, *Fence Posts or Sign Posts? Rethinking Patent Claim Construction*, 157 U. PA. L. REV. 1743, 1771–77 (2009).

¹³⁹ Fromer, *supra* note 138, at 734. See also Mueller, *supra* note 3, at 78. Some say that “patent drafters began to break out of the text a distinct, separate statement of the novel features of the invention as a one sentence ‘claim,’ in order to avoid the possibility that the patent might be viewed as intended to claim everything in the full description of the invention.” Burk, *supra* note 138, at 1767. Others say the patent

specify and point out the part, improvement, or combination, which he claims as his own invention or discovery.”¹⁴⁰ However, subsequently the Supreme Court still concluded that the scope of the patent would be determined “with due weight given to the patent’s written description of the invention and its underlying principles.”¹⁴¹

¶43 The Patent Act of 1870¹⁴² mentioned “claim” twice, requiring a patent applicant to “particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery.”¹⁴³ Although claims were initially used for purposes of determining validity of the application, “after some period of time, courts began employing claims in determining infringement as well.”¹⁴⁴ The result of peripheral claiming was “for claim drafters to attempt to cover, by explicit claim language, every equivalent that a court might previously have recognized under the doctrine of equivalents.”¹⁴⁵ Three Supreme Court decisions—one before and two after the Patent Act of 1870—established that the invention disclosed in the specification limited the scope of a broad patent claim.

¶44 In 1853 in *O’Reilly v. Morse*,¹⁴⁶ the Supreme Court upheld Professor Morse’s claims to the telegraph and elements of the telegraph, but ruled that his broader eighth claim was invalid.¹⁴⁷ In that eighth claim, Morse said that “the essence of my invention” was “the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed for marking or printing intelligible characters, signs, or letters, at any distances, being a new application of that power . . .”¹⁴⁸ The Court said that Morse claimed “the exclusive right to every improvement where the motive power is the electric or galvanic current, and the result is the marking or printing intelligible characters, signs, or letters at a distance.”¹⁴⁹ The Court held that the claim was too broad, because Morse claimed “an exclusive right to use a manner and process which he has not described and indeed *had not invented*, and therefore could not describe when he obtained his patent.”¹⁵⁰

claim “arose not from any administrative, judicial, or legislative requirement. Instead, it was an innovation of patent attorneys, and it was formulated to protect and to expand the rights of patentees.” Duffy, *supra* note 136, at 309. In any case, the claim distinguished the invention from things previously known and defined the invention in broad terms to make it more difficult for defendants to argue the products of the defendant were not equivalent under the doctrine of equivalents. *Id.* at 309–10

¹⁴⁰ Fromer, *supra* note 138 at 732 (quoting Patent Act of 1836 § 6, 5 Stat 117, 119); *see also* CHISUM, *supra* note 77, at vol. 9, app. 11.

¹⁴¹ Fromer, *supra* note 138, at 733 (discussing the Supreme Court’s decision in *Winans v. Denmead*, 56 U.S. 330 (1853)).

¹⁴² CHISUM, *supra* note 77, at vol. 9, app. 14-6.

¹⁴³ Fromer, *supra* note 138, at 734 (quoting “An Act to Revise, Consolidate, and Amend the Statutes Relating to Patents and Copyrights” § 26, 16 Stat 198, 201 (1870)); *see also* CHISUM, *supra* note 77, at vol. 9, app. 14.

¹⁴⁴ Burk, *supra* note 138, at 1769.

¹⁴⁵ *Id.*

¹⁴⁶ 56 U.S. 62 (1853).

¹⁴⁷ *Id.* at 112.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.* at 113 (emphasis added).

¶45 In explaining its holding in *Morse*, the Supreme Court discussed a subsequent patent that Morse had obtained for an improvement of local circuits.¹⁵¹ The Court pointed out that if the eighth claim could be sustained, “his patent for the local circuits would be illegal and void. For he could not take out a subsequent patent for a portion of his first invention, and thereby extend his monopoly beyond the period limited by law.”¹⁵² In other words, the Court was saying, albeit in *dicta*, that an inventor could not obtain a patent on an improvement to a product he had earlier invented, if in fact the inventor’s original patent was broad enough that it covered the improvement.¹⁵³

¶46 In 1895, the Supreme Court decided an infringement suit filed by the Consolidated Electric Light Co. (based on a patent to Sawyer and Man) that nominally was against McKeesport Light Co., but the “real defendant was the Edison Electric Light Company.”¹⁵⁴ The two broader claims were for incandescing conductors made of “carbonized fibrous or textile material,” and the narrower third claim was for an incandescing conductor made of carbonized paper, but it was admitted that the third claim was not infringed.¹⁵⁵ Expressing concern over the exclusive nature of broad patents, the Court said “the fact that paper happens to belong to the fibrous kingdom did not invest them [Sawyer and Man] with sovereignty over this entire kingdom, and thereby practically limit other experimenters to the domain of minerals.”¹⁵⁶

¶47 The Supreme Court rejected the two broader claims of Sawyer and Man in *Consolidated Electric*, saying, “If the patentees had discovered in fibrous and textile substances a quality common to them all, or to them generally, as distinguishing them from other materials, such as minerals, etc., and such quality or characteristic adapted them peculiarly to incandescent conductors, such claim might not be too broad.”¹⁵⁷ In other words, since Sawyer and Mann had not invented species beyond the narrower third claim, the broader claims were invalid.

¶48 In the twentieth century, in *Schriber-Schroth Co. v. Cleveland Trust Co.*,¹⁵⁸ the Supreme Court repeated this basic limitation on patent claim scope in a case involving

¹⁵¹ Morse obtained his patent for the telegraph in 1840, and that patent was reissued in 1848. *Id.* at 106. The patent for the improvement of local circuits was issued in 1846 and reissued in 1848. *Id.*

¹⁵² *Id.* at 114.

¹⁵³ Of course, the fact a Supreme Court statement was *dicta* does not mean it is unimportant. The Federal Circuit has recognized that subordinate federal courts “are bound to follow them.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1347 (Fed. Cir. 2010) (en banc) (citing *Stone Container Corp. v. U.S.*, 229 F.3d 1345, 1349–50 (Fed. Cir. 2000)). *See also* *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1288 (Fed. Cir. 2015) (Dyk, J., concurring in denial of petition for rehearing en banc). The Supreme Court has subsequently cited *Morse* favorably in many decisions. *See, e.g.*, *Dolbear v. Am. Bell Tel. Co.*, 126 U.S. 1, 534 (1888) (“The effect of that decision was, therefore, that the use of magnetism as a motive power, without regard to the particular process with which it was connected in the patent, could not be claimed, but that its use in that connection could.”); *Gottschalk v. Benson*, 409 U.S. 63, 68 (1972); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012).

¹⁵⁴ *Consol. Elec. Light Co. v. McKeesport Light Co.*, 159 U.S. 465 (1895). The Court noted that “the case involved a contest between what are known as the Sawyer and Man and the Edison systems of electric lighting.”

¹⁵⁵ *Id.* at 468, 472.

¹⁵⁶ *Id.* at 476.

¹⁵⁷ *Id.* at 472.

¹⁵⁸ 305 U.S. 47 (1938).

patent claims for automobile pistons.¹⁵⁹ The Court reversed the holding of the Sixth Circuit that the patents were valid¹⁶⁰ and said that “the *patent monopoly does not extend beyond the invention described* . . . it cannot be enlarged by claims in the patent not supported by the description.”¹⁶¹

¶49 In other words, even with peripheral claiming, the Supreme Court made clear that if a patent claim was broader in scope than the invention described in the specification, that claim was invalid. There was no change as a result of the Patent Act of 1952, discussed next.

B. *The Patented Invention is any Embodiment Disclosed in the Specification Within Scope of Claim*¹⁶²

¶50 The Patent Act of 1952 “was intended to recodify, clarify, and revise the 1870 Patent Act’s provisions,” but its “legislative history confirms that no relevant substantive amendments were intended by the changes to the language of Section 112.”¹⁶³ Section 112 (pre-AIA) set forth the requirements for describing an invention in a patent application as follows:

“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

“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention”¹⁶⁴

¹⁵⁹ *Id.* at 49. Mueller points out that “the Court in *Schriber-Schroth* ‘did not expressly state’ that it was applying a written description requirement separate from enablement,” but “the *Ariad* court concluded that ‘that is exactly what the Court did.’” *Mueller, supra* note 3, at 165–66 (citing *Ariad*, 598 F.3d at 1346).

¹⁶⁰ *Cleveland Trust Co. v. Schriber-Schroth Co.*, 92 F.2d 330, 338 (6th Cir. 1937).

¹⁶¹ 305 U.S. at 57 (emphasis added).

¹⁶² Professor Liivak explained that “no matter how broadly you might have invented, only the embodiments that are claimed will need to comply with the validity portions of the patent statute [§§ 101, 102, 103 and 112] and only the claimed embodiments can be infringed.” Oskar Liivak, *Rescuing the Invention from the Cult of the Claim*, 42 SETON HALL L. REV. 1, 31 (2013). However, that disclosure does not require identification of all the precise chemical structures of each embodiment. *See infra* notes 202–03 and 213–14 and accompanying text.

¹⁶³ Joshua D. Sarnoff, *The Historic and Modern Doctrines of Equivalents and Claiming the Future: Part II (1870-1952)*, 87 J. PAT. & TRADEMARK OFF. SOC’Y, 441, 482, 485 (2005). Professor Sarnoff also pointed out that in its limited approval of functional claiming in § 112, ¶6, “Congress was careful to preserve the pre-existing limits on overbroad claiming” *Id.* at 486.

¹⁶⁴ 35 U.S.C. § 112, ¶¶ 1 and 2. Both pre-AIA and post-AIA § 112 contain the clause, “and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.” However, as a result of the AIA, 35 U.S.C. § 282 (b)(3)(A) now provides, “the 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”

¶51 The applicable Senate Report on these two clauses in the 1952 Patent Act said, “[t]he clause relating to the claim is made a separate paragraph to emphasize the distinction between the description and the claim or definition, and the language is modified.”¹⁶⁵ Section 112 (post-AIA) has substantially the same provisions for disclosure as § 112 (pre-AIA).¹⁶⁶

¶52 The first paragraph of § 112 provides that the “*specification shall contain a written description of the invention.*” In *Morse, Consolidated Electric and Schriber-Schroth*, with similar statutory disclosure requirements,¹⁶⁷ the Supreme Court concluded that since the specification did not disclose the scope of what was claimed, the applicable patent claims were not valid. In other words, “courts must go beyond the claims to determine what the ‘inventors actually invented.’”¹⁶⁸

¶53 The second paragraph of § 112 mentions “invention,” but simply requires the claim to reveal what the inventor “regards as the invention.”¹⁶⁹ In *Morse* and *Consolidated Electric*, the inventors regarded their inventions as much broader in scope than the Supreme Court did, but the Court said the actual invention was narrower, as the specification disclosed.¹⁷⁰ Indeed, § 100(a)(post-AIA) provides, “The term ‘invention’ means invention or discovery,” and § 100(j)(post-AIA) provides, “The term ‘claimed invention’ means the subject matter defined by a claim in a patent or an application for a patent.” The “claimed invention” can be narrower than the invention disclosed in the specification, but cannot be broader for patent protection.¹⁷¹

¹⁶⁵ S. REP. NO. 82-1979, at 2412 (1952). Before the Patent Act of 1952, the courts had used the word “invention” to refer to (a) what the inventor had created and also (b) as a “qualitative measure of patentability for new inventions” that Judge Rich referred to as “judicial legislation.” See Judge Giles S. Rich, *Laying The Ghost Of The ‘Invention’ Requirement*, 41 AIPLA Q.J. 1, 29 (2013). The Patent Act of 1952 created a statutory obviousness requirement in § 103 as a substitute for this “judicial legislation” but retained the requirement in § 112 that the applicant in fact disclose her invention in the patent application. *Id.* at 15–18. For detailed discussions of the obviousness requirement, see Douglas L. Rogers, *Obvious Confusion Over Properties Discovered After a Patent Application*, 43 AIPLA Q.J. 489 (2015) and Douglas L. Rogers, *Federal Circuit’s Obviousness Test For New Pharmaceutical Compounds: Gobbledygook?* 14 CHI.-KENT J. INTELL. PROP. 49 (2015).

¹⁶⁶ (a) In General.—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 (b) Conclusion.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.” 35 U.S.C. § 112 (2012).

¹⁶⁷ See CHISUM, *supra* note 77, at vol. 3A, § 7.02[1]–[4], 7-9 to -12.

¹⁶⁸ Christopher A. Cotropia, *What Is The “Invention”?*, 53 WM. & MARY L. REV. 1855, 1879 (2012) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc) & *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

¹⁶⁹ In addition to adding letter designations to the paragraphs of § 112 (pre-AIA), § 112 (post-AIA) added “or joint inventor,” and § 282(b)(3)(A) (post-AIA) limited the consequences of failing to meet the best mode requirement of § 112 (post-AIA). See *infra* note 184. However, the requirements for written description, enablement and definiteness remained essentially the same from § 112 (pre-AIA) to § 112 (post-AIA). See CHISUM, *supra* note 167, at vol. 3, § 7.02[1]–[5], app. 7-9 to 7-14.1.

¹⁷⁰ See *supra* notes 167 and accompanying text.

¹⁷¹ See Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 157–60 (2006); cf. Tun-Jen Chiang, *The Levels of Abstraction in Patent Law*, 105 Nw. U. L. Rev. 1097, 1102–03 (2011) (“The specification describes the invention created by the patentee so that others can make and use it . . . a claim describes only the key inventive features of the invention—those that form the essence of the patentee’s

¶54 The text of §101 supports the position that “invention” refers to embodiments, because it provides, “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement” of any of those categories, is entitled to a patent if the other requirements of the patent statute are satisfied.¹⁷² Machines, manufactures compositions of matter “are real things, as opposed to metaphysical constructs or abstractions. These things are real in the sense that invented things are either physical objects (machines, manufactures, compositions of matter) or they are specific physical acts (processes and methods).”¹⁷³ In *In re Nuijten*, the Federal Circuit addressed a patent claim for a signal with embedded digital watermark encoded according to a given encoding process.¹⁷⁴ The Federal Circuit said the claimed invention was “not a ‘process, machine, manufacture, or composition of matter’ . . . thus, such a signal cannot be patentable subject matter.”¹⁷⁵ In other words, “inventors invent operable embodiments.”¹⁷⁶

¶55 The Supreme Court has recognized that an invention exists before the claim is filed. In *Pfaff v. Wells Electronics, Inc.*,¹⁷⁷ the inventor Pfaff had submitted drawings of his invention to Wells Electronics, and Wells had provided Pfaff with a written confirmation of a previous oral purchase order for the computer chip socket in question, all more than a year before Well’s patent application.¹⁷⁸ Of course, there was no patent claim filed at the critical time: one year prior to the patent application under § 102(b). The Court affirmed the Federal Circuit’s finding that the Pfaff patent was “invalid because the invention had been on sale for more than one year in this country before he filed his patent application.”¹⁷⁹ In other words, “the subject matter invented by the inventor exist[ed] before a patent is ever filed and before any claims have been written.”¹⁸⁰

¶56 The Supreme Court has also held that under § 271(a), a defendant has made the “patented invention” only when it has completed the “operable assembly of the whole

idea.”) If the specification discloses a broader invention than claimed, then generally the broader part disclosed in the specification that is not claimed is deemed to be disclaimed and free for the public to use. See *Johnson & Johnston Assocs., Inc. v. R.E. Service Co., Inc.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc).

¹⁷² There was no change in § 101 as the result of the AIA. 35 U.S.C. § 101.

¹⁷³ Liivak, *supra* note 34, at 68–69.

¹⁷⁴ 500 F.3d 1346, 1348–49 (Fed. Cir. 2007).

¹⁷⁵ *Id.* at 1356. As a result, the Federal Circuit affirmed the decision of the Board of Patent Appeals and Interferences concluding the patent claim did not reflect patentable subject matter.

¹⁷⁶ Liivak, *supra* note 34, at 68.

¹⁷⁷ 525 U.S. 55 (1998).

¹⁷⁸ *Id.* at 57–58. Section 102(b) (pre-AIA) provided that an inventor did not have the right to a patent if the “invention was patented or described in a printed publication in this or a foreign country or in public use of on sale in this country, more than one year prior to the date of the application for patent in the United States.”

¹⁷⁹ *Pfaff*, 525 U.S. at 68–69. However, for cases to which the AIA will apply, “the invention date . . . is no longer relevant to determining which of two rival claimants for a patent will prevail.” Mueller, *supra* note 3, at 22, n.54. The “AIA generally awards the patent to the first inventor *to file* her patent application,” but “a second (i.e., later in time) filer will obtain the patent if the second filer had publicly disclosed the invention before the first filer’s effective filing date and thereafter files her own (i.e., the second filer’s) application in a timely fashion.” *Id.* at 233, n.208.

¹⁸⁰ Liivak, *supra* note 162, at 16.

and not the manufacture of its parts” in the United States.¹⁸¹ The Court added that a “patent covers only the *totality of the elements* in the claim and . . . no element, separately viewed, is within the grant.”¹⁸² In other words, if Patent X claims a product “comprising” A, B and C, then patent X covers both a constructed product composed of A, B, C and D and a constructed product composed of A, B, C and E.¹⁸³

¶57 There are a number of disclosure requirements in §112, including: (1) enablement and (2) written description of the invention.¹⁸⁴ The “enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation.”¹⁸⁵ The written description requirement, discussed next, has been more controversial.¹⁸⁶

¶58 Initially, the U.S. Court of Customs and Patent Appeals (CCPA), a predecessor court to the Federal Circuit,¹⁸⁷ conflated the written description requirement with the

¹⁸¹ *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 528 (1972). *Deepsouth* involved patents held by Laitram for deveining shrimp and whether Deepsouth infringed those patents by making and shipping to foreign customers all the parts for the deveining machines. *Id.* at 523–24. The Supreme Court held there was no infringement because the patented product had not been completed in the United States. *Id.* 525–26, 532. After *Deepsouth*, Congress amended § 271 to add § 271(f)(1) stating that whoever “without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.” See Mueller, *supra* note 3, at 512–17. In *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 444–45 (2007), the Supreme Court explained that 271(f) “expands the definition of infringement to include supplying from the United States a patented invention’s components.” However, § 271(a) still refers to the “patented invention.”

¹⁸² *Deepsouth Packing Co.*, 406 U.S. at 528 (emphasis added) (quoting *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 344 (1961)).

¹⁸³ “Comprising” is an “open” claim term, and “consisting of” is a “closed” claim term. Professors Merges and Duffy write, “If the claim reads ‘an invention comprising elements A, B and C,’ long tradition in the patent field dictates that the claim covers any embodiment of the invention having elements A, B and C and any additional elements.” Merges, *supra* note 6, at 28 (emphasis in original). In contrast, “[i]f you claim ‘An invention consisting of elements A, B and C,’ someone selling a variant that also incorporates element D does not infringe your claim.” *Id.* See also *infra* notes 405–11 and accompanying text for discussion of *In re Schneller*, 397 F.2d 350 (C.C.P.A. 1968).

¹⁸⁴ See *supra* notes 164–66 and accompanying text. Of course, both are satisfied through writing in the application. Omitted from the text accompanying note 164 is the requirement that an applicant disclose the “best mode” for carrying out the invention. However, the AIA provided that “the 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.” 35 U.S.C. § 282(b)(3)(A)(2011). Another requirement in § 112 (pre-AIA) is that the claims particularly point out and distinctly claim “the subject matter which the applicant regards as his invention.” AIA § 112(b) has essentially the same language, but substituted “inventor or a joint inventor” for “applicant” and “the” for “his.” See § 112 (post-AIA). For the most recent Supreme Court decision on the meaning of the definite claim requirement, see *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014).

¹⁸⁵ *Automotive Technologies Int’l, Inc. v. BMW of North America, Inc.*, 501 F.3d 1274, 1282 (Fed. Cir. 2007).

¹⁸⁶ *Cotropia*, *supra* note 168, at 1871.

¹⁸⁷ Mueller, *supra* note 3, at 40. In addition, “Congress in 1958 (72 Stat. 848) declared that the U.S. Court of Customs and Patent Appeals was created under Article III. In 1961, a congressional statute designated the chief judge of the court as a member of the Judicial Conference of the United States. The U.S. Court of Customs and Patent Appeals was abolished in 1982 when its judges and its jurisdiction were transferred to the new U.S. Court of Appeals for the Federal Circuit.” *History of the Federal Judiciary*:

enablement requirement, and concluded that the “original claim, in itself constituted a description in the original disclosure equivalent in scope and identical in language to the total subject matter now being claimed.”¹⁸⁸ Over time, however, the CCPA and then the Federal Circuit applied a written description requirement separate from the enablement requirement, but first only when the patent applicant had amended the claims after the initial application.¹⁸⁹ In a series of subsequent decisions, discussed next, the Federal Circuit established the rule that the written description requirement applied to all patents, not simply those in which the applicant had substantively changed its claims during prosecution.¹⁹⁰

¶59 The *en banc* decision of the Federal Circuit in *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*¹⁹¹ involved genus claims of “methods for regulating cellular responses to external stimuli” to “reduce the harmful symptoms of certain diseases.”¹⁹² Relying on such decisions as *Morse and Schriber*,¹⁹³ the *en banc* Federal Circuit held that “even after the introduction of claims,”¹⁹⁴ the statute required a written description of what the applicant had invented, separate from the enablement requirement.¹⁹⁵

¶60 The Federal Circuit in *Ariad* repeated a number of times that in order for a patent claim to be valid, the specification had to disclose embodiments of the genus.¹⁹⁶ A generic claim could define the boundaries of a broad genus, but “the question may still remain whether the specification, including original claim language, demonstrates that

U.S. Court of Customs and Patent Appeals, Federal Judicial Center, http://www.fjc.gov/history/home.nsf/page/courts_special_cpa.html[<https://perma.cc/83Z6-7GZF>].

¹⁸⁸ *In re Gardner*, 475 F.2d 1389, 1391 (C.C.P.A. 1973), *rehearing denied*, 480 F.2d 879, 879–80 (C.C.P.A. 1973) (“[W]e consider the original claim in itself adequate ‘written description’ of the claimed invention. It was equally a ‘written description’ whether located among the original claims or in the descriptive part of the specification.”).

¹⁸⁹ *In re Ruschig*, 379 F.2d 990, 991, 996 (C.C.P.A. 1967); *In re Smith*, 481 F.2d 910, 914 (C.C.P.A. 1973); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560 (Fed. Cir. 1991).

¹⁹⁰ *See, e.g.*, *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 633 (1998); *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1307, 1311 (Fed. Cir. 2004); *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1337 (Fed. Cir. 2005).

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

¹⁹² *Id.* at 1340. Claim 80 of the ‘516 patent, re-written to include the claim from which it depended, recited: “A method for modifying effects of external influences on a eukaryotic cell, which external influences induce NF- κ B-mediated intracellular signaling, the method comprising altering NF- κ B activity in the cells such that NF- κ B-mediated effects of external influences are modified, wherein NF- κ B activity in the cell is reduced] wherein reducing NF- κ B activity comprises reducing binding of NF- κ B to NF- κ B recognition sites on genes which are transcriptionally regulated by NF- κ B.” *Id.*

¹⁹³ *Id.* at 1345, 1346.

¹⁹⁴ *Id.* at 1345.

¹⁹⁵ *Id.* at 1345–46.

¹⁹⁶ Disclosing embodiments is not the same as constructing a prototype or reducing an invention to practice. As the Federal Circuit explained, “the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement.” *Id.* at 1352. An “actual reduction to practice involves constructing a physical embodiment of the invention that works for its intended purpose.” Mueller, *supra* note 3, at 123, n.32. A “‘constructive reduction to practice’ occurs when an inventor files a patent application that discloses his invention in compliance with the first paragraph of 35 U.S.C. § 112.” *Id.*

the applicant has *invented species sufficient to support a claim to the genus.*¹⁹⁷ Genus claims containing functional language create particular problems, because they “may simply claim a desired result, and may do so without describing *species that achieve that result.*”¹⁹⁸ The court said that the written description requirement meant the applicant must show it “has *invented species sufficient to support a claim to the functionally-defined genus.*”¹⁹⁹ The court added that “merely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species.”²⁰⁰

¶61 The Federal Circuit in *Ariad* explained that an adequate written description “requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.”²⁰¹ It added, “Nor do we set out any bright-line rules governing, for example, the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field.”²⁰² It held that the claims in *Ariad* were invalid because the specification did not satisfy the written description requirement.²⁰³

¶62 More recently, in *Novozymes A/S v. DuPont Nutrition Biosciences APS*,²⁰⁴ the Federal Circuit addressed the validity of a patent issued on a continuation application filed in 2009 that claimed priority from Novozymes’ earlier 2000 provisional application.²⁰⁵ The 2000 provisional application “disclosed a potentially enormous number of alpha-amylase variants,” but “did not point out the specific variants later claimed” in the patent issued to Novozymes (the 2010 Patent).²⁰⁶ After Novozymes had learned of DuPont’s alpha-amylase variant,²⁰⁷ Novozymes added patent claims that the district court subsequently found DuPont infringed.²⁰⁸

¶63 The Federal Circuit in *Novozymes* said one of the issues was “whether the 2000 application demonstrates to one of ordinary skill in the art that, by the application’s filing date, Novozymes had invented the *particular alpha-amylase variants* that Novozymes claimed almost a decade later in the” 2010 patent.²⁰⁹ Since the disclosure had not shown

¹⁹⁷ *Ariad Pharmaceuticals, Inc.*, 598 F.3d at 1349 (emphasis added).

¹⁹⁸ *Id.* (emphasis added).

¹⁹⁹ *Id.* (emphasis added).

²⁰⁰ *Id.* at 1350.

²⁰¹ *Id.*

²⁰² *Id.* at 1351.

²⁰³ *Id.* at 1358.

²⁰⁴ 723 F.3d 1336 (Fed. Cir. 2013).

²⁰⁵ *Id.* at 1341. Section 111(b) covers provisional applications and provides that a claim is not required for a provisional application. If the invention claimed in the nonprovisional application “was adequately supported by the disclosure of the of the provisional application in accordance with 35 U.S.C. §112, ¶1 . . . , the application can claim for the later nonprovisional application the benefit of the earlier provisional application’s filing date . . .” Mueller, *supra* note 3, at 54.

²⁰⁶ *Novozymes A/S*, 723 F.3d at 1343.

²⁰⁷ *Id.* at 1341.

²⁰⁸ The district court granted summary judgment in favor of Novozymes on infringement, and the jury awarded damages to Novozymes exceeding \$18 million. *Id.* at 1338.

²⁰⁹ *Id.* at 1348 (emphasis added).

that by the time of the priority date for the patent application (2000), Novozymes had invented the variant infringed by DuPont, the Federal Circuit held that Novozymes' patent claim was invalid.²¹⁰ In other words, although *Ariad* made clear that a genus claim does not have to expressly identify in the specification all the species in a claimed genus,²¹¹ under *Novozymes* the specification does have to adequately disclose the species which the patentee subsequently claims someone else is infringing.

¶64 After *Ariad* genus patents can still issue, since a specification can adequately disclose a genus with "either a representative number of species falling within the scope of the genus or structural features common to the members of the genus."²¹² Professor Liivak explained that "the description of an actual embodiment that has been reduced to practice can be part of the support for a broader genus claim when the specification also discloses additional information, like some 'correlation between function and structure,' of the genus, or as put by the Supreme Court, some 'quality common to' the genus."²¹³ Indeed, most claims are genus claims in one respect, since Professor Crouch has pointed out that "most claims cover an infinite variety of potential embodiments each involving a minor tweak in one way or another."²¹⁴

¶65 The question remains what happens once the USPTO has awarded a genus patent for a composition, assuming the defendant does not challenge the validity of the genus patent under one of the AIA post grant procedures to challenge validity.²¹⁵ This article discusses that question next.

²¹⁰ *Id.* at 1348 and 1351. See also *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1301 (Fed. Cir. 2014) (requiring that the patents must at least describe some species representative of antibodies that are structurally similar to Stelara, the allegedly infringing product).

²¹¹ See *supra* notes 202–03 and accompanying text.

²¹² *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d at 1350 (Fed. Cir. 2010) (en banc). In 2009, before the *en banc* decision in *Ariad*, Professor Adams wrote that the written description requirement would "eliminate the . . . circumstance where an inventor could make a valid claim to a genus containing species that the inventor did not invent." Adams, *supra* note 94, at 65. Professor Adams was correct in concluding that genus patents could only issue in the future if the inventor had invented the species claimed. *Supra* at notes 191-204 and accompanying text. See also Dennis Crouch, *Federal Circuit: To Satisfy the Written Description Requirement*, PATENTLY-O (Jan. 8, 2016), <http://patentlyo.com/patent/2014/07/description-requirement-representative.html> [https://perma.cc/P6H5-282H] ("By design, patent claims generally cover a set of a variety of potential embodiments. . . . The courts have never required that all potential embodiments be disclosed. . . . [T]he operative question . . . [is] how many different species (embodiments) of an invention must be described in a patent document before the applicant can properly claim rights to the genus of all related species.").

²¹³ Liivak, *supra* note 34, at 89.

²¹⁴ *Id.* As mentioned above, *supra* note 6, "genus" and "species" are simply relative terms when comparing one claim to another, understanding that one is a genus compared to the other, and the second is a species compared to the genus.

²¹⁵ See, e.g., §§ 311-319 (post-AIA) (*inter partes* review) and §§ 321-329 (post-AIA) (post-grant review). In *inter partes* review—§ 316(e) (post-AIA)—and post grant review—§ 326(e) (post-AIA)—the challenger to a patent has the burden of proving invalidity by a preponderance of the evidence. The Supreme Court granted cert. on Jan. 15, 2016 in *In re Cuozzo Speed Tech., LLC*, a case involving *inter partes* review procedures. See *In re Cuozzo Speed Tech., LLC*, 793 F.3d 1268 (Fed. Cir. 2015).

C. *The Presumption is that a Patentee Invented the Species Within the Scope of its Patented Genus Claim*

¶66 Once an individual obtains a patent (including of course a genus patent), there is a presumption that the patent is valid, and that presumption can only be rebutted by clear and convincing evidence.²¹⁶ This presumption particularly makes sense with the written description requirement because of the oath or declaration an applicant must sign and submit to the USPTO that “he believes himself to be the original and first inventor of the process, machine, manufacture, or composition of matter, or improvement thereof, for which he solicits patent.”²¹⁷

¶67 In *Diamond Scientific Co. v. Ambico, Inc.*,²¹⁸ the Federal Circuit addressed a similar situation where a patentee assigned its patent to another party and signed an affidavit for the assignee that the patent was valid, but the assignor subsequently was sued for infringement by the assignee and defended it on the ground that the patent was invalid. The Federal Circuit said that the primary consideration was “the measure of unfairness and injustice that would be suffered by the assignee if the assignor were allowed to raise defenses of patent invalidity.”²¹⁹ The Federal Circuit held in such a situation that the assignor “should be estopped from defending patent infringement claims by proving that what he assigned was worthless.”²²⁰ Similarly, when an applicant for a genus patent obtains a patent for a genus after submitting an oath or declaration to the USPTO that it invented the genus, the applicant should be estopped from subsequently taking a different position and saying it had not invented the species when (a) applying for a patent for a species within the genus, or (b) trying to enforce the subsequent species patent within the scope of the genus against a third party.

¶68 Can the holder of a genus patent at least limit any estoppel by arguing that she cannot be required to have invented species within the genus resulting from advances in technology not known at the time of the genus invention? It is true that patentees have at times been victorious in infringement litigation against defendants selling products using after-arising technology.²²¹ However, the two reasons this has occurred would not be applicable to First Inventions by a pharmaceutical company with a broad genus patent

²¹⁶ 35 U.S.C. § 282(a) provides in relevant part, “A patent shall be presumed valid. . . . The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.” In *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238 (2011), the Supreme Court held that § 282 “requires an invalidity defense to be proved by clear and convincing evidence.” *Id.* at 2242. In a concurring opinion joined by Justices Scalia and Alito, Justice Breyer said, “I believe it worth emphasizing that in this area of law as in others the evidentiary standard of proof applies to questions of fact and not to questions of law.” *Id.* at 2253.

²¹⁷ 35 U.S.C. § 115 (pre-AIA). Section 115(b)(2) (post-AIA) similarly requires an oath or declaration that the applicant “believes himself or herself to be the original inventor or an original joint inventor of a claimed invention in the application.” An alternate oath or declaration can be submitted if the inventor is under an obligation to assign the invention to the applicant and has refused to sign the oath. § 115(d) (post-AIA).

²¹⁸ *Diamond Scientific Co. v. Ambico, Inc.*, 848 F.2d 1220 (Fed. Cir. 1988).

²¹⁹ *Id.* at 1225.

²²⁰ *Id.* at 1226.

²²¹ See Bernard Chao, *The Infringement Continuum*, 35 CARDOZO L. REV. 1359, 1359–68 (2014); and Lemley, *supra* note 9, at 1003–05.

and a subsequent patent application by that company for a species within the scope of the genus.

¶69 First, compliance with the enablement doctrine is determined at the time the patent applicant files its application,²²² so “[a]n inventor can properly claim broad subject matter so long as her research enables one skilled in the art to make and use her claimed invention *as that invention was understood at the filing date.*”²²³ On the other hand, in determining the existence of infringement, “Literal claim scope is not limited to the technologies that are already in existence at the time a claim is filed. It routinely encompasses technology . . . that can be realized only after a post-filing technological advance has occurred.”²²⁴ As a result of this “temporal paradox,”²²⁵ technologies unknown at the time of the patent application have not been taken into account in determining whether the specification enabled the claim, but have been taken into account in determining if the patent claim covered an accused product at the time of the alleged infringement.²²⁶

¶70 Yet now that the written description requirement under *Ariad* is a separate requirement than enablement, for a patent claim to be valid the inventor must have invented/possessed the scope of the genus at the time of the application.²²⁷ Therefor the temporal paradox does not apply for written descriptions, and Professor Collins has concluded that “the principal impact of the written description requirement has been to restrict the reach of literal claim scope into after-arising technology.”²²⁸ He added that “all Federal Circuit cases that use the written description doctrine to invalidate claims have achieved a single goal: they have invalidated claims that were deemed to reach too far into after- arising technology, i.e., technology that is not invented until after the patent applicant files her application.”²²⁹ Similarly recognizing that *Ariad* limits the

²²² *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004) (“Whether the earlier applications enable the claims of the ‘561 patent is determined as of the filing date of each application.”).

²²³ *Merges, supra* note 6, at 284.

²²⁴ Kevin Emerson Collins, *Enabling After-Arising Technology*, 34 J. CORP. L. 1083, 1086 (Summer 2009).

²²⁵ *Merges, supra* note 6, at 284 (emphasis added).

²²⁶ *Merges and Duffy* give the hypothetical of a patent for “fuzzballs,” assuming they were new, nonobvious and useful, and assuming further that at the time of application fuzzballs were only made of wool and cotton. The technology evolved and fuzzballs could be made from synthetic fibers. They write, “Thus the definition of fuzzballs used in the question, ‘Did you enable the making of all fuzzballs?’ does not change over time, while the definition of the same term in the question, ‘Did someone infringe the claim to all fuzzballs?’ does change to reflect the inevitable growth of fuzzball technology.” *Id.* at 285; *cf. Promega Corp. v. Life Tech. Corp.*, 773 F.3d 1338, 1350 (Fed. Cir. 2014) (whether a claim is enabled by the specification, in light of after-arising technologies, may depend on whether the term “comprising” is used in one of the individual limitations of a claim rather than the preamble to the claim).

²²⁷ *Supra* notes 112–204 and accompanying text. *See also AbbVie Deutschland GmbH & Co. KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1301 (Fed. Cir. 2014) (“functionally defined claims can meet the written description requirement if a reasonable structure-function correlation is established, whether by the inventor as described in the specification or known in the art at the time of the filing date.”); *Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011) (“[W]hen the four corners of the specification directly contradict information that the patentee alleges is “well-known” to a person of skill at the effective filing date, no reasonable jury could conclude that the patentee possessed the invention.”).

²²⁸ Kevin Collins, *An Initial Comment on Ariad: Written Description and the Baseline of Patent Protection for After-Arising Technology*, 2010 PATENTLY-O PAT. L. J. 24, 60 (2010).

²²⁹ *Id.* at 62–63.

ability of patentees to cover after-arising technology in their claims of literal infringement, Professor Cotropia concluded that “after-arising technologies can fall within a patent’s scope of exclusivity only by resorting to the doctrine of equivalents.”²³⁰

¶71 Turning to after-arising technology and the doctrine of equivalents, “the proper time for evaluating equivalency—and thus knowledge of interchangeability between elements—is at the time of infringement, not at the time the patent was issued.”²³¹ Therefore, “[t]he doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes.”²³² It follows that the doctrine of equivalents is not applicable when the claim was captured in drafting the original genus claim.

¶72 Put another way: “Application of the doctrine of equivalents is the exception . . . , not the rule.”²³³ It applies when there is no literal infringement, as the Supreme Court indicated when it said, “The scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described.”²³⁴ Similarly, Professor Mueller has said, “The doctrine of equivalents permits a finding of patent infringement liability for accused devices that are not encompassed within the literal scope of a claim.”²³⁵ A species within the scope of a genus is not an equivalent to the genus, but part of the literally claimed genus, so there is no authority for applying the doctrine of equivalents when there is literal infringement.

¶73 Professor Holbrook observed that “the Federal Circuit has precluded access to the doctrine of equivalents if the asserted equivalent is one that should have been in the inventor’s possession during the application process.”²³⁶ Of course, the First Inventor has already submitted an oath that she was in possession of – had invented - the species.²³⁷ The Supreme Court vacated an earlier Federal Circuit decision in *Festo* and limited the use of the doctrine of equivalents when there had been a narrowing amendment during patent prosecution, but allowed the doctrine of equivalents to “capture” products encompassing after-arising technologies when the “equivalent may have been unforeseeable at the time of the application.”²³⁸ In the case of a species within the scope of a genus patent claim by the same party, the same party has already submitted an oath that she invented the genus, and the genus claim covers the species, so the

²³⁰ Christopher A. Cotropia, *‘After-Arising’ Technologies and Tailoring Patent Scope*, 61 N.Y.U. ANN. SURV. AM. L. 151, 153 (2005).

²³¹ Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 37 (1997).

²³² *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 733 (2002).

²³³ *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991).

²³⁴ *Festo Corp.*, 535 U.S. at 732.

²³⁵ Mueller, *supra* note 3 at 107, note 86.

²³⁶ Holbrook, *supra* note 56, at 15 (citing *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 493 F.3d 1368, 1382 (Fed. Cir. 2007)) (rejecting the patent claim, because, “Not only was the use of a non-magnetic sleeve disclosed in the prior art, the ‘125 patent application itself clearly recognized the possibility of using a non-magnetic material for the sleeve.”)

²³⁷ *Supra* note 217.

²³⁸ *Festo Corp.*, 535 U.S. at 740. The Supreme Court added two other situations in which the doctrine of equivalents could apply, neither of which would be applicable to the case of a genus patent and subsequent species patent within the scope of the genus: “[T]he rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.” *Id.* at 740–41.

Supreme Court's description of when the doctrine of equivalents could be available for unforeseeable events would be of no help to the First Inventor who has already literally claimed that species.²³⁹

¶74 As a result, the possibility of after-arising technologies does not provide a valid basis for arguing that courts should allow a pharmaceutical company to circumvent *Morse*, *Schriber* and *Ariad*.

D. Summary

¶75 The "invention is not simply a shorthand reference for the claimed subject matter," but a "substantive technical concept" of the "inventor's own solution to some technical problem for which the inventor seeks a patent."²⁴⁰ Defining "the invention by the detailed technology discussion in the patent specification's descriptions and drawings" appropriately "grounds exclusivity in what the inventor has actually done or plans to do."²⁴¹ A claim may be narrower than what is disclosed in the specification and still be valid,²⁴² but if it is broader than what is disclosed, the claim is invalid, and the USPTO should reject the application.²⁴³

¶76 Under *Ariad*, an application for a genus patent "must demonstrate sufficient support in the specification to justify the scope of the claim by showing that the inventor was *in possession of the entirety of the claimed invention*." (emphasis added)²⁴⁴ Once the patent is granted, there is a presumption the patent is valid,²⁴⁵ which means the inventor invented the species claimed at the time of the patent application. All species within the scope of the genus constitute the patented invention.²⁴⁶

¶77 The next part of this article argues that this presumption of patent validity should prevent the holder of the genus patent from defending a double patenting challenge to its subsequent patent for a species within the genus by arguing he had not really invented, or

²³⁹ There is language in *In re Hogan*, 559 F.2d 595, 606–07 (C.C.P.A. 1977) that may suggest that a claim for a pioneer invention "can literally encompass later-developed technologies." Cotropia, *supra* note 231, at 167. However, *Hogan* occurred decades before *Ariad* split the written description requirement from enablement that limited the reach of claims into subject matter encompassing after-arising technology. In addition, Professor Cotropia notes, "T[he court in *Hogan* did not specifically hold that claim language can literally include after-arising technologies. In fact, the weight of Federal Circuit authority indicates the opposite." *Id.*; see also *Plant Genetic Systems, N.V. v. Dekalb Genetics Corp.*, 315 F.3d 1335, 1340–42 (Fed. Cir. 2003). Moreover, in the case of a genus patent and a patent for a species within the scope of the genus by the same inventor, the genus patent has already been granted, and in many such cases it was admitted that the species was within the literal scope of the genus. See, e.g., *Otsuka Pharm. Co. Ltd. v. Sandoz, Inc.*, 678 F.3d 1280 (Fed. Cir. 2012); *infra* notes 431–51 and accompanying text; *AbbVie Inc. v. Mathilda and Terence Kennedy Inst. of Rheumatology*, 764 F. 3d 1366 (Fed. Cir. 2014); *infra* notes 454–73 and accompanying text. There would be no basis for applying the doctrine of equivalents.

²⁴⁰ Liivak, *supra* note 162, at 5.

²⁴¹ Cotropia, *supra* note 168, at 1855–56.

²⁴² If a claim is narrower than what has been disclosed, then what is disclosed but not claimed is free to the public to use. See *Johnson & Johnston Assocs. v. R.E. Service Co.*, 285 F.3d 1046 (Fed. Cir. 2002) (en banc).

²⁴³ *Supra* notes 162 and 171.

²⁴⁴ Timothy R. Holbrook, *Patents, Presumptions, and Public Notice*, 86 IND. L.J. 779, 794 (2011) (emphasis added); see also *supra* notes 191–204 and accompanying text for discussion of *Ariad*.

²⁴⁵ *Supra* note 217.

²⁴⁶ *Supra* notes 181–82 and accompanying text.

possessed, the species at the time he obtained the genus patent. Put simply, a patentee should not be allowed to argue on the one hand he has invented the full scope of a genus but on the other hand subsequently defend a challenge to its species patent on the ground that he had not really invented the full scope of the genus at the time of the genus application.

III. IT SHOULD BE PROHIBITED DOUBLE PATENTING FOR AN INVENTOR OR EMPLOYER TO APPLY FOR A PATENT FOR A SPECIES WITHIN SCOPE OF GENUS PATENT HELD BY SAME INVENTOR OR EMPLOYER

A. *Supreme Court/Supreme Court Justice: One Person May Not Cover the Same Invention with Two Patents*

¶78 In the 1800s federal courts announced and applied the common sense principle that “no patent can issue for an invention actually *covered* by a former patent, especially to the same patentee, although the terms of the claims may differ.” (emphasis added)²⁴⁷ If by “covered” the courts had meant that a patentee could not hold two patents that were the same, then any person could easily navigate around such doctrine by obtaining a second patent that was only different in minor ways (e.g., the first patent covered 100 embodiments of a widget, whereas the second patent only covered 99 of the same embodiments) and essentially extend the first patent by years.²⁴⁸ The Supreme Court and its justices did not so limit the principle.

¶79 Before discussing at length the most significant Supreme Court decision on what has become known as double patenting, *Miller v. Eagle Mfg. Co.*,²⁴⁹ the Court discusses three earlier decisions because the Court in *Miller* had done so in its holding. In none was there consideration of whether the two patents “covered” the “same invention” limited to comparing the patent claims.

¶80 Even before the practice of patent claims had appeared,²⁵⁰ the Circuit Court for the District of Massachusetts had addressed double patenting in *Odiorne v. Amesbury Nail Factory*.²⁵¹ Here, the plaintiff had obtained two patents on machinery for cutting, griping and heading nails: one in 1807 and the other in 1810 for the “invention and improvements.”²⁵² Supreme Court Justice Story, sitting as a Circuit Justice, said, “[i]t

²⁴⁷ *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894) (emphasis added).

²⁴⁸ Professors Merges and Duffy point out that under the Patent Act of 1952, if two different individuals applied for the same patent, that would be addressed by an interference and determination of priority under § 102(g). Merges, *supra* note 6, at 1145.

²⁴⁹ See CHISUM, *supra* note 77, at vol. 3A, § 9.02[6], pp. 9-9 to 9-10 (“Miller . . . is the leading Supreme Court case on double patenting.”). See *infra* notes 271–303 and accompanying text discussing *Miller*.

²⁵⁰ *Supra* notes 134–45 and accompanying text.

²⁵¹ *Odiorne v. Amesbury Nail Factory*, 18 F. Cas. 578, 2 Mason 28 (Cir. Ct. D. Mass. 1819).

²⁵² *Id.* at 578. Both were issued to Jesse Reed. *Id.* At the time, § 1 of the patent statute provided that a “citizen or citizens of the United States” could be eligible to receive a patent for an invention if “he or they have invented any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter, not known or used before the application.” CHISUM, *supra* note 77, at vol. 9, app. 10-1. There was no separate section expressly discussing or defining what constituted prior art. *Id.* at app. 10-1 to 10-5.

cannot be, that a patentee can have in use at the same time two valid patents for the same invention; and if he can successively take out at different times new patents for the same invention, he may perpetuate his exclusive right during a century.”²⁵³ He added that a different result “would completely destroy the whole consideration derived by the public for the grant of the patent, viz. the right to use the invention at the expiration of the term specified in the original grant.”²⁵⁴ He concluded that the first patent “is an estoppel to any future patent for the same invention.”²⁵⁵

¶81 By the time of *James v. Campbell* in 1881,²⁵⁶ patent applications included claims,²⁵⁷ but the Supreme Court looked beyond the claims to the specifications for the patents, which involved implements for postmarking letters.²⁵⁸ The original patent was issued in 1863,²⁵⁹ but that was surrendered and reissued in 1864, 1869 and 1870,²⁶⁰ with additional matter added in the process.²⁶¹ After discussing the drawings and other parts of the specifications,²⁶² the Court stated the general principle that “the patentee could not include in a subsequent patent any invention embraced or described in a prior one granted to himself, any more than he could an invention embraced or described in a prior patent granted to a third person.”²⁶³

¶82 In 1891, as the Supreme Court had in *James*, the Supreme Court in *McCreary v. Pennsylvania Canal Co.*²⁶⁴ also looked beyond the claims to the rest of the specification to compare the inventions.²⁶⁵ *McCreary* involved two patents—one issued to John McCreary²⁶⁶ and the other to Elijah and John McCreary²⁶⁷—that involved improvements

²⁵³ *Id.* at 579. Quoting from *Odiorne* and closely following its language, the Federal Circuit in *Gilead Sci., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014) restated the principle as follows: “‘It cannot be’ that a patentee can obtain two patents in sequence ‘substantially for the same invention [] and improvements’; ‘it would completely destroy the whole consideration derived by the public for the grant of the patent, viz., the right to use the invention at the expiration of the term.’” *Id.* at 1212.

²⁵⁴ *Odiorne*, 18 F. Cas. at 579.

²⁵⁵ *Id.*

²⁵⁶ *James v. Campbell*, 104 U.S. 356 (1881).

²⁵⁷ *Supra* notes 138–45 and accompanying text.

²⁵⁸ *James*, 104 U.S. at 357.

²⁵⁹ *Id.* at 359.

²⁶⁰ *Id.* at 357, 371. The Supreme Court first approved the practice of reissuing defective patents in 1832, and that practice was codified in the Patent Act of 1836. Mueller, *supra* note 3, at 405. See 35 U.S.C. §§ 251–252 for current provisions for the reissuance of patents.

²⁶¹ *James*, 104 U.S. at 375–76 (“Another new matter . . . is the making of the blotter of cast iron, steel or other suitable material. The original specification . . . excludes such material. . . . the patentee has added two new diagrams to his drawings.”)

²⁶² *Id.* at 360, 375, 376, 379.

²⁶³ *Id.* at 382. The Court concluded: the claims with the additional matter were void. *Id.* at 375. The broad claims were void as anticipated by inventions patented in England and the United States. *Id.* at 378–79. The broad claims were void because the defendant did not use the specific device covered by the remaining claim of the second patent. *Id.* at 383.

²⁶⁴ *McCreary v. Pa. Canal Co.*, 141 U.S. 459 (1891).

²⁶⁵ The Court was quoting from the third paragraph of the specification of U.S. Patent No. 129,844 when it said, “[i]n patent numbered 129,844 the patentee stated that his improvement upon the prior patent consisted ‘in substituting for the projecting cut-water and notch, described in said patent for centering the boats together and forming a universal joint, a chain attached at both ends to one boat, and at its center to a central point on the adjacent end of the other boat,’ etc.” 141 U.S. at 462.

²⁶⁶ *See* U.S. Patent No. 129,844.

²⁶⁷ *See* U.S. Patent No. 125,684.

in steering devices for canal boats.²⁶⁸ The Court noted that the “combination of the earlier patent . . . is substantially contained in the later” and said that “if it be identical with it, or only a colorable variation from it, the second patent would be void, as a patentee cannot take out two patents for the same invention.”²⁶⁹

¶83

In 1894, the Supreme Court gave its most detailed discussion of the prohibition against double patenting - one inventor obtaining two patents covering similar structures, but with modifications of a spring - in *Miller v. Eagle Mfg. Co.*²⁷⁰ In *Miller* there were two patents derived from the same initial patent application²⁷¹ for improvements in “wheeled cultivators,” and defendants claimed that “the invention shown in each of the patents in suit is identical.”²⁷² However, the 1879 patent had 12 claims,²⁷³ and those claims differed from the 5 claims of the 1881 patent.²⁷⁴ Although the two sheets of drawings for both patents in the specifications seemed to be the same,²⁷⁵ the 1879 patent specification said the invention “consists in a spring which serves the double purpose of lifting or holding down the plows at will; and it is further stated that one spring may be adapted to serve all, or either one or more, of the offices above enumerated.”²⁷⁶ On the other hand, the specification of the 1881 patent described a narrower scope for the 1881 patent, describing “the same invention or device covered by the patent of December 16, 1879, [but] attempts to limit the invention and patent to the lifting operation of the springs, increasing as the beams are raised.”²⁷⁷

²⁶⁸ *Id.* at 461–62. However, the plaintiffs did not assert John McCreary’s earlier patent in the infringement suit. *Id.*

²⁶⁹ *Id.* at 467 (emphasis added). The master found that McCreary was limited to such profits as arose from the use of the improvement identified in the second patent. *Id.* at 463. Since no damages were proved for the improvement covered by the second patent, the Supreme Court affirmed the finding of the master. *Id.* at 467–68.

²⁷⁰ 151 U.S. 186 (1894). See also CHISUM, *supra* note 77, at vol. 3A, § 9.02[6], pp. 9-9 to 9-10.

²⁷¹ *Id.* at vol. 3A, § 9.02[6], p. 9-10 (“Because of an interference with another application, Wright divided his application. The first patent (#222,767) issued on December 16, 1879, for the double action claim. After disposition of the interference, the second patent (#242,497) issued on June 7, 1881.”).

²⁷² *Miller*, 151 U.S. at 187.

²⁷³ U.S. Patent No. 222,767, pp. 2–3.

²⁷⁴ U.S. Patent No. 242,497, p. 3.

²⁷⁵ Sheets 1 and 2 of U.S. Patent No. 222,767 and U.S. Patent No. 242,497.

²⁷⁶ *Miller*, 151 U.S. at 200.

²⁷⁷ *Id.* at 193. Chisum refers to the later ’497 patent as a “generic device. . . (i.e., a spring that provides no lifting force when in the operative position but lifting force when raised).” CHISUM, *supra* note 77, at vol. 3A, § 9.02[6], p. 9-11. However, claims 1–3 of the earlier ’767 patent and the third paragraph of the specification for the ’767 patent made clear it applied where one or both functions were involved, as a result of adapting springs on the cultivator (genus patent): “In carrying out my invention the one spring may be adapted to serve all or either one or more of the offices above enumerated [downward force and lifting] and may be modified in its form, construction, and arrangement, as desired, provided its mode of action is retained.” On the other hand, all the claims of the later ’497 patent showed a single lifting function with adapted springs. See ’497 patent claims 1-5. See also ’497 patent p. 1, ll. 20-24 (“To this end the invention consists in applying lifting-springs in such manner that they exert upon the beams a maximum power or strain when the latter are above an operative position.”). The Court in *Miller* quoted the third paragraph of the specification from the ’767 patent (*Id.* at 188-189), so regardless of whether today a court would give the specifications less weight and treat the second claim as generic relative to the first under *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), the Supreme Court in *Miller* did not treat the subsequent ’497 patent claims as generic. If it had, it could have easily rejected the second patent as invalid under its statement that a “second patent, although containing a broader claim, more general [sic] in its

¶84 The Supreme Court in *Miller* then summarized its view of existing case law, such as *Odiorne, James* and *McCreary*.²⁷⁸ The Court said that “no patent can issue for [1] an *invention actually covered by a former patent*, [2] *especially to the same patentee*, [3] although the *terms of the claims may differ*.”²⁷⁹ The third quoted phrase, “terms of the claims may differ,” suggests that in determining whether the same invention is involved, courts must look at the embodiments of the inventions disclosed in the specifications and not simply what the draftsman claimed to be the invention.²⁸⁰ Although one might argue that this statement could refer to the use of different words in two claims that meant the same thing (e.g., twelve inches vs. a foot), the specifications showed the springs in the two cultivators were adapted to perform different functions.²⁸¹ In other words, this was not a situation where the claims used different words to mean the same thing but a situation where the claims used different words and the specifications showed the springs differed.

¶85 The second quoted phrase, “especially to the same patentee,” suggests that a patent for an improvement to a third party could be treated differently than a patent to the First Inventor for an improvement within the scope of the First Patent.²⁸² While a different party could have a blocking patent for the Improvement, the First Inventor would not be allowed to obtain such a Follow-On Patent because he already had received his reward for the genus that included the species subsequently claimed.²⁸³

¶86 The first quoted phrase, “covered by a former patent,” appears to refer to any invention within the scope of the claims of the first patent. That statement should preclude granting a patent for a species within the scope of the genus to the same inventor, because the genus would have covered and given the exclusive right to make and sell that species to the First Inventor.²⁸⁴ Indeed although *Morse* was not decided on double patenting, the dicta that *Morse* “could not take out a subsequent patent for a portion of his first invention, and thereby extend his monopoly beyond the period limited by law”²⁸⁵ is consistent with the principle stated in *Miller* 40 years later.

¶87 The Court in *Miller* also said that a “second patent, although containing a broader claim, more general in its character than the specific claims, contained in the prior

character, than the specific claims, contained in the prior patent, is also void.” *Miller*, 151 U.S. at 198. It did not reject the second patent under the principle that a species of a genus anticipates a subsequent and broader genus. Thus, it seems the Court considered the ’497 patent narrower in scope than the earlier ’767 patent.

²⁷⁸ *Id.* at 198.

²⁷⁹ *Id.* at 198 (emphasis added).

²⁸⁰ The Supreme Court has expressed concern about not allowing attorneys to maneuver around patent principles with clever drafting. *See supra* note 33.

²⁸¹ *See* ’497 patent para. 3 and ’767 patent para. 3.

²⁸² Indeed, the Court observed, “If the two patents in question had been granted to different parties, it admits of no question that the last would have been held an infringement of the first.” *Miller*, 151 U.S. at 200.

²⁸³ *See supra* notes 83–85 and accompanying text for Professor Duffy’s suggestion that there are policy reasons for treating improvements by First Inventors differently than improvements by third parties.

²⁸⁴ *Supra* note 3.

²⁸⁵ *O’Reilly v. Morse*, 56 U.S. 62, 114 (1864).

patent, is also void.”²⁸⁶ This is a reflection of the now recognized principle – at least when the earlier patent is prior art - that a species anticipates a genus.²⁸⁷

¶88 In addition, the Court in *Miller* discussed the situation “where the second patent covers matter described in the prior patent, essentially distinct and separable from the invention covered thereby. . . .”²⁸⁸ The Court explained, “A single invention may include both the machine and the manufacture it creates; and in such cases, if the inventions are really separable, the inventor may be entitled to a monopoly of each.”²⁸⁹ In other words, if an inventor creates a new and useful machine²⁹⁰ that produces a new and useful widget, she could patent both the machine and the widget the machine produced. The Court in *Miller* continued that in order for the second patent to be upheld in that situation, “it must distinctly appear that the invention covered by the later patent was a separate invention, distinctly different and independent from that covered by the first patent.”²⁹¹

¶89 Although the Court did not directly explain the meaning of “distinctly different and independent,” it added that the improvement “must consist in something more than a mere distinction of the breadth or scope of the claims of each patent.”²⁹² A species within the scope of a genus is only different in breadth and scope from the genus claim.²⁹³ Therefore, the statement that a mere distinction of the breadth or scope of the claims – as well as the earlier statement in *Miller* “covered by a former patent”²⁹⁴ – should eliminate granting a species patent within the scope of a genus patent to the inventor who had already patented the genus.

¶90 The Supreme Court agreed that an inventor could make an improvement on his own invention and obtain a patent “where the invention is clearly distinct from, and independent of, one previously patented.”²⁹⁵ However, the Court concluded there was no distinct difference between the inventions in *Miller*, since the “matter sought to be covered by the second patent” was “inseparably involved in the matter embraced in the former patent.”²⁹⁶ This is consistent with rejecting a patent application by an inventor for a species after that inventor obtained a genus patent that covered the species, since the species patent would be “inseparably involved in the matter embraced in the former

²⁸⁶ *Miller*, 151 U.S. at 198.

²⁸⁷ Mueller, *supra* note 3, at 177 (“A heuristic to keep in mind for anticipation in the species/genus context is that species anticipates genus, but genus does not necessarily anticipate species.”).

²⁸⁸ *Miller*, 151 U.S. at 198.

²⁸⁹ *Miller*, 151 U.S. at 199. See also ERNEST BAINBRIDGE LIPSCOMB III, PATENT CLAIMS § 20:6, pt. 3, ch. 20 (3d ed. 2015) (discussing *Miller* and stating, “An apparatus and a product made by the apparatus are distinct inventions if it can be shown that the apparatus as claimed is not an obvious apparatus for making the product, and the apparatus as claimed can be used to make another materially different product, or that the product as claimed can be made by another materially different apparatus,” citing MPEP § 806.05(g)(9th ed.)).

²⁹⁰ At the time of *Miller*, there was no non-obviousness requirement. Congress passed that requirement in 1952. Mueller, *supra* note 3, at 276.

²⁹¹ *Miller*, 151 U.S. at 198 (emphasis added).

²⁹² *Id.*

²⁹³ A species within a genus has an additional limitation, but by the definition of a genus, the species, even with the additional limitation, is within the scope of the genus claim. Mueller, *supra* note 3.

²⁹⁴ *Supra* notes 280 and 285 and accompanying text.

²⁹⁵ *Miller*, 151 U.S. at 199.

²⁹⁶ *Id.* at 200.

patent.”²⁹⁷ On the other hand, if a subsequent patent claim by the First Inventor was not within the scope of the First Invention, that patent claim should issue,²⁹⁸ because the patent he had already received had not covered the subsequent invention.

¶91 The Supreme Court in *Miller* explained “It certainly did not involve patentable novelty to drop or omit from the patent a claim for the depressing action of the spring arrangement which might be effected by any mere mechanical contrivance.”²⁹⁹ The Court continued that “a patentee cannot so split up his invention for the purpose of securing additional results, or of extending or of prolonging the life of any or all of its elemental parts.”³⁰⁰ The Court held that the second patent was void.³⁰¹

¶92 The Supreme Court in *Miller* did not discuss or even identify the statutory basis for the prohibition on double patenting. This is not surprising, since Professor Menell has observed that “the most influential patent jurists [of the nineteenth century] . . . operated in a less formal, common-law-oriented mode. . . . they did not typically tie their interpretation strictly to statutory text . . . they evolved patent law into a workable, dynamic system.”³⁰² As discussed next, however, the Federal Circuit has identified a statutory basis for double patenting and constructed a complicated set of rules Supreme Court in *Miller*.

B. Double Patenting in the Federal Circuit

1. Introduction

¶93 As set forth above in IIC, a person inventing a new and useful composition of matter has a right to a patent for that composition, assuming the other criteria for patentability are satisfied. A person does not have the right to a patent, however, if that patent claim exceeds the scope of the embodiments disclosed in the specification. The embodiments are key. Moreover, “patented invention” in § 271(a) refers to any composition satisfying the elements of a genus patent claim, even though many of those compositions would fit within the definition of a narrower genus (e.g., a widget of A+B+C+D and a widget of A+B+C would be a patented invention of and would infringe a patent for a widget comprising A+B).

¶94 Yet in a confusing and inconsistent string of cases discussed in this IVB, the Federal Circuit has focused on the boundaries of the claims rather than the embodiments the claims cover. This allows skillful drafters to extend the exclusive rights under patent law by first claiming the world and subsequently claiming a smaller part of the world. The Federal Circuit’s decisions are inconsistent with the principle announced in *Miller* and *Morse* and with some earlier decisions of the CCPA and the Fourth and Seventh Circuits before the creation of the Federal Circuit, discussed below.

²⁹⁷ *Id.* at 200.

²⁹⁸ Assuming the other criteria for a patent were satisfied.

²⁹⁹ *Id.* Chisum says that this reason for the holding in *Miller* “is sounder on the facts.” CHISUM, *supra* note 77 at vol. 3A, § 9.02[6], p. 9-11.

³⁰⁰ *Miller*, 151 U.S. at 201.

³⁰¹ *Id.* at 200.

³⁰² Peter S. Menell, *Forty Years of Wandering in the Wilderness*, 63 STAN. L. REV. 1289, 1308–09 (2011).

¶95 The Federal Circuit has labeled as “double patenting”³⁰³ its version of the *Miller* principle that “no patent can issue for an invention actually covered by a former patent, especially to the same inventor.”³⁰⁴ The Federal Circuit explained, “If an inventor could obtain several sequential patents on the same invention, he could retain for himself the exclusive right to exclude . . . far beyond the term awarded to him under the patent laws,” and concluded that the “doctrine of double patenting was primarily designed to prevent such harm by limiting a patentee to one patent term per invention or improvement.”³⁰⁵

¶96 The Federal Circuit has identified two “types” of double patenting: “same invention type double patenting” and “obviousness type double patenting,”³⁰⁶ also sometimes known, respectively, as statutory double patenting and nonstatutory double patenting.³⁰⁷ The appellate courts and scholars have concluded that the basis for the same invention type double patenting prohibition is §101, since it provides that “whoever invents” a product meeting the requirements for a patent may obtain “a patent” (interpreted to mean one patent) for her invention.³⁰⁸ However, another statutory basis is the word “new” in §101: “Whoever invents or discovers any *new* and useful process, machine, manufacture, or composition of matter”³⁰⁹ If a patent application asks for a patent on a composition of matter set forth in an earlier patent, the composition of matter in the second patent application would not be “new” under the commonly understood meaning of “new,” so should not qualify for a patent under § 101.³¹⁰

¶97 Somewhat more obliquely, courts have referred to obviousness-type double patenting as a “judicially created doctrine.”³¹¹ Recently, however, the Federal Circuit said that “obviousness type double patenting is grounded in the text of the Patent Act,” referring to § 101.³¹² Also, as discussed below,³¹³ as a result of the passage of the AIA,

³⁰³ *Gilead Sci., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1212 (Fed. Cir. 2014) (citing *Miller*).

³⁰⁴ *Miller*, 151 U.S. at 198.

³⁰⁵ *Gilead Sci., Inc.*, 753 F.3d at 1212.

³⁰⁶ *In re Longi*, 759 F.2d 887, 892–93 (Fed. Cir. 1985).

³⁰⁷ *Mueller*, *supra* note 3, at 72.

³⁰⁸ *In re Vogel*, 422 F.2d 438, 441 (C.C.P.A. 1970) (“35 U.S.C. § 101 prevents two patents from issuing on the same invention”); *Merges*, *supra* note 6, at 1145; *Mueller*, *supra* note 3, at 72.

³⁰⁹ 35 U.S.C. § 101 (emphasis added).

³¹⁰ Merriam-Webster defines “new” as “having recently come into existence.” *New*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/new> (last visited Oct. 9, 2015). There has been growing recognition by the courts that “new” in § 101 means what it says and is not a historical relic or identical to novelty in § 102. In *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), the Supreme Court rejected the argument that newness could be disregarded when evaluating patentable subject matter under § 101 and acknowledged that “the § 101 patent-eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap.” *Id.* at 1304. In *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), involving Myriad’s patent claim for isolated DNA and cDNA segments, the Supreme Court said the issue was whether “Myriad’s patents claim any ‘new and useful . . . composition of matter’ under § 101 or instead claimed naturally occurring phenomena.” *Id.* at 2116. In *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343 (Fed. Cir. 2015), the Federal Circuit recognized that “pragmatic analysis of § 101 is facilitated by considerations analogous to those of §§ 102 and 103 as applied to the particular case.” *Id.* at 1347. See also Rebecca Eisenberg, *Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After In re Bilski*, 3 CASE W. RESERVE J.L. TECH. & INTERNET 1, 54–55 (2012).

³¹¹ *Eli Lilly & Co. v. Barr Labs, Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001).

³¹² *AbbVie Inc. v. Mathilda and Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1372 (Fed. Cir. 2014).

³¹³ *Infra*, notes 345–52 and accompanying text.

there is now a more clear statutory basis for obviousness type double patenting, since § 3(b)(2) of the AIA incorporates by reference the intent of Congress in the CREATE Act that the double patenting prohibition should apply when there is no prior art.

2. Significance of “prior art” for double patenting

¶98

When analyzing double patenting, it is necessary to discuss briefly the technical nature of “prior art,” since the Federal Circuit has said that “‘double patenting’ is normally applied as a ground of rejection when the patent used to support the double patenting rejection is not available as a reference to show ‘prior art’ under 35 U.S.C. § 102 or 103.”³¹⁴ Of course, a person cannot obtain a patent for an invention unless it is novel within the meaning of 35 U.S.C. § 102 (pre-AIA),³¹⁵ and for an invention to lack novelty—to be anticipated—there must be “a single prior art disclosure of all elements of the claimed invention,”³¹⁶ either expressly or inherently.³¹⁷ Novelty, however, “does not mean that the invention has not previously existed in an absolute sense. Rather, it means that the invention, as claimed, does not fall within—is not anticipated by—one of the seven categories of prior art defined by Congress in 35 U.S.C. Section 102.”³¹⁸ Section 102(a) pre-AIA provides that in order for a prior art reference—such as a printed publication—to be “prior” art, it must have existed “before the invention.”³¹⁹

³¹⁴ *In re Land*, 368 F.2d 866, 868 (C.C.P.A. 1966). Professor Crouch has said that an obviousness-type double patenting is only relevant when a prior patent cannot be considered prior art as defined by Sections 102 and 103(a) of the Patent Act. Dennis Crouch, *Obviousness-Type Double Patenting and Splitting Ownership (CAFC Says Don't Do It)*, PATENTLY-O (May 8, 2009), <http://patentlyo.com/patent/2009/05/obviousness-type-double-patenting-and-splitting-ownership-cafc-says-dont-do-it.html>[<https://perma.cc/RS5D-YWQX>]. In certain cases, however, in which the Federal Circuit looked at the specification of the earlier patent to determine whether there was double patenting, the courts effectively treated the earlier patent specification as prior art. See *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1385–86 (Fed. Cir. 2003) (“a claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use.”); *Sun Pharm. Ind., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1389 (Fed. Cir. 2010) (affirming a finding of double patenting when “an earlier patent claims a compound, disclosing the utility of that compound in the specification, and a later patent claims a method of using that compound for a particular use described in the specification of the earlier patent.”); *Takeda Pharm. Co., Ltd. v. Doll*, 561 F.3d 1372, 1378 (Fed. Cir. 2009) (“On remand, the district court should determine whether these processes were disclosed before January 8, 1990, the date of filing of the ‘216 process patent.”). In *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1286, 1297 (Fed. Cir. 2012), the earlier genus patent was prior art for the subsequent species patent, which the Federal Circuit analyzed for double patenting. The Federal Circuit said “[T]he patent principally underlying the double patenting rejection need not be prior art.” *Id.* at 1297. This article does not address these apparent inconsistencies.

³¹⁵ Lisa A. Dolak & Michael L. Goldman, *Responding to Prior Art Rejections – An Analytical Framework*, 83 PAT. & TRADEMARK OFF. SOC’Y 5 (2001); Kirk M. Hartung, *‘Prior Art’: The Undefined Key to Section 103 of the 1952 Patent Act*, 32 DRAKE L. REV. 703, 704–05 (1952).

³¹⁶ *Structural Rubber Prod. Co. v. Park Rubber Co.*, 749 F.2d 707, 715 (Fed. Cir. 1984).

³¹⁷ *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999).

³¹⁸ Dolak, *supra* note 316, at 5 (discussing pre-AIA § 102).

³¹⁹ 35 U.S.C. § 102(a) (pre-AIA) (“A person shall not be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent . . .”). As discussed below in Part V, the AIA changes both what constitutes an art reference and when an art reference is prior art.

¶99 Even though patents are expressly mentioned in § 102(a) pre-AIA as a category of prior art, there are a number of situations in which an earlier patent might not constitute “prior art” to a pending patent application, particularly when the applicant for the second patent is the same person as the holder of the earlier patent.³²⁰ After all, it would be impossible for an inventor to disclose her invention (in a printed publication or anywhere) “before the invention” as required in § 102(a) (pre-AIA).³²¹ Professors Merges and Duffy wrote that “only a third party can create novelty problems under § 102(a), whereas anyone—including the inventor . . . —can create prior art that serves as a statutory bar under 1952 Act §102(b),”³²² which only requires public disclosure or use more than a year before the patent application. The predecessor court to the Federal Circuit, the Court of Customs and Patent Appeals (CCPA), said, “Absent a statutory bar under 35 U.S.C. § 102(b), (c), or (d), applicant’s own invention cannot be ‘prior art’ to him.”³²³

¶100 In short, pre AIA there are art references in existence that may not constitute prior art. The double patenting doctrine fills a potential gap in preventing persons from circumventing the technicalities of prior art and obtaining two patents on the same invention.³²⁴

3. What person must hold the patents

¶101 In *Otsuka Pharmaceutical Co. Ltd. v. Sandoz, Inc.*,³²⁵ the Federal Circuit said, “The double patenting doctrine ‘precludes *one person* from obtaining more than one valid patent for either (a) the ‘same invention,’ or (b) an ‘obvious’ modification of the same invention.”³²⁶ The language in *Otsuka* - “one person from obtaining” - and the language in both pre-AIA and AIA §101 - “Whoever invents . . . is entitled to a patent” - indicate that the inventor of both patents should be the same. Indeed, under §102(pre-AIA), Professor Merges explains, “If the second application were filed by a different inventor, .

³²⁰ The AIA changed the timing for judging whether an art reference was “prior” from “before the invention” in § 102(a) (pre-AIA) to “before the effective filing date of the claimed invention” in § 102(a)(1) and (2) (post-AIA). As a result, certain disclosures by the inventor which might not be prior art pre-AIA can be prior art post-AIA. This article discusses the significance of that change in Part V.

³²¹ Other categories of prior art in § 102(pre-AIA) similarly refer to “before the invention by the applicant for patent” and “before such invention.” See § 102(e)(pre-AIA) and § 102(g) (pre-AIA).

³²² Merges, *supra* note 6, at 341, n.2.

³²³ *In re Fout*, 675 F.2d 297, 300, n.2 (C.C.P.A. 1982). The court added, “However, applications having the same inventor and claiming the same invention are subject to rejection for double patenting. In contrast, if the inventors are different, no such rejection can be made; rather, an interference is in order.” *Id.* Under § 102(b), an inventor loses her right to a patent if her invention was in “public use” or “on sale” in this country for more than one year prior to the patent application. Under § 102(c), an inventor loses her right to an invention if she has abandoned her invention. Under AIA § 102(d), an inventor loses her right to a patent if “the invention was patented or caused to be patented, or was the subject of an inventor’s certificate, by the applicant . . . in a foreign country . . . filed more than twelve months before the filing of the application in the United States.”

³²⁴ Crouch, *Splitting Ownership*, *supra* note 315.

³²⁵ *Otsuka Pharm. Co. Ltd. v. Sandoz, Inc.*, 678 F.3d 1280 (Fed. Cir. 2012).

³²⁶ *Id.* at 1297 (Fed. Cir. 2012) (quoting *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985)).

. . . The PTO would declare an interference and then apply the priority rules in §102(g) to determine which inventor was entitled to the patent.³²⁷

¶102 The principle of one individual inventor³²⁸ obtaining only one patent for the same invention does not address in what circumstances double patenting may arise when there are joint inventors. The prevailing view is that double patenting can exist when there is one common individual inventor among the inventors listed in the two patents.³²⁹ First of all, in *Miller*, although it was not necessarily talking about joint inventors, the Supreme Court said that “no patent can issue for an invention actually covered by a former patent, especially to the same patentee,”³³⁰ which suggests that double patenting might be present when the patentees are not the same.³³¹ In *In re Hubbell*,³³² the Federal Circuit expressly found double patenting applicable when there were multiple inventors for both patents and only one common inventor for the two patents.³³³ As reflected in the next section, however, there are some decisions seemingly in tension with *Hubbell*.³³⁴

¶103 The more significant practical question for pharmaceutical companies may be what happens when the individual employees are the inventors, and the company is the assignee for either both patents or the patent and patent application.³³⁵ Professor Merces and Duffy say that under the CREATE Act,³³⁶ discussed below, obviousness type double patenting “can arise where the two patents have different inventors but the same

³²⁷ Merces, *supra* note 6, at 1145.

³²⁸ The inventor is the individual “who has exerted the creative mental effort in the act of invention.” 3 MOY’S WALKER ON PATENTS § 10:13 (4th ed. 2013).

³²⁹ 35 U.S.C. § 116(a) provides, “When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.”

³³⁰ *Miller v. Eagle Mfg. Co.*, 151 U.S. 198 (1894) (emphasis added).

³³¹ *Id.*; *supra* notes 283–84 and accompanying text.

³³² *In re Hubbell*, 709 F.3d 1140 (Fed. Cir. 2013).

³³³ *Id.* at 1147 (“Based on the foregoing, although Hubbell argues that we should create a specific exception barring application of obviousness-type double patenting in instances where the conflicting claims share only common inventors, rather than common ownership, we see no valid basis for doing so.”). MPEP § 804¶I.A now provides, “Double patenting may exist between an issued patent and an application filed by the same inventive entity, a different inventive entity having a common inventor, a common applicant, . . .,” citing *Hubbell*.

³³⁴ See, e.g., *In re Sarett*, 327 F.2d 1005, 1016 (C.C.P.A. 1964); *In re Kaplan*, 789 F.2d 1574 (Fed. Cir. 1986); *infra* notes 365–72 and 423–28 and accompanying text.

³³⁵ Professor Merces has explained that this is a typical situation, with the employees having initial rights to the patents, but with contractual obligations to assign such patents to the employer. See Robert P. Merces, *The Law and Economics of Employee Inventions*, 13 HARV. J.L. & TECH. 1, 5–10 (1999).

³³⁶ See H.R. REP. NO. 108-425, at 5–6 (2004) (“Congress intends that subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of title 35, and a claimed invention shall be deemed to be owned by the same person, or subject to an obligation of assignment to the same person where specific conditions are satisfied. The Act achieves this by eliminating the use of certain information and prior art in obviousness determinations in the circumstances addressed in the legislation. . . . The doctrine of ‘obviousness-type double patenting,’ a judicial doctrine used by courts to prevent patentees from obtaining an unjustifiable extension of the amount of time to exercise a patent’s right to exclude, shall apply to such patents. . . . Congress intends that parties who seek to benefit from this Act to waive the right to enforce any patent separately from any earlier patent that would otherwise have formed the basis for an obviousness-type double patenting rejection.”).

assignee.”³³⁷ They explained that “while § 103(c) [pre-AIA] allows a firm to obtain patents on obvious variations created by different researchers, the courts have still invoked the double patenting rule to ensure that the two patent terms expire simultaneously.”³³⁸ They added that as a result, the “double patenting doctrine is growing more important to large research corporations.”³³⁹

¶104 There have been four iterations of what initially was 35 U.S.C. § 103(c) (pre-AIA). The first of these four iterations was a response to a 1973 decision of the CCPA that an earlier invention by an employee that only satisfied § 102(g) (pre-AIA)³⁴⁰ in interference proceedings could also be cited as prior art to invalidate as obvious the patent claim of a subsequent invention made by a different employee of the same company.³⁴¹ As a result, in 1984 Congress amended § 103(c) (pre-AIA) and “effectively gave corporations the right to patents on obvious variants of in-house efforts qualifying as prior invention under 35 U.S.C. 102(f) or (g)” (pre-AIA).³⁴² In the second iteration, as part of the American Inventors Protection Act of 1999, § 103(c) (pre-AIA) “was further modified to include commonly owned prior art under 102(e) (pre-AIA) . . . (i.e., disclosures in earlier-filed patents or published patent applications of ‘another’) in the list of categories of prior art that ‘shall not preclude patentability’ under § 103” (pre-AIA).³⁴³

¶105 In the third iteration of § 103(c) (pre-AIA), Congress passed the CREATE Act, which excluded from the obviousness determination information generated by parties to a joint research agreement involving the inventor only if it qualified as prior art under §§ 102(e) (pre-AIA) (information disclosed in earlier-filed published patent applications of “another” person as of the date of the application), 102(f) (information derived from another) and 102(g) (pre-AIA) (private inventive activity of another).³⁴⁴The House

³³⁷ *Merges*, *supra* note 6, at 1145. The question of how to treat two patents with different inventors but the same assignee is not a new issue. See John F. Witherspoon, *So-Called Common Assignee Double Patenting – an Issue in Search for a Home*, 4 APLA Q. J. 329, 349 (1976) (“Co-assigned different inventor entity cases, particularly where joint activity of co-workers is involved, present a unique problem requiring special attention. . . . Legislative response to this increasingly complex problem is an idea whose time has come.”). Thanks to Charles L. Gholz for pointing out this article.

³³⁸ *Merges & Duffy*, *supra* note 6, at 1146.

³³⁹ *Id.*

³⁴⁰ In *In re Bass*, 474 F.2d 1276, 1289 (C.C.P.A. 1973), the CCPA interpreted § 102(g) to mean “the use of the prior invention of another who had not abandoned, suppressed, or concealed it under the circumstances of this case which include the disclosure of such invention in an issued patent, is available as ‘prior art’ within the meaning of that term in § 103 by virtue of § 102(g).” Section 102(g) applied to a patent application when there had been prior non-public use in the United States by another party of the same invention as the claimed in the patent application. *Nard*, *supra* note 43, at 290–91. The AIA eliminated § 102(g) and substituted a provision for prior user rights in post-AIA § 273. *Id.* at 297–99.

³⁴¹ See also *Mueller*, *supra* note 3, at 287.

³⁴² *Id.* at 290. Section 102(f) represented the “central principle” that a person cannot simply copy someone else’s invention and obtain a patent for it. The AIA eliminated § 102(f), but not that central principle. *Id.* at 219. The 1984 amendment added the following language to § 103: “Subject matter developed by another person, which qualifies as prior art only under subsections (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.” *Id.* at 289.

³⁴³ *Id.* at 290. The AIPA provided in § 4807(a), “Section 103(c) of title 35, United States Code, is amended by striking ‘subsection (f) or (g)’ and inserting ‘one or more of subsections (e), (f) and (g).’” See Pub. L. No. 106-113, 113 Stat. 1501 (1999)

³⁴⁴ See H.R. REP. NO. 108-425, *supra* note 337, at 5. As a result of the CREATE Act, § 103(c)(1)

Report accompanying the CREATE Act explained Congress intended that the courts apply the double patenting prohibition in place of consideration of such disclosures in determining obviousness.³⁴⁵ That Report also said, “Congress intends that parties who seek to benefit from this Act to waive the right to enforce any patent separately from any earlier patent that would otherwise have formed the basis for an obviousness-type double patenting rejection.”³⁴⁶

¶106 In the fourth iteration of § 103(c), as part of the AIA, Congress moved what had been § 103(c) (pre-AIA) to § 102(b)(2)(C) (post-AIA), so what had been only a limitation on what a court could consider for purposes of determining obviousness also became a limitation on what references a court could consider in determining both novelty and obviousness.³⁴⁷ Section 102(b)(2) (post-AIA) provides that a disclosure shall not be considered prior art if “(C) the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.”³⁴⁸ In addition, § 102(c) (post-AIA) provides that § 102(b)(2) (post-AIA) is satisfied if: “(1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention; (2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and (3) the application to patent the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.”³⁴⁹ As a result, parties can “enter into joint-research agreements in order to exclude previous patent disclosures as prior art, even after they have developed the second invention, as long as no patent application has yet been filed for the second invention.”³⁵⁰

¶107 Significantly, the AIA also effectively gave the force of law to the CREATE Act legislative history on double patenting through an uncodified part of the AIA.³⁵¹ Specifically, AIA § 3(b)(2) provides, “The enactment of section 102(c) of title 35, United States Code, under paragraph (1) of this subsection is done with the same intent to promote joint research activities that was expressed, including in the legislative history,

provided, “Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.” Pub. L. No. 108-453, 118 Stat. 3596 (2004).

³⁴⁵ H.R. REP. NO. 108-425, *supra* note 337, at 6. That Report cited four decisions of the CCPA and Federal Circuit as examples of double patenting, without any suggestion that these examples were the extent of the double patenting prohibition, and preceded the decisions with the phrase, “See, e.g.” *Id.* One of the decisions in that Report cited *Miller* as authority for the double patenting prohibition. *See In re Goodman*, 11 F.3d 1046, 1052 (Fed. Cir. 1993) (citing *Miller*).

³⁴⁶ H.R. REP. NO. 108-425, *supra* note 337, at 6.

³⁴⁷ Mueller, *supra* note 3, at 268–69; Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. B. J. 465, 487 (2012).

³⁴⁸ 35 U.S.C. § 102(b)(2)(C) (post-AIA); Mueller, *supra* note 3, at 269.

³⁴⁹ § 102(c) (post-AIA); Mueller, *supra* note 3, at 269; Matal, *supra* note 348, at 487.

³⁵⁰ Matal, *supra* note 348, at 487.

³⁵¹ *Id.* at 486; Pub. L. No. 112-29, 125 Stat. 284, § 3(b)(2) (2011). In light of the “transfer” of § 103(c) (pre-AIA) to § 102 (post-AIA) and its application to both obviousness and novelty, *see supra*, note 348, it is not clear why the same conclusion would not also apply to same invention double patenting.

through the enactment of the . . . ‘CREATE Act.’” AIA § 3(b)(2) further directs that the “United States Patent and Trademark Office shall administer section 102(c) of title 35, United States Code, in a manner consistent with the legislative history of the CREATE Act that was relevant to its administration by the United States Patent and Trademark Office.”³⁵²

¶108 Professor Crouch, before the adoption of the AIA, concluded that “an obviousness type double patenting rejection requires a link between the two applications—either in terms of inventorship or ownership.”³⁵³ Similarly, MPEP § 804.II.B provides that obviousness type double patenting can arise when the two patents or patent applications are commonly owned or subject to a joint research agreement. Of course, the determinations made on whether the same person is holding two patents can raise difficult questions (such as whether affiliated corporations are the same entity), and no legal standard is without grey areas.³⁵⁴

¶109 Where the Federal Circuit has significantly—and inconsistently—restricted the double patenting prohibition stated by the Supreme Court in *Miller*, it equates the invention with the boundary of the claims rather than considering all embodiments disclosed by the specification and claims.

4. Federal Circuit has eviscerated and ruled inconsistently on double patenting

¶110 The Federal Circuit has eviscerated the double patenting doctrine and ruled inconsistently with predecessor courts by determining the invention from the “boundary” of the claims rather than the embodiments disclosed by the specification and claims. In contrast, the Supreme Court cases in the 1800s compared the inventions described in the specifications, even after the practice of peripheral claiming had commenced.³⁵⁵

¶111 Due to the importance of the Patent Act of 1952, this article next reviews a number of appellate decisions since the Patent Act of 1952 and explains that there is no basis for concluding that the Patent Act of 1952 changed the meaning of the term “invention.” This review discloses that the Federal Circuit has disregarded not only *Miller* but some earlier appellate cases and improperly changed double patenting from (a) a principle under § 101 to prevent patent holders from extending exclusive rights over some of the same embodiments in successive patents into (b) only an alternate obviousness analysis

³⁵² America Invents Act 35 U.S.C. § 3(b)(2)

³⁵³ Crouch, *Splitting Ownership*, *supra* note 315. Section 102(c) (post AIA) provides: Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if: (1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention; (2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and (3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.”

³⁵⁴ See, for instance, the discussion of *Sarett* and *Kaplan*, *infra* at notes 365366–73 and 424–29 and accompanying text.

³⁵⁵ *Supra*, Part IVA, notes 248–302 and accompanying text.

under § 103 (pre-AIA) comparing the boundaries of the claims rather than the embodiments disclosed in the specifications.³⁵⁶

¶112 A few years after the adoption of the Patent Act of 1952, in *Weatherhead Co. v. Drillmaster Supply Co.*,³⁵⁷ the Seventh Circuit³⁵⁸ held that if a person received a genus patent and subsequently received a species patent within the scope of the patented genus, the second patent constituted prohibited double patenting.³⁵⁹ *Weatherhead* was an infringement suit involving two patents to the same inventor for metal packing rings/joints.³⁶⁰ The earlier issued,³⁶¹ more general ‘413 patent applied to “material sufficiently hard to shear said tube and [] sufficiently ductile to be radially contracted.”³⁶² The more specific claims in the subsequent ‘217 patent were for rings “made of low carbon steel which has been surface hardened by means of a potassium cyanide bath.”³⁶³ The Seventh Circuit found, “No one could manufacture the device claimed in ‘217 without infringing ‘413,” so held that “the appellants are guilty of double patenting and their second patent (No. 2,171,217) is invalid.”³⁶⁴ In other words, the Seventh Circuit held—consistent with the position taken in this article—that the ‘217 patent for a species within the scope of the earlier genus patent granted to the same inventor constituted improper double patenting.

¶113 In 1964, in contrast, the CCPA held there was no double patenting in *In re Sarett*,³⁶⁵ an often cited case involving a genus and subsequent species patent, which did not involve the same inventors. Related, but not identical parties filed on the same day

³⁵⁶ This article does not contest using § 101 as an alternate obviousness analysis under § 103 (either pre-AIA or post-AIA) when there is no prior art, but contends the double patenting prohibition is more than just a check on obviousness in those situations. The double patenting prohibition highlighted in different ways in *Morse*, *Miller*, and *Singer*, *supra* notes 1–2, 146–53, 271–302 and 25–27, is also a check on attempts by the inventor or his employer after the genus patent to gain longer exclusive rights over parts of the genus.

³⁵⁷ 227 F.2d 98 (7th Cir. 1955).

³⁵⁸ Prior to the creation of the Federal Circuit in 1982, the applicable federal regional circuit court of appeals heard appeals in patent infringement cases. In 1982, all appeals from patent cases were consolidated in the newly created Federal Circuit. Mueller, *supra* note 3, at 40, 47–48.

³⁵⁹ 227 F.2d at 102.

³⁶⁰ *Id.* at 99–100. Apparently the earlier issued patent was not considered prior art because the two patents were by the same inventor, Kreidel, and the applications leading to the patents had been copending for some period of time. *Id.* There are seemingly inconsistent decisions on the effect of copending applications by the same inventor. *Compare* *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1277 (Fed. Cir. 1992) (“Neither is statutory ‘prior art’ to the other because the patent applications were copending and, further, because there can be no “prior invention by another” (cf. 35 U.S.C. § 102(g)) because both are the inventions of Zosel.”); *In re Coleman*, 189 F.2d 976, 978 (C.C.P.A. 1951) (“Since these patents were copending with the appealed application they do not constitute technical prior art references but are to be looked to only for what they claim”); *In re Fong*, 378 F.2d 977, 980 (C.C.P.A. 1967) (“We must reject the premise that common ownership and copendency in themselves necessarily preclude consideration of a patent as a part of the prior art.”)

³⁶¹ The ‘413 patent was issued on December 6, 1938, and the ‘217 patent was issued on August 29, 1939. *Id.* at 99.

³⁶² *Id.* at 101, citing claim 11 of the ‘413 patent. *See also* U.S. Patent No. 2,139,413 pp.3, ll, 29–31 (filed Oct 25, 1933).

³⁶³ 227 F.2d at 100. *See also* U.S. Patent No. 2,171,217, pp. 3, ll, 17–18, 26–27 (filed Aug 17, 1937).

³⁶⁴ 227 F.2d at 102 (emphasis added).

³⁶⁵ *In re Sarett*, 327 F.2d 1005, 1016 (C.C.P.A. 1964).

what became the *Arth* patent and what was the *Sarett* application.³⁶⁶ Also, although there was a genus patent and a subsequent species patent application, the species patent claim was not clearly within the scope of the earlier genus.³⁶⁷ One claim of the *Arth* patent contained “a broad, functional, generic expression,” for oxidizing alcohols,³⁶⁸ but that claim also included additional process limitations³⁶⁹ not included in the *Sarett* application.³⁷⁰ The court said that “we are concerned only with what this patent claims”³⁷¹ in determining the invention and found that the difference in the claims were “were more than enough to convince us that ‘patentable distinction’ exists” between the claims of the *Sarett* Application and the *Arth* Patent.³⁷² Although *Sarett* shows that the CCPA only considered the claims rather than embodiment, because the case involves related, but not identical parties, it does not constitute precedent against the argument in this article that a genus patent to one inventor and a subsequent application for a species patent within the scope of the genus to the same inventor constitutes improper double patenting.

¶114 In 1966 in *In re Walles*,³⁷³ the CCPA essentially removed same invention type double patenting when it held that claimed subject matter in two patents (or a patent and patent application) had to be identical for there to be double patenting, in spite of the Supreme Court’s statement in *Miller* that there could be the same invention even though “the terms of the claim may differ.”³⁷⁴ *Walles* involved a rejected claim defining a resin *per se* and an earlier patent for a hair setting composition which contained the resin identified in the claims of the later patent, and applicants who were the same as the holders of the earlier patent.³⁷⁵ The court said that the “term same ‘invention’ is too broad a term to fit in with the law of double patenting, because of the diversity of meanings of ‘invention,’” quoting not Supreme Court cases but a 1933 text for authority.³⁷⁶ The CCPA explained, “We may not ignore or discard any portions of the claimed subject

³⁶⁶ One application was filed by appellant Sarett (the *Sarett* application) and one application (which became a patent) was filed jointly by Arth, Poos and Sarett (the *Arth* patent). *Id.* at 1010. Since the *Sarett* application and what became the *Arth* Patent were filed on the same day in 1951, neither application nor the patent could have been prior art. *Id.* at 1007.

³⁶⁷ The court noted, “No simple relationship exists between the claims of *Arth et al.* and appellant’s claims. Some of appellant’s claims are more specific, some more generic to those of *Arth et al.* Some are hybrid.” *Id.* at 1012.

³⁶⁸ *Id.* at 1005, 1009.

³⁶⁹ *Id.* at 1008, 1010.

³⁷⁰ *Id.* at 1010 (“We will not at this point go into the reasoning of the Patent Office, which in essence asks us to ignore specific process step limitations in the patent claims on the ground that they are ‘conventional’ steps.”). Also, compare claim 8 of the *Sarett* Application, *id.* at 1006, with claim 9 of the *Arth* Patent, *id.* at 1008.

³⁷¹ *Id.* at 1007.

³⁷² *Id.* at 1016. The court cited these differences in the claim rather than considering the embodiments disclosed in the specification: “each of the appealed claims defines an oxidation with Sarett’s specific oxidizing agent followed by a conventional ‘recovery’ of any desired and undefined kind. Patent claims 10 and 12 by contrast define five-step processes involving isomerization of one of the recovered products as in the case of claim 11, fully discussed above.” *Id.*

³⁷³ *In re Walles*, 366 F.2d 786, 791–92 (C.C.P.A. 1966).

³⁷⁴ 151 U.S. at 198.

³⁷⁵ 366 F.2d at 787–88. The rejected application resulted from a division of a parent case, from which the patent was also based, so the earlier patent was not prior art. *Id.* at 787.

³⁷⁶ *Id.* at 789 (quoting STRINGHAM ON DOUBLE PATENTING).

matter.³⁷⁷ The court added it had “to determine independently precisely what subject matter is defined in the two sets of claims,” disregarding the specifications.³⁷⁸

¶115 Seeming to suggest—incorrectly—that case law on double patenting before the Patent Act of 1952 was irrelevant, the CCPA in *Wallles* said, “Whatever meaning the term ‘invention’ may have possessed prior to the 1952 Patent Act, it is clear that the term ‘invention’ now means the subject matter which the applicant claims and regards as his ‘invention.’”³⁷⁹ Subsequent Federal Circuit cases have similarly limited same-invention type double patenting to identically claimed subject matter.³⁸⁰ As set forth above, however, *after* the passage of the Patent Act of 1952, the Supreme Court in *Pfaff* recognized that the “invention” arose before and independently of the claim, so the Patent Act of 1952 did not limit “invention” to the claim.³⁸¹ Moreover, the Federal Circuit in such cases as *Ariad* limited the patentable invention to the scope of the invention disclosed in the specification.³⁸² Finally, the sparse legislative history in the Patent Act of 1952 did *not* suggest any change in the definition of “invention.”³⁸³

¶116 Under the narrow standard in *Wallles*, a skilled draftsman could avoid a same invention type double patenting challenge to a second patent application by adding a minor limitation to a claim, or in other words, by slightly narrowing the scope of the original patent.³⁸⁴ Only considering the claims as the invention effectively makes same invention type double patenting a dead letter. In *Ariad*, the Federal Circuit rejected the idea that claims reflected the invention, saying “the *principal function of claims*” is “to provide notice of the boundaries of the right to exclude and to define limits; it *is not to describe the invention*.”³⁸⁵ In contrast, the “written description discloses and teaches.”³⁸⁶

³⁷⁷ *Id.* . The court held there was no double patenting and reversed the rejection of the patent application, saying, “Based on the facts of record, we know no theory of law concerning ‘double patenting’ which permits us to find that the inventions are ‘patentably indistinct.’” *Id.* at 791–92.

³⁷⁸ *Id.* at 789.

³⁷⁹ 366 F.2d at 714.

³⁸⁰ *See, e.g.*, *Sun Pharm. Ind., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1384–85 (Fed. Cir. 2010); *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001).

³⁸¹ *Supra* note 177–80 and accompanying text.

³⁸² 598 F.3d at 1349. The applicant could draft a claim narrower than the scope disclosed in the invention. *See also* notes 162 and 171 above.

³⁸³ Section 100(a) (pre-AIA) contained the following definition: “The term ‘invention’ means invention or discovery.” 35 U.S.C. § 100 (1952) (current version at 21 U.S.C. § 100 (2012)). The Senate Report explained, “Paragraph (a) is added only to avoid repetition of the phrase ‘invention or discovery’ and its derivatives throughout the revised title.” S. REP. NO. 82-1979, at 16 (1952). Also, the Senate Report explained the two clauses in § 112 mentioning invention as follows: “The clause relating to the claim is made a separate paragraph to emphasize the distinction between the description and the claim or definition, and the language is modified.” *Id.* at 19. This suggests an intent to consider the description in the specification in addition to the claim. As a result of the AIA, § 101(j) (post-AIA) now provides, “The term ‘claimed invention’ means the subject matter defined by a claim in a patent or an application for a patent.” 21 U.S.C. § 100 (2012). This seems to confirm that the claim shows what the inventor claims is its invention, whereas the specification must disclose what the invention is.

³⁸⁴ The Supreme Court has cautioned against an interpretation of patent law that leaves it open to the vagaries of skilled drafters. *See, e.g.*, note 33 above.

³⁸⁵ 598 F.3d at 1347 (emphasis added).

³⁸⁶ *Id.*

It naturally follows that any embodiment of a claimed genus disclosed in the specification made by a third party is an infringing species of the patented invention.³⁸⁷

¶117 In 1970, in *Tidewater Patent Development Co. v. K.M. Kitchen*,³⁸⁸ the Fourth Circuit took the approach of the Seventh Circuit in *Weatherhead*, in finding the applicable patent invalid for double patenting because the same party had received a patent for a genus and subsequent patent for a species within the scope of the genus.³⁸⁹ *Tidewater* involved two patents for a permanent hair waving solution issued from applications which had been copending.³⁹⁰ *Tidewater* was the holder of both patents,³⁹¹ and the court noted that, if upheld, “such repetitive patenting would extend the effectiveness of 710 from its expiry in December 1968 to 323’s terminal date of February 1973.”³⁹² The Fourth Circuit in *Tidewater* said that double patenting could exist even if the claims did not mutually “read on” (infringe) each other.³⁹³ The ‘710 patent was “classified as a generic patent relating to hair waving, while ‘323 is designated as a species patent.”³⁹⁴ The court added, “Proof of double patenting is found in the concession of *Tidewater* that any product made under 323 would infringe 710.”³⁹⁵

¶118 The court in *Tidewater* noted that an earlier patent granted to one party “does not invalidate a later patent to him for a distinct, different and separable invention whether generic or specific, whether an original machine or process, or both, or an improvement thereon which is not actually claimed or secured by the earlier patent.”³⁹⁶ Immediately preceding this statement, the court in *Tidewater* explained that an inventor could have multiple inventions, and the inventor could “secure all these inventions by a single patent,” referring to multiple claims in a single patent application rather than two patents or a patent and patent application as discussed in this article.³⁹⁷ On the issue of two patents, the court in *Tidewater* concluded that “the species patent must fall if within the coverage of the genus patent.”³⁹⁸

³⁸⁷ *Pfaff*, 525 U.S. 55 at 57–58.

³⁸⁸ 371 F.2d 1004 (4th Cir. 1967).

³⁸⁹ *Id.* at 1012–13.

³⁹⁰ One patent application was filed June 16, 1941 and issued on December 4, 1951 as the ‘710 patent; and the other application was filed August 13, 1949 and issued on February 28, 1956 as the ‘323 patent, and thus the patents were copending for some period of time. *Id.* at 1006. Court decisions on whether applications that were copending could be prior art have not always been consistent. In *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1277 (Fed. Cir. 1992), in discussing double patenting and two patent applications that had been copending, the court said, “[n]either is statutory ‘prior art’ to the other because the patent applications were copending and, further, because there can be no ‘prior invention by another’ (cf. 35 U.S.C. § 102(g)) because both are the inventions of Zosel.” On the other hand, in *In re Fong*, 378 F.2d 977, 980 (C.C.P.A. 1967), the CCPA said, “We must reject the premise that common ownership and co-pendency in themselves necessarily preclude consideration of a patent as a part of the prior art.”

³⁹¹ 371 F.2d at 1006.

³⁹² *Id.* at 1011.

³⁹³ *Id.* at 1009 (quoting *In re Zickendraht*, 319 F.2d 225, 229 (C.C.P.A. 1963) (“Double patenting may exist even where, as here, the claims in two cases are not mutually cross-readable.”)).

³⁹⁴ 371 F.2d at 1006.

³⁹⁵ *Id.* at 1009. The court reversed the finding of infringement. *Id.* at 1013.

³⁹⁶ *Id.* at 1010 (quoting *Remington Rand BusinessBus. Serv., Inc. v. Acme Card SystemSys. Co.*, 71 F.2d 628, 633–34 (4th Cir. 1934)).

³⁹⁷ *Id.*

³⁹⁸ 371 F.2d at 1011.

¶119 Chisum argues that the opinion in *Tidewater* is “contrary to the accepted notion that an inventor may obtain a patent on a later nonobvious improvement,” citing the statement by the Supreme Court in *Morse*: “Nor can its [the second patent to the inventor] validity be impeached upon the ground that it is an improvement upon a former invention, for which the patentee had himself already obtained a patent.”³⁹⁹ However, the fact that the Supreme Court in *Morse* recognized that an inventor who already held a patent could obtain a patent for some improvements does not suggest that the inventor could obtain patents for all improvements. Indeed the paragraph from *Morse* that Chisum quoted concluded by saying, “All that the law requires of him is that he shall not claim as new, what is covered by a former invention, whether made by himself or any other person.”⁴⁰⁰

¶120 A review of the Supreme Court’s discussion of *Morse*’s separate patent for local circuits⁴⁰¹ indicates that the patent for an improvement in local circuits was not within the scope of the earlier invention,⁴⁰² so there was no reason *Morse* could not also patent the local circuits, since the eighth claim in *Morse* was invalidated.⁴⁰³ The Court in *Morse* said that if the eighth claim (for all uses of electro-magnetism to transport messages over a distance) could have been sustained, *Morse*’s subsequent patent for local circuits would have been “illegal and void.”⁴⁰⁴ The Court explained that *Morse* “could not take out a subsequent patent for a portion of his [eighth claim] . . . and thereby extend his monopoly beyond the period limited by law.”⁴⁰⁵ The Court was saying that the same inventor could not obtain a patent on an improvement to a genus patent if in fact the inventor’s genus patent was broad enough that it covered the improvement. The decision in *Morse*, in other words, is not a basis for challenging the decision in *Tidewater*.

¶121 In 1968, the CCPA in *In re Schneller*⁴⁰⁶ followed the positions of the Seventh Circuit in *Weatherhead* and the Fourth Circuit in *Tidewater* and confirmed the significance of a person obtaining a patent for a genus and subsequently applying for a species patent within the scope of the genus.⁴⁰⁷ The court said that the “fundamental reason” for the rule against double patenting was “to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about.”⁴⁰⁸ *Schneller* argued that his patent claimed ABCX and that his rejected

³⁹⁹ See CHISUM, *supra* note 77, at vol. 3A, § 9.03[2][b][iii], p. 9-35; *supra* note 46.

⁴⁰⁰ 56 U.S. at 122 (emphasis added).

⁴⁰¹ *Id.* at 121, 123 (“A telegraph which prints the intelligence it conveys at different places, by means of the current, as it passes along on the main line, must necessarily require a different combination and arrangement of powers from the one that prints only at the end. The elements which compose it may all have been used in the former invention; but it is evident that their arrangement and combination must be different to produce this new effect.”)

⁴⁰² Compare claim 1 (“short local independent circuit or circuits”) and Sheets 1-4 of U.S. Patent No. 4,453 with claims 1-8 and sheets 1-4 of U.S. Patent No. 1,647.

⁴⁰³ See *supra* note 150 and accompanying text.

⁴⁰⁴ 56 U.S. at 114.

⁴⁰⁵ *Id.*

⁴⁰⁶ *In re Schneller*, 397 F.2d 350 (C.C.P.A. 1968).

⁴⁰⁷ The patent and rejected claim were for clip systems for securing gypsum lath to supports in partition walls. *Id.* at 350–51.

⁴⁰⁸ *Id.* at 354. Since there had been a division of the initial application, the court discussed § 121, which provides that if the USPTO determines that an application contains two or more distinct inventions and requires the application to be divided into two applications, the first patent granted cannot be cited as prior art against the second patent, unless they were independent and distinct inventions. *Id.* The court said,

application claimed ABCY.⁴⁰⁹ The court pointed out, however, that the 1960 Patent had used “comprising” in the transition.⁴¹⁰ The result was that Schneller “obtained a patent claiming ... ABCX, but so claiming these combinations as to cover them no matter what other feature is incorporated in them, thus covering effectively ABCXY.”⁴¹¹ In other words, the ‘329 patent was a genus patent due to the use of “comprising,” and the rejected claims were a species within the scope of the genus. The court took the position of this article in affirming the rejection of the claim as an example of double patenting, because the “protection he already had would be extended, albeit i[n] somewhat different form, for several years beyond the expiration of his patent, were we to reverse.”⁴¹²

¶122

In 1970 in contrast, in *In re Vogel*⁴¹³ the CCPA set a two-part test for determining if there was obviousness-type double patenting, which test the Federal Circuit has subsequently followed⁴¹⁴ and which still focuses on a comparison of the boundaries of the claims rather than determining under *Miller* whether the earlier patent covered embodiments claimed in the subsequent species patent.⁴¹⁵ The court in *Vogel* said the first part of the test was, “Is the same invention being claimed twice?”⁴¹⁶ As in *Wallis*,⁴¹⁷ the court in *Vogel* said that “‘invention’ here means what is defined by the claims.”⁴¹⁸ The court in *Vogel* then said that the second part of the obviousness-type double patenting test was: “Does any claim in the application define merely an obvious variation of an invention disclosed and claimed in the patent?”⁴¹⁹ In making that determination, the court said the disclosure in the earlier patent was not prior art.⁴²⁰ If the second claim was

“The public policy considerations underlying 35 U.S.C. 121 permit separate patents on ‘independent and distinct’ inventions which are initially ‘claimed in one application.’” *Id.* However, the court also said that “no such determination has been made” and added that voluntary separation of claims by the applicant needed to be scrutinized carefully, “because it can lead to the improper proliferation of patents on the same invention with the inherent result of extending timewise a patentee’s right to exclude others from the invention disclosed in the original application and on which his patent has issued.” *Id.*

⁴⁰⁹ *Id.* at 354.

⁴¹⁰ *Id.*

⁴¹¹ *Id.* at 356.

⁴¹² *Id.*

⁴¹³ *In re Vogel*, 422 F.2d 438 (C.C.P.A. 1970).

⁴¹⁴ See *In re Kaplan*, 789 F.2d 1574, 1579 (Fed. Cir. 1986); *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1278 (Fed. Cir. 1992); *In re Hitachi Metals, Ltd.*, 603 Fed. App’x 976, 979 (Fed. Cir. 2015).

⁴¹⁵ *Vogel* involved a patent held by Vogel claiming a method for preparing pork products and a patent application by Vogel claiming methods for preparing packaged meat products and for preparing beef products. 422 F.2d at 439–40.

⁴¹⁶ *Id.* at 441.

⁴¹⁷ See *supra* notes 373–79 and accompanying text.

⁴¹⁸ 422 F.2d at 441. The court added that same invention meant identical subject matter and that an “invention defined by a claim reciting ‘halogen’ is not the same as that defined by a claim reciting ‘chlorine,’ because the former is broader than the latter.” *Id.* However, it added that “claims may be differently worded and still define the same invention,” giving the example of a claim reciting 36 inches and a claim reciting three feet. *Id.*

⁴¹⁹ *Id.*

⁴²⁰ The Federal Circuit did say that the embodiment in the specification could be used to determine the meaning of the words in the claims and could be helpful in deciding if the second claim would have been obvious, since the specification “sets forth at least one tangible embodiment within the claim, and it is less difficult and more meaningful to judge whether that thing has been modified in an obvious manner.”

merely an obvious variation of the first, then there was double patenting and that claim would be invalid.⁴²¹

¶123 Since *Vogel* was decided before *Ariad*, one question was apparently not raised. As discussed above, before *Ariad* a patent claim that was enabled when the application was filed could be “expanded” at the time of an alleged infringement to cover accused products that employed after-arising technologies, but not after *Ariad*.⁴²² The question today would be, if the species within the genus was not obvious to the applicant at the time of the filing of the genus claim, how could he have appropriately claimed he had invented that species at the time of the application for the genus patent?⁴²³

¶124 In 1986, in *In re Kaplan*,⁴²⁴ shortly after the creation of the Federal Circuit, the Federal Circuit only considered the claims of the genus patent and patent claims for the species application (within the scope of the genus) in determining that there was no double patenting. Kaplan had a patent for a generic catalytic process for producing certain chemicals,⁴²⁵ and Kaplan and Walker (the Kaplan/Walker application) jointly filed—while the application that became the Kaplan patent was pending—a patent application for the preferred mode of practicing the Kaplan patent with a specific organic solvent.⁴²⁶ Due to the differences in the claims, the court held that “the same invention is not being claimed” in the Kaplan patent and the Kaplan/Walker application, so the court concluded there was no double patenting.⁴²⁷ Even if the Federal Circuit in *Kaplan* had considered the embodiments in the specifications in determining “invention,” however, the court might not have concluded there was double patenting, since the purpose of double patenting is to prevent the same party from extending its exclusive rights through a second patent.⁴²⁸ The court in *Kaplan* noted that “a sole inventor and joint inventors including the sole inventor are separate ‘legal entities,’ a legal proposition from which certain legal consequences flow.”⁴²⁹ Therefore, *Kaplan* is not precedent for one

Id. at 442. However, consideration of the specification was only to determine if the second claim was obvious, not to determine if the earlier genus claim covered the subsequent species claim.

⁴²¹ Unless the applicant had filed a terminal disclaimer, which could “prevent undue timewise extension of monopoly.” *Id.* The last sentence of pre-AIA § 253 provides that “any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted.” 35 U.S.C. § 253 (2011). Post-AIA § 253(b) has substantially the same sentence, but there are certain limitations on when the courts will allow the filing of a terminal disclaimer. See *infra* note 464.

⁴²² *Supra* notes 223–27 and accompanying text. Also, since the genus claim literally covered the species, there would be no basis for applying the doctrine of equivalents to cover after-arising technology, even assuming the second patent was the result of after-arising technology. *Supra* notes 228–40.

⁴²³ The court held that in light of the patent for preparing pork products, the rejected claim for preparing beef products did not constitute double patenting. *Id.* at 442. However, the rejected claim for preparing meat did constitute double patenting in light of the patent for preparing pork products. *Id.* at 442–43.

⁴²⁴ *In re Kaplan*, 789 F.2d 1574 (Fed. Cir. 1986).

⁴²⁵ *Id.* at 1574–76.

⁴²⁶ *Id.* at 1575. The application for the Kaplan patent was filed on January 2, 1975 and granted on March 16, 1976. *Id.* at 1574. The great-great-grandparent of the Kaplan/Walker application was filed on September 30, 1975. *Id.* Both the Kaplan patent and the Kaplan/Walker application were assigned to Union Carbide Corporation. *Id.*

⁴²⁷ *Id.* at 1581.

⁴²⁸ *Gilead Sci., Inc.*, 753 F.3d at 1212.

⁴²⁹ *Kaplan*, 789 F.2d at 1575. This article argues that the holder of a patent for a genus should be estopped from obtaining a subsequent patent for a species within the scope of the genus.

pharmaceutical company obtaining a broad patent on a chemical composition and then obtaining a patent on a species within the scope of the genus.

¶125 In 2012 and 2014, after its *en banc* decision in *Ariad*, one might suspect that the Federal Circuit would change its understanding of “invention” to give more prominence to the specification. However, a review of two recent Federal Circuit decisions, discussed next, reveals that *Ariad* did not influence the Federal Circuit on double patenting. This perhaps reflects what Professor Collins has said, that “patent litigation and scholarship are frequently conducted within distinct doctrinal silos. Courts . . . take on disclosure issues (section 112, paragraph 1), functional claiming issues (section 112, paragraph 6), or utility issues (section 101) in isolation, assuming that each doctrine maps onto a distinct normative problem.”⁴³⁰ Such separation of *Ariad*’s teaching on § 112 from *Miller*’s teaching on § 101 is not warranted.⁴³¹

- i) *Otsuka Pharmaceutical Co., Ltd. v. Sandoz, Inc.*⁴³²
No double patenting under § 101

¶126 In the Federal Circuit *Sandoz* was unsuccessful in challenging the validity of Otsuka’s patent for its antipsychotic drug, marketed under the brand name Abilify®.⁴³³ Otsuka held U.S. Patent No. 4,734,416 (the ‘416 patent), which issued on March 29, 1988 and covered approximately nine trillion compounds,⁴³⁴ including a broad genus of compounds that generically encompassed aripiprazole, although aripiprazole was not specifically disclosed.⁴³⁵ The narrower patent allegedly infringed by the defendants was U.S. patent No. 5,006,528 (the ‘528 patent), issued on April 9, 1991.⁴³⁶ Claim 12 of the ‘528 patent specifically claimed aripiprazole,⁴³⁷ the active ingredient in Abilify®.⁴³⁸

⁴³⁰ Kevin Emerson Collins, *An Initial Comment on Ariad: Written Description and the Baseline of Patent Protection for After-Arising Technology*, 2010 PATENTLY-O PAT. L.J. 60, (2010).

⁴³¹ Anna B. Laakmann, *An Explicit Policy Lever for Patent Scope*, 19 MICH. TELECOMM. & TECH. L. REV. 43, 60 (2012) (“Patent scholars observe a propensity for formalism in the Federal Circuit’s patent jurisprudence. The court depicts patent law as an ordered system founded upon a few abstract, discrete categories and higher principles. It perceives each of the statutory requirements as a distinct silo, rigidly adhering to the notion that each substantive doctrine operates separately and independently from the others.”).

⁴³² *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1283 (Fed. Cir. 2012).

⁴³³ The ‘528 patent received a five year extension of its term under § 156 for the period of the FDA’s regulatory review. See Certificate Extending Patent Term Under 35 U.S.C. § 156 at p. 14 of U.S. Patent No. 5,006,528. See also discussion of extension of patent terms under §156 *supra* at notes 71-75 and accompanying text. With the five year term extension of the ‘528 patent for Abilify® and a six month period of pediatric exclusivity, the ‘528 patent was to expire on April 20, 2015. *Otsuka*, 678 F.3d at 1285.

⁴³⁴ *Otsuka*, 678 F.3d. at 1286. The ‘416 patent expired on March 29, 2005. *Id.* The Federal Circuit said the ‘416 patent constituted prior art. *Id.* at 1286. The court also said, “The patent principally underlying the double patenting rejection need not be prior art.” *Id.* at 1297.

⁴³⁵ *Otsuka Pharm. Co. Ltd. v. Sandoz, Inc.*, 2010 WL 4596324, *3 (D.N.J. 2010). The briefs of both parties noted that a claim of the ‘416 patent “covers” or “encompasses” aripiprazole. *Id.*

⁴³⁶ 678 F.3d at 1285. One of the inventors of the ‘416 patent was Yasuo Oshiro, who was also one of the inventors of the ‘528 patent. See p. 1 of the ‘416 patents.

⁴³⁷ *Otsuka*, 2010 WL 4596324, at *4 (“Claim 12 of the ‘528 patent is directed to the compound aripiprazole, which has the chemical name 7- $\{4-[4-(2,3\text{-dichlorophenyl})-1\text{-piperazinyl}]\text{-butoxy}\}$ -3,4-dihydrocarbostyryl. (‘528 Patent at col. 19, lines 18–19.)”)

⁴³⁸ 678 F.3d at 1284-1285.

Otsuka's listing for Abilify® in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") contained references to both the '416 patent and the '528 patent as covering aripiprazole.⁴³⁹

¶127 The defendants in *Otsuka* challenged the '528 patent on the grounds of (1) obviousness under § 103 and (2) obviousness type double patenting for one compound disclosed in claim 13 of the '416 patent.⁴⁴⁰ On obviousness type double patenting the Federal Circuit did not seem to consider relevant that the drug claimed in the '528 patent (aripiprazole) was within the scope of the genus claim of the '416 patent, or that Otsuka had listed both the '416 patent and '528 patent in the Orange Book as covering aripiprazole.⁴⁴¹

¶128 Instead, the Federal Circuit agreed with Otsuka and said, "In the context of claimed chemical compounds, an analysis of nonstatutory obviousness-type double patenting—like an analysis under § 103—entails determining, *inter alia*, whether one of ordinary skill in the art would have had reason or motivation to modify the earlier claimed compound to make the compound of the asserted claim with a reasonable expectation of success."⁴⁴² Under this test, a modified obviousness test under § 103, the Federal Circuit was only comparing the genus claim limits with the subsequent species claim limits.⁴⁴³

¶129 The Federal Circuit affirmed the decision of the district court that there was no obviousness type double patenting, because "the prior art would not have provided a skilled artisan with a reason to make the necessary structural changes to the unsubstituted butoxy to yield aripiprazole."⁴⁴⁴ The court explained that "the evidence here not only demonstrates the unpredictability of minor structural changes on a compound's antipsychotic properties, but also indicates that the prior art would not have provided the

⁴³⁹ *Otsuka*, 2010 WL 4596324 at *2.

⁴⁴⁰ *Id.* at **8-28 (obviousness) and **28-29 (obviousness type double patenting). A review of the appellate briefs filed in the Federal Circuit reveals that the defendants did not claim the '416 patent anticipated the '528 patent. *See* 2011 WL 4735195 (C.A. Fed.), 2011 WL 4735196 (C.A. Fed.), 2011 WL 3796762 (C.A. Fed.), 2011 WL 3796763 (C.A. Fed.), 2011 WL 1748636 (C.A. Fed.), 2011 WL 1748637 (C.A. Fed.), 2012 WL 3597032 (C.A. Fed.), 2012 WL 2450061 (C.A. Fed.).

⁴⁴¹ These facts were apparent in the decision, *see supra* notes 433-438, but the reasoning of the court, discussed in the next paragraph, disregarded these facts that point to double patenting.

⁴⁴² 678 F.3d at 1298. In *Graham v. John Deere Company of Kansas City*, 383 U.S. 1 (1966), the Supreme Court held that the "ultimate question of patent validity is one of law," but identified "several basic factual inquiries: the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined." *Id.* at 17. The Court added, "Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Id.* at 17-18. In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Supreme Court discussed how to weigh the various considerations for the obviousness inquiry set forth in *Graham*, focusing on predictability of results. *See* Christopher A. Cotropia, *Predictability and Nonobviousness in Patent Law After KSR*, 20 MICH. TELECOMM. & TECH. L. REV. 391, 425, 393 (2014). *See also* Douglas L. Rogers, *Federal Circuit's Obviousness Test For New Pharmaceutical Compounds: Gobbledygook?*, 14 CHI.-KENT J. INTELL. PROP. 49 (2015); Douglas L. Rogers, *Obvious Confusion Over Properties Discovered After a Patent Application*, 43 AIPLA Q.J. 489 (2015).

⁴⁴³ 678 F.3d at 1297 (It "is the claims that are compared when assessing double patenting" (quoting *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 943 (Fed. Cir. 1992))).

⁴⁴⁴ 678 F.3d at 1299. The Federal Circuit in *Otsuka* also affirmed the district court's conclusion that defendants failed to prove that the '528 patent claims at issue were obvious under § 103. *See id.* at 1290-96.

skilled artisan with a reason to make the necessary structural changes to the unsubstituted butoxy to yield aripiprazole.”⁴⁴⁵

¶130 In other words, the Federal Circuit was not taking into account the principle in *Miller* that “no patent [the ‘528 patent] can issue for an invention actually covered by a former patent [the ‘416 patent], especially to the same patentee, although the terms of the claims may differ.”⁴⁴⁶ Similarly, the Federal Circuit was not considering the Supreme Court’s statement in *Morse* that a patentee “could not take out a subsequent patent for a portion of his first invention [the part of the invention covered by the ‘416 patent], and thereby extend his monopoly [for aripiprazole] beyond the period limited by law.”⁴⁴⁷ These historic principles remain valid today and also reflect the recent emphasis of the Supreme Court and patent law scholarship that patent law must achieve a balance between First Inventors and Improvers to promote competition for improvements.⁴⁴⁸

¶131 The extension of the exclusive rights in *Otsuka* was clear, since the ‘528 patent was to expire on April 20, 2015, compared to the earlier expiration of the ‘416 patent on March 29, 2005.⁴⁴⁹ *Otsuka* had received the genus ‘416 patent, so the ‘416 patent was presumed to be valid under § 282. Under *Ariad* and *Novozymes* it should have been presumed that *Otsuka* had disclosed in the specification for the ‘416 patent sufficient species to support the scope of the claims, including the species on which *Otsuka* subsequently sued on the ‘528 patent.⁴⁵⁰ In *Odiorne*, Justice Story concluded that the earlier patent was “an estoppel to any future patent for the same invention,”⁴⁵¹ and under § 271(a) the patented invention includes any completed embodiment containing the elements of the patent claim.⁴⁵²

¶132 *Otsuka* should have been estopped from subsequently arguing in defense of its ‘528 patent that it wasn’t obvious and that it really hadn’t conceived of the species in the ‘528 patent, especially since *Otsuka* listed in the Orange Book that both the ‘416 and ‘528 patents covered aripiprazole. Under prosecution history estoppel, parties are estopped from narrowing the scope of their claims to avoid prior art and obtain a patent and subsequently trying to recover that abandoned scope against a defendant in infringement litigation through a finding of infringement under the doctrine of equivalents.⁴⁵³ Just as they do for prosecution history estoppel and assignor estoppel, the courts should reject the approach of a company obtaining a broad patent through its representation that it had invented the genus and subsequently obtaining a narrower patent on species within the scope of the genus patent by arguing that it had not really invented or possessed that species when it applied for the genus patent.⁴⁵⁴

⁴⁴⁵ *Id.* at 1299. Earlier in the decision the Federal Circuit said that the parties had agreed that the ‘416 patent was prior art to the ‘528 patent. *Id.* at 1286.

⁴⁴⁶ *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894).

⁴⁴⁷ *O’Reilly v. Morse*, 56 U.S. 62, 114 (1853).

⁴⁴⁸ *Supra*, notes 49-60.

⁴⁴⁹ 678 F.3d at 1285-86.

⁴⁵⁰ For *Ariad*, see *supra* notes 191-204 and accompanying text; for *Novozymes*, see *supra* notes 205-12 and accompanying text, and for the presumption of validity, see *supra* note 217.

⁴⁵¹ 18 F. Cas. at 579.

⁴⁵² *Supra* notes 181-82.

⁴⁵³ See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 723 (2002); *Nard*, *supra* note 43, at 547-48; and *supra* notes 219-21.

⁴⁵⁴ A third party improver is not in the same position, since the third party has not already

ii) *AbbVie Inc. v. Mathilda and Terence Kennedy Institute of Rheumatology Trust*⁴⁵⁵
Double patenting under §101

¶133 In 2014, in *AbbVie* the Federal Circuit again only considered the claims and disregarded the actual invention. The Trust's two separately filed patents involved combination therapies to treat rheumatoid arthritis with an antirheumatic drug and an anti-TNF α antibody.⁴⁵⁷ The genus patent, the '766 patent, expired on October 8, 2012,⁴⁵⁸ and the subsequent species patent, the '422 patent, was scheduled to expire on August 21, 2018.⁴⁵⁹ The genus patent claimed a method for co-administering rheumatoid arthritis treatment to all individuals in need of such treatment.⁴⁶⁰ Co-administering was defined to include concomitant use and adjunctive uses of the medicines.⁴⁶¹ The species patent was directed to treating a smaller group of patients within the genus of patients, individuals with active need, and called for adjunctive use of the same medicines, one of the categories of the '766 patent for administering the medicines.⁴⁶²

¶134 Focusing on the claims and a modified version of the § 103 obviousness test,⁴⁶³ similar to the test it had set forth in *Vogel*,⁴⁶⁴ the Federal Circuit in *AbbVie* said, "First, the court 'construes the claim[s] in the earlier patent and the claim [s] in the later patent and determines the differences.' Second, the court 'determines whether those differences render the claims patentably distinct.'"⁴⁶⁵ The court continued, "A later claim that is not

submitted an oath to the U.S. Patent Office that it had invented the species within the genus patent.

⁴⁵⁵ *AbbVie Inc. v. Mathilda and Terence Kennedy Inst. of Rheumatology*, 764 F.3d 1366 (Fed. Cir. 2014).

⁴⁵⁶ Tumor Necrosis Factor Alpha. *Id.* at 1369. The "named inventors of the '766 and '422 patents discovered that a protein called Tumor Necrosis Factor Alpha (TNF α) is partially responsible for the inflammation rheumatoid arthritis causes. This discovery led the inventors to research antibodies that block the TNF α protein." *Id.*

⁴⁵⁷ *Id.*

⁴⁵⁸ *Id.*

⁴⁵⁹ *Id.* at 1369. Abbvie was a licensee of the '766 patent but refused to enter into a license for the '422 patent and sued the Trust for a declaratory judgment that the '422 patent was invalid. *Id.* at 1368.

⁴⁶⁰ *Id.* at 1370.

⁴⁶¹ *Id.* at 1371.

⁴⁶² *Id.* at 1370.

⁴⁶³ In *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1377, n.1 (Fed. Cir. 2003), the Federal Circuit said, "The distinctions between obviousness under 35 U.S.C. § 103 and non-statutory double patenting include: 1. The objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application; 2. Obviousness requires inquiry into a motivation to modify the prior art; nonstatutory double patenting does not; 3. Obviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not." In *AbbVie*, the Federal Circuit acknowledged that part of the obviousness-type double patenting analysis was "analogous to an obviousness analysis under 35 U.S.C. § 103" (764 F.3d at 1378) but did not discuss or cite either of the two recent major obviousness decisions by the Supreme Court, *Graham* and *KSR*, discussed *supra* at note 441.

⁴⁶⁴ *Supra* notes 410-20 and accompanying text.

⁴⁶⁵ 764 F.3d at 1374. If a patent application would otherwise involve obviousness-type double patenting, the problem may be solved by the applicant submitting a terminal disclaimer under 35 U.S.C. § 253(b), so that the term of the second patent would end with the termination of the first patent. *See, e.g.*, MPEP § 804.III ¶3; *Gilead Sci., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1217 (Fed. Cir. 2014). However, the Federal Circuit has said, "As a general rule, a terminal disclaimer filed to overcome an obviousness-type double patenting rejection is effective only where the application and conflicting patent are commonly owned." *In re Hubbell*, 709 F.3d 1140, 1148 (Fed. Cir. 2013).

patentably distinct from,’ i.e., ‘is obvious over[] or anticipated by,’ an earlier claim is invalid for obviousness-type double patenting.⁴⁶⁶ The court added that “the nonclaim portion [the specification] of the earlier patent ordinarily does not qualify as prior art against the patentee.”⁴⁶⁷

¶135 The Federal Circuit noted that the Trust “admits that the claims of the ‘442 patent are encompassed by those of the ‘766 patent,”⁴⁶⁸ or in other words, “the genus claimed in the ‘766 patent (treating all patients in need thereof) is broader than the species claimed in the ‘442 patent (treating patients with ‘active disease,’ i.e., particularly sick patients).”⁴⁶⁹

¶136 The court said, “It is well-settled that a narrow species can be non-obvious and patent eligible despite a patent on its genus.”⁴⁷⁰ However, the court also noted that some species of a patented genus were not patentable separately from the genus.⁴⁷¹ It said that species were not patentable apart from the genus when the “genus is so limited that a person of ordinary skill in the art can ‘at once envisage each member of this limited class”⁴⁷² In other words, “species are unpatentable when prior art disclosures describe the genus containing those species such that a person of ordinary skill in the art would be able to envision every member of the class.”⁴⁷³ The Federal Circuit held that since the ‘442 patent did “not claim a species manifesting unexpected results” the ‘442 patent “would have been obvious over the ‘766 patent.”⁴⁷⁴

¶137 In an obviousness analysis the focus on the claims makes sense, because both pre-AIA and post-AIA, § 103 specifically directs the court’s attention to the subject matter *claimed*.⁴⁷⁵ In contrast, § 101⁴⁷⁶ directs the court’s attention to the actual invention, such as a composition of matter. As set forth above,⁴⁷⁷ in *Miller* and *Ariad* the courts looked at the actual product disclosed in the specification—and not simply the claims—in *Miller* under § 101 to determine if one inventor had covered the same invention with two patents, and in *Ariad* under § 112 to determine the actual invention of the inventor.

⁴⁶⁶ 764 F.3d at 1374.

⁴⁶⁷ *Id.* at 1379 (citing *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1379 (Fed. Cir. 2012)).

⁴⁶⁸ 764 F.3d at 1370.

⁴⁶⁹ *Id.* at 1378.

⁴⁷⁰ *Id.* at 1379 (citing *Eli Lilly & Co. v. Bd. of Regents of Univ. of Wash.*, 334 F.3d 1264, 1270 (Fed.Cir.2003)); *In re Kaplan*, 789 F.2d 1574, 1577–78 (Fed.Cir.1986); *In re Sarett*, 327 F.2d 1005, 1014 (1964); CHISUM, *supra* note 77, at vol. 3A, § 9.03[2][b][ii].

⁴⁷¹ 764 F.3d at 1379.

⁴⁷² *Id.*

⁴⁷³ *Id.*

⁴⁷⁴ *Id.* at 1381. For critiques of the Federal Circuit’s consideration of unexpected results in determining obviousness, see Mark A. Lemley, *Expecting the Unexpected* (Sept. 28, 2015) (Stanford Public Law, Working Paper No. 2666626), SSRN:<http://ssrn.com/abstract=2666626>; Douglas Rogers, *Obvious Confusion over Properties Discovered After a Patent Application*, 43 AIPLA Q.J. 489 (Fall 2015).

⁴⁷⁵ Section 103 (pre-AIA) directs the court to determine “if the differences between the subject matter sought to be patented and the prior art . . . would have been obvious.” § 103 (post-AIA) directs the court to determine “if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious.”

⁴⁷⁶ Section 101 provides, “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. . . .”

⁴⁷⁷ *Supra* notes 271-302 and accompanying text for *Miller*; *supra* notes 191-204 and accompanying text for *Ariad*.

¶138 The outcome in *Abbvie* was consistent with the argument in this article that the double patenting prohibition should prevent a company which has obtained a genus patent for a pharmaceutical composition from then receiving a patent for a species within the genus. However, the Federal Circuit relied on the weakened double patenting doctrine that is essentially an alternate obviousness analysis under § 103(pre-AIA) and can fail to serve the purpose of the double patenting prohibition—to prevent a patentee from gaining an unjustified time wise extension of its exclusive rights. If Congress wants to grant pharmaceutical companies further extensions, Congress should do that rather than the courts.

IV. SUMMARY

¶139 The Federal Circuit has essentially changed the prohibition in *Miller* from consideration of the embodiments disclosed in the specification to only giving consideration to the boundaries of the claims as an alternate method of applying an obviousness analysis, generally when the earlier patents were not technically prior art under § 102.⁴⁷⁸ This has made it easier for skillful drafters to avoid the prohibition. Only considering the boundaries of the claims is an implicit rejection of the principle about the “invention” in *Morse*, *Consolidated Electric*, *Deepsouth* and *Ariad*. That limited consideration has allowed pharmaceutical manufacturers to extend the statutory period of exclusivity for their products beyond period specified in 35 U.S.C. 154.⁴⁷⁹

¶140 If on the day before a genus patent were to expire, the holder of the genus patent obtained a patent on a species within the genus, it then would have had 40 years (minus one day) to exclude others from making or using that species, instead of the 20 years permitted by 35 U.S.C. §§ 154(a)(2). Surely this would conflict with the principle the Supreme Court stated in *Miller* that “no patent can issue for an invention actually covered by a former patent, especially to the same patentee, although the terms of the claims may differ,”⁴⁸⁰ and the principle in *Morse* that an inventor “could not take out a subsequent patent for a portion of his first invention, and thereby extend his monopoly beyond the period limited by law.”⁴⁸¹

¶141 Under *Ariad*⁴⁸² a party cannot obtain a patent if the specification does not disclose/support the scope of the patent, and once a patent is granted, that patent is presumed valid. It is inconsistent for an inventor, or an employer of the inventor, to defend against a double patenting challenge from a defendant in litigation by arguing that the inventor of the species patent had not possessed the species when it obtained the species patent. There should be a finding of double patenting when the species patent is within the scope of the genus patent and the same party or pharmaceutical company holds

⁴⁷⁸ *Supra* notes 431–73 and accompanying text discussing *Otsuka* and *Abbvie*.

⁴⁷⁹ Subject of course to the statutory adjustments permitted under 35 U.S.C. § 154(b) for delays “due to the failure of the PTO” and extensions permitted under § 156 for delays cause by FDA review. *Supra* notes 71–75 and accompanying text; Mueller, *supra* note 3, at 22–24.

⁴⁸⁰ *Miller*, 151 U.S. at 198.

⁴⁸¹ *Morse*, 56 U.S. at 114.

⁴⁸² And under *Morse*, *Consolidated Electric* and *Schriber-Scroth*, *supra* notes 146-161 and accompanying text.

both patents.⁴⁸³ There should not be the same result if an unrelated party obtained the subsequent species patent, because the unrelated party would not already have submitted an oath to the Patent Office that it had invented the full scope of the genus.

¶142 The next section argues that although double patenting prohibition is an obscure doctrine, there will be an increased need for a strengthened double patenting doctrine in AIA cases, because of two loopholes that give companies an incentive to remove certain references as prior art and/or not disclosing preferred embodiments of the genus.

V. THE AMERICA INVENTS ACT INCREASES THE NEED IN SOME RESPECTS FOR A STRENGTHENED DOUBLE PATENTING DOCTRINE

¶143 The AIA changes “prior art” in a number of ways. For instance, it changes the date for determination of whether an art reference is “prior” art from the date of the invention to the effective filing date of the patent application.⁴⁸⁴ This in turn means that some disclosures of an inventor which pre-AIA were not prior art (because the inventor could not disclose the invention before its invention) could in the future be prior art (since the inventor could disclose the invention after its invention but before the filing of a patent application for the invention) and cause a patent to be rejected for anticipation or obviousness. However, in addition to changing the date on which “prior art” is determined, the AIA creates a number of exceptions to prior art for a variety of disclosures by the inventor.⁴⁸⁵

¶144 Since the courts have normally only applied double patenting when the earlier patent was not prior art,⁴⁸⁶ and the AIA changes what constitutes prior art, there has been discussion about the need for the double patenting doctrine once more cases apply the post-AIA patent statutes.⁴⁸⁷ Professor Crouch has said, “[a]t the margins there continues

⁴⁸³ Of course, no legal standard is without ambiguities. It might be argued that trying to determine whether a subsequent species patent was within the scope of an earlier genus patent would be too complicated, but that is a difficult argument to make convincingly. First, the *Ariad* standard already requires a comparison of the disclosure in the specification to the claim. Second, under the strengthened definiteness § 112 standard of *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014), the Supreme Court has held that patent claims “read in light of the specification delineating the patent, and the prosecution history” must “inform, with reasonable certainty, those skilled in the art about the scope of the invention.” Even under the former definiteness standard, the courts appeared to be able to answer that question without any uncertainty. In *Otsuka*, for instance, the district court indicated that the briefs of both parties had noted the claims of the species patent fell within the scope of the genus patent. 2010 WL 4596324, *3. Similarly, in *AbbVie*, the Federal Circuit said that the Trust admitted the claims of the genus ‘766 patent were within the scope of the subsequent species patent. 764 F.3d at 1370.

⁴⁸⁴ 35 U.S.C. § 102(a)(1)(2) (post-AIA).

⁴⁸⁵ Dennis Crouch, *Does Obviousness Type Double Patenting Survive the AIA?* (September 23, 2014), <http://patentlyo.com/patent/2014/09/obviousness-patenting-survive.html> (accessed Dec. 26, 2015) (such as “disclosures originating from the inventors (Section 102(b)); as well as prior patent applications from the same patent-owne[r] and that were still unpublished by the latter filing date (Section 102(b)(2)(c).”).

⁴⁸⁶ *Supra* Part IV(B)(2), note 316 and accompanying text.

⁴⁸⁷ Crouch, *Does Obviousness Type Double Patenting Survive the AIA?*, *supra* note 485 (“What is unclear is whether the courts will be willing to apply the rewritten statute in a way that eliminates old forms of prior art that are no longer part of the statute.”); Olga Berson, *Challenging Patent Validity Under The AIA: Strategic And Tactical Considerations When Deciding Whether To Pursue Ex Parte Reexamination*

to be potential for applicants to ‘play games’ with the filing system in order to extend their effective patent term.⁴⁸⁸ However, he added that the “potential is so reduced from ages past and the statute now defines prior art at such an explicit level of detail that we leave little room for a judicially created doctrine that further eliminates patents.”⁴⁸⁹ Yet, as mentioned above, in the AIA there is now an express statutory basis for obviousness type double patenting, since (1) the CREATE Act of 2003 expressed the intent of Congress that obviousness type double patenting prohibition continue and (2) Section 3(b)(2) of the AIA essentially incorporates the CREATE Act intent into the patent statutes in § 102(c) (post-AIA).⁴⁹⁰ There has been no suggestion that the prohibition on same invention type double patenting would change, since that is based on § 101, and § 101 has not changed under the AIA.⁴⁹¹

¶145 There are at least two areas impacted by the AIA that increase the need for the strengthened double patenting doctrine argued for in this article. The first is the expansion of the ability of pharmaceutical companies to remove existing knowledge and references from the definition of prior art both for purposes of anticipation and obviousness. The second is the elimination of the “best mode” requirement as “a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable . . .”⁴⁹²

¶146 § 102(c) (post-AIA) increases the ability of pharmaceutical companies to prevent existing information from being considered prior art in three ways. First, whereas § 103(c) (pre-AIA) only precluded the information identified in § 103(c) (pre-AIA) from being considered prior art for purposes of obviousness, under AIA § 102(b)(2) and (c) (post-AIA), the identified information cannot be considered prior art either for purposes of obviousness or anticipation.⁴⁹³ Second, whereas under § 103(c) (pre-AIA) the claimed subject matter and earlier invention had to be commonly owned at the time of the claimed invention, under § 102(b)(2) and (c) (post-AIA), the claimed subject matter and earlier invention only have to be commonly owned by the effective filing date of the claimed invention, which gives the pharmaceutical company additional time to remove that

Or Inter Partes Review As Part Of The Overall Litigation Strategy, Aspatore 6 (November 2012), 2012 WL 6636452, p. 6 (“While the AIA has substantially revised Section 102 and adopted a first-to-file priority principle for patent claims based on applications filed on or after March 16, 2013, it is commonly held that ‘the AIA maintains the existing principle that an inventor’s own work does not constitute prior art unless it is a public disclosure more than a year before the application filing date’”) (quoting DONALD S. CHISUM, 2 CHISUM ON PATENTS § 5.03(3)(f); Matal, *supra* note 348, at 486 (“One significant feature of the legislative history of the CREATE Act, effectively given the force of law by section 3(b)(2) of the AIA, is its assurance that double-patenting rules will apply to patent-disclosure subject matter and claimed inventions deemed to be commonly owned pursuant to pre-AIA § 103(c). . . . The Committee Report for the original CREATE Act emphasized that “[t]he doctrine of ‘obviousness-type double patenting,’ a judicial doctrine used by courts to prevent patentees from obtaining an unjustifiable extension of the amount of time to exercise a patent’s right to exclude, shall apply to such patents [i.e., patents benefiting from the CREATE Act.]”) For the legislative history of the CREATE Act, see *supra* note 337.

⁴⁸⁸ Crouch, *Does Obviousness Type Double Patenting Survive the AIA?*, *supra* note 485.

⁴⁸⁹ *Id.*

⁴⁹⁰ *Supra* notes 345–52 and accompanying text.

⁴⁹¹ *Supra* note 172.

⁴⁹² 35 U.S.C. § 282 (b)(3)(A) (post-AIA).

⁴⁹³ Mueller, *supra* note 3, at 291–92.

information from prior art.⁴⁹⁴ Third, post AIA the earlier invention will not be considered prior art to the claimed subject matter if at the effective filing date of the claimed invention, the subject matter disclosed and the claimed invention were “subject to an obligation of assignment to the same person.”⁴⁹⁵ A strengthened double patenting prohibition will be an important compensating balance for this removal of certain references as prior art.

¶147 Second, the effective elimination of the best mode requirement may make it routine for “patentees to attempt to assert both patent rights and trade secret rights for preferred embodiments of their invention in certain types of cases.”⁴⁹⁶ Professors Love and Seaman argue convincingly that this change “provides a strong incentive for inventors to include in current and future patent applications less detail than in applications prosecuted in prior decades.”⁴⁹⁷ They add, “In light of widespread dissatisfaction in the patent community with the level of disclosure and detail in many patents now in force, . . . any reform that lowers the disclosure bar is due a heavy dose of skepticism.”⁴⁹⁸

¶148 Professors Love and Seaman even cite an article from a Baker Botts attorney alerting clients that “the inventor may still pursue patent protection for his or her invention, and seek broadly-worded patent claims covering numerous different implementations, while at the same time maintaining in secret (and thus keeping from the world) his or her best mode for practicing the invention.”⁴⁹⁹ Although the article notes that there would be risk with such an approach that the lowered disclosure might cause a court to find the disclosure defective,⁵⁰⁰ the enticement of less disclosure might cause companies to try such an approach and then subsequently try to patent a narrower species within the genus if courts do not adopt the strengthened double patenting prohibition argued for in this article.

¶149 In a number of ways, therefore, the strengthened double patenting prohibition argued for in this article may be more important post-AIA than pre-AIA.

CONCLUSION

¶150 Patent law should promote innovation and competition not simply for so-called pioneer inventions such as new chemical compositions, but also for improvements to those compositions, such as follow-on drugs. Supporting that goal of promoting competition for improvements, under the double patenting prohibition announced by the Supreme Court in the 1800s, one inventor should not receive two patents covering the same invention. Unlike third parties developing an improvement to a patented product, the First Inventor has already submitted an oath or declaration that she invented the full

⁴⁹⁴ *Id.* at 291.

⁴⁹⁵ 35 U.S.C. § 102(b)(2)(C) (post-AIA).

⁴⁹⁶ Brian J. Love & Christopher B. Seaman, *Best Mode Trade Secrets*, 15 YALE J. L. & TECH. 1 (2012). Thanks to Professor Love for pointing this out to me.

⁴⁹⁷ *Id.* at 15.

⁴⁹⁸ *Id.*

⁴⁹⁹ Robert L. Maier, *The Big Secret of the America Invents Act*, INTELL. PROP. TODAY 20 (Dec. 2011), http://files.bakerbotts.com/files/Uploads/Documents/Maier_DEC11.pdf.

⁵⁰⁰ *Id.* at n.9.

scope of the invention at the time of filing the application for the genus patent.⁵⁰¹ Once the inventor obtains a genus patent on that composition—after that representation—the courts should prevent that inventor and her employer from subsequently obtaining a patent on a species within the genus and further excluding competition. The inventor and the inventor’s employer should not have a second bite at the apple and more years of exclusive rights.

¶151 The rapid rise of prices for pharmaceutical products is a national problem threatening U.S. citizens’ access to life-saving medicines. Returning the double patenting prohibition to the principles announced by the Supreme Court in the 1800s would be a welcome return to historic values, an important step in increasing competition for improvements and a logical step toward constraining the rapid rise in pharmaceutical prices.

¶152 Additional research is necessary to determine whether a similar estoppel argument should apply to the anticipation analysis under § 102 (pre-AIA and post-AIA) when an inventor has obtained a genus patent and subsequently applies for a patent on a species within the scope of the genus patent, and the genus patent is prior art. Should the inventor be estopped under § 102 (pre-AIA and post-AIA) from arguing that the genus patent did not anticipate the species and that she had not really invented the claimed species at the time of filing the application for the genus patent?

⁵⁰¹ See Oskar Liivak, *Overclaiming is Criminal* (Sept. 7, 2016), Cornell Legal Studies Research Paper No. 16-35. Available at SSRN: <https://ssrn.com/abstract=2836165> or <http://dx.doi.org/10.2139/ssrn.2836165> (“Every patent applicant is required to file an oath swearing that the applicant is the ‘original inventor’ of the claimed subject matter.”)

