

2005

The Inventor's Contribution

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Recommended Citation

Robin Feldman, *The Inventor's Contribution*, 2005 *UCLA J.L. & Tech.* 6 (2005).

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Author: Robin Cooper Feldman

Source: UCLA Journal of Law & Technology

Citation: 2005 UCLA J.L. & TECH. 6 (2005).

Title: *The Inventor's Contribution*

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The Inventor's Contribution

Robin C. Feldman¹

Abstract

The patent system, as conceptualized in American legal theory, is an exchange. The system begins by offering incentives for individuals to develop scientific advancements and to reveal those advancements to society. In return for the sphere of rights conferred with the patent, society requires inventors to teach others how to practice their invention. This disclosure is frequently described as the quid pro quo, the inventor's contribution in exchange for the powerful patent grant.

In the last decade, courts have become embroiled in a dispute over whether the disclosure doctrines contain a separate written description requirement. The intensity of the debate reflects the gravity of the issues at stake. Disclosure has become the vehicle for determining the reach of a patent, particularly in the field of biotechnology. As this role has developed, courts have drawn heated criticism for allowing disclosure to venture beyond the technical realm and into broader questions of sufficiency of the invention.

This piece argues that such critics are aiming their fire at the wrong threat. Chaos in the modern disclosure doctrines does not arise because courts are improperly conceptualizing the nature of the disclosure inquiry. On the contrary, the issues addressed in the separate written description doctrine properly reside in the disclosure inquiry and reflect legitimate concerns. The problem, however, lies in the doctrinal approach chosen. The exquisitely complex issues can be resolved by harmonizing disclosure with other areas of patent law and by properly applying traditional disclosure doctrines. A separate written description doctrine is simply unnecessary.

¹ Associate Professor; *Director*, Law & Biosciences Project, U.C. Hastings College of the Law. I am grateful to Margreth Barrett, Dan Burk, Matthew Greene, Mark Lemley, Jeff Lefstin, Rob Merges, Malla Pollack, and Arti Rai for their insights. I wish to thank Greg Kline and Amy Hsiao for their research assistance. I am also indebted to Linda Weir, U.C. Hastings Public Services librarian, for her invaluable research and insights.

Introduction

[¶1] The patent system, as conceptualized in American legal theory, is an exchange.² Bring forth your inventions and, assuming they constitute a sufficient advancement, we will grant you the right to exclude others for a limited time. The logic for the exchange flows from a public policy desire to create incentives for individuals to develop scientific advancements and to reveal those advancements to society at large.

[¶2] One could imagine the foundation of the patent system resting on the natural rights of inventors to hold property interests in the fruits of their intellectual labors. Indeed, such rights-based conceptions of intellectual property can be found in some foreign theories and even in early American debates on the subject of intellectual property rights, particularly copyright.³ Nevertheless, since at least the establishment of the United States Constitution, the American theory of granting patents has rested firmly on the consequentialist ground of promoting the progress of science.⁴ We enter into the bargain to create the consequence of promoting science.

² See, e.g., *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) (noting that exclusive patent rights are given in exchange for disclosing the invention to the public); *Brenner v. Manson*, 383 U.S. 519, 534 (1966) (“The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.”); Michael D. Plimier, *Genentech, Inc. v. Novo Nordisk & University of California v. Eli Lilly and Co.*, 13 BERKELEY TECH. L.J. 149, 149 (1998).

³ See, e.g., Mass. Act of Mar. 17, 1783, reprinted in COPYRIGHT ENACTMENTS OF THE UNITED STATES, 1783-1906, COPYRIGHT OFFICE BULLETIN NO. 3, at 4 (1906) (the preamble noted the purpose of copyright law as encouraging inventions and respecting the “natural rights of all men”). See also Jane C. Ginsburg, *A Tale of Two Copyrights: Literary Property in Revolutionary France and America*, 64 TUL. L. REV. 991 (1990) (includes history of Early American copyright laws and its influence by continental Europe).

⁴ For a description of consequentialist and nonconsequentialist, or rights-based, theories, see UTILITARIANISM AND BEYOND 3-4 (Amartya Sen & Bernard Williams eds., 1982) (describing the consequentialist view that one should evaluate actions based on the state of affairs that will occur as a result) and SAMUEL SCHEFFLER, THE REJECTION OF CONSEQUENTIALISM 4-5 (1982) (describing

[¶3] The terms of the bargain are fairly simple. In exchange for the sphere of rights conferred with the patent, society requires inventors to reveal their inventions. The disclosure requirement is frequently described as the quid pro quo, the inventor's contribution in exchange for the powerful patent grant.⁵

[¶4] In the last decade, the courts have become embroiled in a dispute over the proper requirements for disclosure. Although centered on biotechnology cases, the debate extends into other fields as well.⁶ In particular, the debate concerns whether the disclosure language of the patent act should be read to contain a separate and distinct written description requirement.

[¶5] The Federal Circuit first identified a separate written description requirement in 1997.⁷ Since its emergence, the doctrine has spawned remarkably intense exchanges in the normally calm atmosphere of appellate opinions, with some judges repeatedly calling for a re-examination. The tension in the area was particularly evident in 2004 in the case of *Rochester v. Searle* which applied the written description doctrine. Although the Federal Circuit denied en banc review in the case, the denial itself produced five separate dissenting and concurring opinions, arguing over whether a written description requirement should exist and, if so, what the contours should be.⁸

nonconsequentialist theories as resting on the view that actions may be judged as right or wrong independent of the resulting consequences).

⁵ See, e.g., *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002) (“[D]escription is the quid pro quo of the patent system.”).

⁶ See, e.g., *In re Curtis*, 354 F.3d 1347 (Fed. Cir. 2004) (concerning dental floss); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998) (concerning artificial hip sockets); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998) (concerning sectional sofas); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565 (Fed. Cir. 1997) (concerning automated sales terminals); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991) (concerning double lumen catheters).

⁷ See *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

⁸ See *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303 (Fed. Cir. 2004) (denial of en banc).

[¶6] The call for further illumination, if not complete re-examination, was echoed in a government brief in 2002 which noted politely but pointedly that, “[a]lthough this Court has addressed the “written description” requirement of § 112 on a number of occasions, its decisions have not taken a clear and uniform position regarding the purpose and meaning of the requirement.”⁹

[¶7] The intensity of the debate reflects the gravity of the issues at stake. The disclosure debate, as it is playing out in the courts, has become the vehicle for deciding how far patent rights should reach, particularly in the face of uncertain and rapidly evolving fields such as biotechnology. As this issue has evolved, the courts have drawn heated criticism for allowing the disclosure doctrines, particularly written description, to venture beyond narrow, technical questions and into broader questions of the reach and sufficiency of an invention itself.¹⁰

[¶8] This piece argues that such critics are aiming their fire at the wrong threat. Disclosure, by its nature, encompasses issues related to whether an inventor’s creation is sufficient to obtain the patent rights desired. As the guarantor of society’s receipts in the patent bargain, disclosure plays the role of ensuring that the inventor has given enough. What the inventor reveals must be sufficient, regardless of whether any insufficiency is due to the fact that the patent holder has not given us enough of the invention or the fact that the patent holder simply does not have enough to give.

[¶9] The chaos in the disclosure doctrines does not arise because modern courts are improperly conceptualizing the nature of the disclosure inquiry. On the contrary, the issues that are being addressed in the separate written description doctrine properly reside

⁹ See *id.* at 1309 (Rader, J., dissenting from denial of en banc) (citing brief of amicus curiae at 4-5 requesting en banc consideration in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002)).

¹⁰ See *id.* at 1314.

in the disclosure inquiry and reflect legitimate concerns that arise with rapidly evolving fields such as biotechnology.

[¶10] The problem lies with the doctrinal approach chosen. Creation of a separate written description doctrine is simply unnecessary. The exquisitely complex problems reflected in judicial attempts to create a separate written description doctrine can be solved without a separate written description doctrine.

[¶11] Part I of this article describes the history and development of the modern disclosure doctrines. Part II frames the written description question as encompassing whether an inventor sufficiently possessed something that is later claimed. This part then considers ways to conceptualize the question utilizing doctrines other than disclosure but concludes that the question properly resides in a disclosure inquiry.

[¶12] Having argued that the modern written description doctrine addresses concerns that belong in the disclosure inquiry, Parts III and IV identify how to address those concerns without resorting to the chaos of a separate written description doctrine. Part V describes navigating disclosure issues without a separate written description doctrine. In sum, while the concerns reflected in the modern written description requirement are legitimate and properly reside in the disclosure inquiry, they can be resolved without a separate written description test.

I. Development of the Modern Disclosure Doctrines

[¶13] Since 1790, the patent laws have required that an inventor set forth sufficient information to enable a person skilled in the art to make and use the invention.¹¹ As the Supreme Court noted in 1832, “a correct specification and description of the thing discovered . . . is necessary in order to give the public, after the privilege shall expire, the advantage for which the privilege is allowed, and is the foundation of the power to issue a patent.”¹² The language of the current Patent Act §112 states the following:

[¶14] 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 . . .¹³

[¶15] This language in its current form, and in prior incarnations, has been interpreted to include an “enablement” requirement.¹⁴ The enablement requirement embodies the notion of teaching society what is necessary to practice the invention. The applicant need not have reduced the invention to practice, as long as the inventor provides sufficient information to allow others to practice the invention.¹⁵

[¶16] Although the enablement requirement reaches back to the patent statute of 1790, courts in recent decades have identified a separate and distinct written description requirement in the language cited above. The instinct for a separate written description

¹¹ See 3 DONALD S. CHISUM, CHISUM ON PATENTS § 7.03 (2003).

¹² *Grant v. Raymond*, 31 U.S. 218, 219 (1832); see also *J.E.M. Ag Supply, Inc. v Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 142 (2001) (noting in the context of utility patents that in addition to novelty, utility, and nonobviousness an inventor “must describe the plant with sufficient specificity to enable others to ‘make and use’ the invention after the patent term expires”); *Univ. of Rochester*, 375 F.3d at 1311 (Rader, J., dissenting) (citing *J.E.M. Ag Supply*).

¹³ 35 U.S.C. § 112 (2005).

¹⁴ See 3 CHISUM, *supra* note 11, at § 7.03; see also *id.* at § 7.02 (describing the disclosure requirements as embodied in the Patent Acts of 1790, 1793, 1836, 1870, & 1952).

¹⁵ See, e.g., *Pfaff v. Wells Elecs. Inc.*, 525 U.S. 55, 61 (1998) (“[I]t is well settled that an invention may be patented before it is reduced to practice.”); *Skil Corp. v. Lucerne Prod., Inc.*, 684 F.2d 346, 350 (6th Cir. 1982), *cert. denied*, 459 U.S. 991 (1982) (“[T]he filing of an application is a constructive reduction to practice which completes the invention.”).

requirement flows from the courts' struggle to reign in the expansive reach of patent holders, particularly in fields of great uncertainty.

[¶17] The language of the Patent Act provides ammunition for both sides of the argument of whether § 112 contains a written description requirement separate from enablement. The opening of § 112 states, “[t]he specification shall contain a written description of the invention, *and* of the manner and process of making and using it” (emphasis added).¹⁶ This could be read to suggest that the section contains two requirements: a written description *and* something else related to teaching the world how to make and use the invention.

[¶18] Examining more of the language, however, suggests a different interpretation. The expanded sentence states, “[t]he 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”.¹⁷ This could suggest that all of the early language in the clause simply explains the notion of enablement. From this perspective, the phrases “written description,” “manner and process of making,” and “full and clear terms” all expand on the notion of what is required to properly enable a patent, rather than suggesting something separate from, and in addition to, enablement.

[¶19] Reading the expanded sentence provides a more natural interpretation of the language and comports with a general dictate to interpret legislative intent in light of the

¹⁶ 35 U.S.C. §112 (2005).

¹⁷ *Id.*

complete language written.¹⁸ If this interpretation is accurate, the separate written description test simply should not exist. Nevertheless, given the arguments on both sides, the lack of relevant legislative history, the ambiguity of the language, and the substantial body of current case law applying a separate written description requirement, significant questions remain. In particular, is the modern written description doctrine, in terms of the issues addressed and the approach taken, consistent with the theoretical goals of the § 112 disclosure inquiry?

[¶20] The separate written description requirement began with cases in the late 1960s and early 1970s concerning the proper scope of a patent when an applicant adds claims during the application process.¹⁹ These early cases involved priority issues, in which the court had to determine which of two inventors could properly claim to be the first to invent. The requirement was aimed at preventing applicants from adding new matter to an application as it moved through the Patent and Trademark Office and thereby preventing an accurate determination of which inventor can claim to be first to invent.²⁰

[¶21] Early cases concerned patent holders who initially claimed a group of chemical compounds but, while the application was pending, added claims related to specific compounds within the group.²¹ Later cases concerned other types of modern

¹⁸ See, e.g., *Gen. Dynamics Land Sys. v. Cline*, 540 U.S. 581 at 596 (2004) (quoting *Jones v. United States*, 527 U.S. 373, 389 (1999), quoting *Jarecki v. G.D. Searle & Co.*, 367 U.S. 303, 307 (1961) (reminding that statutory language must be read in context given that a phrase gathers meaning from the words around it)).

¹⁹ See *In re Barker*, 559 F.2d 588, 591 (C.C.P.A. 1977), *cert. denied*, 434 U.S. 1064 (1978) (finding that the court has clearly recognized a written description requirement separate and distinct from the enablement requirement); 3 CHISUM, *supra* note 11 at § 7.04.

²⁰ See *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004); see also 35 U.S.C. § 132 (2005) (requiring that an amendment cannot introduce new matter into the disclosure of the invention).

²¹ See *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967); see also *Fields v. Conover*, 443 F.2d 1386 (C.C.P.A. 1971).

technologies and eventually more traditional technologies such as wooden shingles and reclining sofas.²²

¶22] As with all other moments in the life of the separate written description doctrine, the extension of the doctrine to simple, mechanical inventions drew heated criticism. For example, in a case concerning application of the separate written description doctrine to wooden shingles, Chief Judge Markey filed a spirited dissent noting the following:

¶23] I respectfully, but heartily dissent. . . . How incongruous. How exaltive of form over substance. How illustrative of stare decisis rampant. . . . The attempt to create historical and current statutory support for a “separate description” requirement, which was solely a judicial . . . response to chemical cases . . . is mistaken.²³

¶24] The Federal Circuit, and its predecessor Court, the Court of Customs and Patent Appeals, added the separate written description requirement in priority cases “to ensure that the inventor had possession, as of the filing date . . . of the specific subject matter later claimed.”²⁴ The doctrine reflected concerns about patent holders who mark out broad territory with their claims and then fill in information later, either as their own

²² See, e.g., *Reiffin v. Microsoft Corp.*, 214 F.3d 1342 (Fed. Cir. 2000) (concerning alleged infringement of plaintiff’s patent on multithreaded computer application); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998) (concerning reclining sofas); see also *Barker*, supra note 19 at 588 (concerning wooden shingles).

²³ *Barker*, supra note 19 at 594 (Markey, J. dissenting).

²⁴ *In re Wertheim*, 541 F.2d 257, 262 (C.C.P.A. 1976); see also *Purdue Pharma, L.P. v. F.H. Faulding & Co.*, 48 F. Supp. 2d 420, 427, 430 (D. Del. 1999), *aff’d* 230 F.3d 1320 (Fed. Cir. 2000) (noting that the policy behind the written description requirement is to prevent overreaching and post hoc claims that were not part of the original invention; “to show that at the time of the filing, the inventor was in possession of what is now claimed.”); cf. Timothy R. Holbrook, *Enabling Enablement in Patent Law*, (unpublished manuscript on file with author *available at* <http://justinhughes.net/ipsc2005/papers/Paper-HOLBROOK.doc>) (last modified July 25, 2005) (arguing in the context of enablement, rather than written description, that the law should focus only on confirming possession as the theoretical goal as opposed to other goals such as teaching society to practice the invention).

research advances or as they see the research of others advance.²⁵ The focus was on the interplay between original claims and claims added while the patent was pending at the Patent and Trademark Office.²⁶

[¶25] In the 1997 *Lilly* case, however, the Federal Circuit expanded written description beyond priority cases.²⁷ The patent holder in *Lilly* had created rat insulin through a process that involved rat DNA.²⁸ DNA is made up of a sequence of building blocks known as nucleotides.²⁹ The patent holder in *Lilly* isolated and identified the segment of rat DNA that coded for rat insulin. The patent holder succeeded in transferring that nucleotide sequence to a vector, essentially a piece of carrier DNA that would accept and absorb the rat sequence.³⁰ The patent holder then transferred the vector containing the rat DNA sequence to a microorganism in which the sequence would continue its work of coding for rat insulin.³¹

[¶26] Based on this work with the rat genome, the patent holder included not only claims related to rat insulin, but also claims to things such as any plasmid vector containing any mammalian sequence coding for mammalian insulin and capable of inclusion in a microorganism to replicate a mammalian insulin, including human insulin.³² In other words, the patent holder claimed that information obtained in the

²⁵ See *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (quoting *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991) for the proposition that written description guards against the inventor overreaching by insisting that the inventor recount sufficient detail to determine whether future claims can be encompassed within the original creation).

²⁶ See 3 CHISUM, *supra* note 11, at § 7.04[1][c].

²⁷ *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

²⁸ See *id.* at 1562.

²⁹ See BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 46 (3d ed. 1994).

³⁰ See *Regents of the Univ. of Cal.*, 119 F.3d at 1563 (describing the claims) and 1567-68 (noting that the applicants description of the portion of rat DNA that codes for rat insulin was insufficient to cover claims of mammalian DNA). For a detailed explanation of recombinant technology, see ALBERTS ET AL., *supra* note 29, at 1375-76.

³¹ See *Regents of the Univ. of Cal.*, 119 F.3d at 1563.

³² See *id.*

discovery of rat insulin, combined with knowledge in the field about sequencing and manipulating DNA segments, provided sufficient disclosure of the steps to obtain all mammalian insulin.

[¶27] The notion of claiming a group of items based on production of a subset of those items was not new to patent law. The question for the *Lilly* case, however, concerned what would be required to show that the patent holder's invention could properly encompass the full group. The Federal Circuit answered that question in *Lilly* by requiring that claims for DNA related inventions must be supported by a description of the nucleotide sequence.³³ In *Lilly*, the patent holder's claims to inventions related to insulin created from human DNA failed because the patent holder had only provided the nucleotide sequence of the relevant rat DNA, not the human DNA.

[¶28] *Lilly* did not rule out the possibility of claiming a group of items such as all mammalian insulin by defining only a subset of items. The decision, however, required that the inventor must be able to describe features common to a substantial portion of the group and to describe those features with particularity such as reference to a common nucleotide sequence.³⁴

[¶29] Having failed to support claims related to DNA that codes for human insulin with work on rat DNA, the patent holder tried another approach. The patent holder tried to support its claims to the human DNA that codes for insulin by providing information on the human insulin itself. In particular, the patent holder argued that providing the amino acid sequence of the human insulin is sufficient to claim inventions related to the

³³ See *id.* at 1569.

³⁴ See *id.*

human DNA even without providing the nucleotide sequence of the human DNA.³⁵ This too proved insufficient for the court given the relationship between DNA and proteins such as insulin.³⁶

[¶30] As described before, DNA is composed of nucleotide building blocks. The sequence of the nucleotides operates as instructions which a cell may translate to produce a given protein.³⁷ Proteins are *not* made up of nucleotides. They are comprised of a sequence of amino acids folded into complex, three-dimensional shapes.³⁸ Life would be much simpler if the translation of the DNA nucleotide sequence into the amino acid sequence of a protein involved simple one-to-one matching. Unfortunately, different combinations of nucleotides can produce the same amino acid, and an enormous number of combinations can be contemplated that could code for a particular amino acid sequence.³⁹ As a result, the *Lilly* court declined to find that having the amino acid sequence of the protein could support claims related to the DNA.⁴⁰

[¶31] Having identified a separate written description requirement for all disclosure cases, not simply those in the narrow area of priority, the *Lilly* court had to answer two questions. First, what constitutes a sufficient written description for a single, DNA related invention? Second, what constitutes a sufficient written description to claim a group of DNA related inventions based on information concerning only one or a few

³⁵ See *id.* at 1567.

³⁶ See *id.*

³⁷ See ALBERTS ET AL., *supra* note 29, at 106.

³⁸ See *id.*

³⁹ See *id.*; *cf.* In re Deuel, 51 F.3d 1552, 1558 (Fed. Cir. 1995) (noting that a prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein); In re Bell, 991 F.2d 781, 785 (Fed. Cir. 1993) (noting same).

⁴⁰ See Regents of the Univ. of Cal, 119 F.3d at 1567.

members of the group? The *Lilly* court answered both questions with the same requirement: nucleotide sequence.

[¶32] In light of this requirement, the patent holder in *Lilly* could not satisfy written description based on its work with rat DNA because an inventor would not be permitted to move from a subset to the full mammalian group unless the relevant DNA sequences were the same for all members of the group. While human and rat DNA coding for insulin might be similar, even substantially similar, they would not be the same.⁴¹ In addition, the *Lilly* patent holder could not satisfy written description based on knowledge of the amino acid sequence of the protein because the amino acid sequence of a protein does not directly yield the nucleotide sequence of the DNA.⁴²

[¶33] Delineating the contours of the expanded written description requirement proved quite difficult for the Federal Circuit in the cases following *Lilly*. For example, in the *Enzo Biochemical* case in 2002, the Federal Circuit initially held that a patent failed to satisfy the written description requirement when the inventor deposited a sample of the relevant material rather than providing the nucleotide sequence. At the time of *Enzo* patent holders had routinely deposited genetic inventions rather than sequencing them. The decision produced such a firestorm of criticism that the Federal Circuit vacated and reissued the opinion three months later.⁴³ In the reissued *Enzo* opinion, the Federal Circuit found that deposit satisfies the written description requirement.⁴⁴ The court suggested further that the structural details of sequencing might not be necessary where

⁴¹ See *Univ. of Cal. v. Eli Lilly & Co.*, 39 U.S.P.Q.2d 1225, 1241 (noting that the rat insulin sequence differed by four amino acids from the human insulin sequence).

⁴² See *id.*

⁴³ The first opinion issued April 2, 2002. The opinion was reissued on July 15, 2002. See *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002).

⁴⁴ See *id.*

sufficient information concerning the link between function and structure of the group exists.⁴⁵

¶34] Although *Enzo II* expanded the methods of satisfying the written description requirement for genetic inventions beyond simply providing the nucleotide sequence, the opinion left much confusion in its wake, including what relationship between structure and function would suffice to allow a patent holder to reach from an individual invention to the group. In addition, *Enzo II* appears to be directly in conflict with the *Lilly* requirements for nucleotide sequencing.

¶35] Moreover, having explained that the written description requirement is separate and distinct from enablement, the court has been unable to articulate a workable line between the two. As Judge Rader noted in a recent dissent, separating out written description and enablement gives trial courts the unenviable task of explaining to jurors that the patent's disclosure can enable a skilled artisan to make and practice the invention, but still not inform that same artisan that the inventor was in possession of the invention.⁴⁶ How is it possible that the invention could enable a skilled artisan to make the invention yet not inform the inventor, presumably also a skilled artisan, of the same information in a way that the inventor could articulate it in a patent application? After eight years, the doctrine is chaotic at best.⁴⁷

⁴⁵ See *id.* at 1324-25 (adopting the PTO Guidelines view that written description may be satisfied for a group where sufficient correlation between structure and function is known for the group).

⁴⁶ See *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004) (Rader, J., dissenting to the denial of review en banc).

⁴⁷ See, e.g., Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 CASE W. RES. L. REV. 691 (2004); Note: Stephen J. Burdick, *Moba v. Diamond Automation, Inc.: Questioning the Separate Written Description Requirement*, 19 BERKELEY TECH. L.J. 133, 151 (2004) (criticizing the written description requirement for creating confusion without supplementing the enablement requirement); Harold C. Wegner, *The Disclosure Requirements of the 1952 Patent Act: Looking Back and a New Statute for the Next Fifty Years*, 37 AKRON L. REV. 243, 244 (2004) (describing the separate written description requirement as a problem of judicial activism); Warren D. Woessner, "Do Over!"—*The Federal Circuit*

II. Criticism of Expanding Written Description Beyond Priority

[¶36] Although the *Lilly* decision has received considerable criticism,⁴⁸ a significant focus of the criticism has centered on expanding the written description requirement beyond priority cases.⁴⁹ In particular, dissenting judges have argued that the *Lilly* doctrine takes a question intended to resolve a limited, technical issue and transforms the question into a full-blown inquiry into the validity of the patent. As a result, the core patentability inquiry rests on the written description language of § 112, language which is insufficient to bear such weight.⁵⁰ This line of criticism implies that

Takes a Second Look at Enzo v. Gen-Probe, 85 J. PAT. & TRADEMARK OFF. SOC'Y 275, 285 (2003) (urging the court to deliver *Lilly* and *Enzo* to the “doctrinal scrap heap” in order to allow biotechnology patent law to continue productively); Eli A. Loots, *The 2001 USPTO Written Description Guidelines and Gene Claims*, 17 BERKELEY TECH. L.J. 117, 134 (2002) (characterizing the current conflict between the norms of the scientific community and the legal system as a “widening gulf”); Mark D. Janis, *On Courts Herding Cats: Contending with the “Written Description” Requirement (And Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U. J.L. & POL'Y 55, 62-63 (dissecting arguments in favor of a separate written description doctrine and concluding that neither the Federal Circuit nor the C.C.P.A. has ever articulated a persuasive rationale for distinguishing the written description requirement from the enablement requirement); Kevin S. Rhoades, *The Section 112 “Description Requirement”—A Misbegotten Provision Confirmed*, 74 J. PAT. & TRADEMARK OFF. SOC'Y 869, 869-70 (1992) (arguing that the separate written description requirement is not supported by either the language or the history of Section 112).

⁴⁸ For example, in an opinion dissenting from the Federal Circuit’s refusal to hear *University of Rochester v. Searle*, en banc, Judge Rader lists thirty-one academic articles criticizing the *Lilly* decision. See *University of Rochester v. G.D. Searle & Co., Inc.*, 375 F.3d 1303, 1314 (Fed. Cir. 2004).

⁴⁹ See, e.g., *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 977 (Fed. Cir. 2002) (Rader, J., dissenting) (denial of rehearing en banc); Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 834-35 (Fall, 1999) (noting that *Lilly* broke new ground in applying written description to claims filed in the original patent rather than later-filed claims and criticizing the move as a form of elevated enablement); Shraddha A. Upadhyaya, *The Postmodern Written Description Requirement: An Analysis of the Application of the Heightened Written Description to Original Claims*, 4 MINN. INTELL. PROP. REV. 65, 120-21 (2002) (arguing that the “written description requirement cannot and should not serve any function other than to guarantee that subsequently filed claims are entitled to the benefit of the original application”); see also Janis, *supra* note 47, at 60 (arguing that the written description requirement enjoys a prominence wholly out of proportion to its humble origins).

⁵⁰ See *Enzo Biochem*, 323 F.3d at 988 (Linn, J., dissenting) (denial of rehearing en banc) (arguing that the new written description elevates possession to the posture of a statutory test of patentability, which it is not, and fosters further confusion in what is already a confusing area of Federal Circuit precedent); *Univ. of Rochester*, 375 F.3d at 1307-08 (Rader, J., dissenting) (denial of rehearing en banc) (arguing that in a sense, the *Eli Lilly* doctrine converts confusing Federal Circuit doctrine into a validity question).

the expanded written description doctrine reaches issues that have not existed in the disclosure inquiry and do not belong in that inquiry.

[¶37] The written description inquiry in non-priority cases, however, addresses the same theoretical issue as in priority cases. In priority cases, the question is whether the inventor had something when that thing is added later in the application process. In non-priority cases, the question is whether an inventor had something when that thing emerges in the scientific world after the patent has been granted. The difference between the two inquiries is just a matter of timing. Did an inventor try to reach beyond the initial invention during the patent prosecution process or did the inventor try to reach beyond the initial invention after the patent was granted? Both circumstances, however, concern how far an inventor can reach given the disclosure provided.

[¶38] Given that priority and non-priority cases concern the same issue, the relevant question is not whether it is improper to expand written description. Rather, the relevant questions are whether the issues addressed in the modern written description test properly belong in the disclosure inquiry and whether the current written description doctrine adequately resolves those issues.

[¶39] The question of whether an inventor actually had what is later claimed manifests as two different types of problems, regardless of whether the question arises in a priority or a non-priority setting. These are narrowing problems and expanding problems. With a narrowing problem, the inventor identifies and provides information on a broad range of substances without adequately explaining how to choose among the substances to reach the desired result. To determine whether there is a narrowing

problem, a court essentially is asking, “Did you really teach us how to practice your invention or did you give us the alphabet with assurances that we could compose Shakespeare?”

[¶40] The classic case of a narrowing problem is *In re Ruschig*, a case that concerned a chemical compound used for treating diabetes.⁵¹ The original specification in the application identified a formula that could encompass approximately half a million compounds.⁵² The specification also disclosed some particular compounds, but not the one at issue in the case.⁵³ The patent holder added the compound at issue in an amendment to the application, at a time when a competitor had already begun using the compound for the treatment of diabetes.⁵⁴

[¶41] The patent holder argued that a skilled chemist would have found certain indicators in the specification to significantly narrow the choices from the half a million possible compounds and that other indicators in the specification would have led a chemist eventually to the specific formula later claimed.⁵⁵ The court rejected the claim, arguing that the patent holder had failed to adequately guide anyone toward the actual compound:

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

⁵¹ See *In re Ruschig*, 379 F.2d 990, 991 (C.C.P.A. 1967).

⁵² See *id.* at 993.

⁵³ See *id.*

⁵⁴ See *id.* at 991.

⁵⁵ See *id.* at 993-94. For a good, brief description of the formula and the compounds at issue in *In re Ruschig*, see Joseph M. Manak, *The Law of Written Description in Pharmaceutical and Biotechnology Patents*, 23 BIOTECH. L. REP. 30, 36-37 (2004).

Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.⁵⁶

[¶43] The possession problem in *Ruschig* concerned a failure to sufficiently narrow the field. The court was unwilling to accept naming a large group without some indication of how to navigate the group to arrive at what was eventually claimed.⁵⁷

[¶44] Possession problems also may manifest in the form of attempts to expand the field. The *Lilly* case offers such an example.⁵⁸ In *Lilly*, the patent holder's specification identified and explained how to obtain the segment of rat DNA that coded for rat insulin. From that information, the inventor claimed all mammalian segments of DNA that code for mammalian insulin. The court, however, refused to allow the inventor to expand beyond the examples described in order to reach human or mammalian substances.

[¶45] Regardless of whether the problem is one of improperly narrowing or improperly expanding the information initially provided in the patent application, both inquiries concern whether the inventor had sufficient possession of what is later claimed. There might be varying reasons why the inventor did not have possession.⁵⁹ In either case, however, the core question is whether this inventor had possession of what is later claimed.

⁵⁶ See *Ruschig*, 379 F.2d at 994-95.

⁵⁷ *Ruschig* is considered one of the classic cases in which the court begins to identify a written description requirement separate and distinct from enablement. See, e.g., *Upadhyaya*, *supra* note 49. In particular, the court noted that “[it] is beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him.” See *Ruschig*, 379 F.2d at 995. Although the *Ruschig* court identified the problem as outside enablement, however, the court did not yet suggest an additional requirement in § 112. Rather, the court suggested that the problem was outside § 112 entirely, identifying it as a “fact” problem. See *id.*

⁵⁸ See *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); see also text accompanying notes 27-32 (describing the *Lilly* case).

⁵⁹ See *infra* notes 76-79 (explaining that lack of possession could exist either because the information was not knowable given the state of the art or because the inventor did not appreciate the information, even though those skilled in the art would have).

[¶46] One could ask whether this entire line of inquiry -- whether an inventor sufficiently possessed something that is later claimed -- belongs in a disclosure analysis at all. One could, for example, conceptualize the question as part of a novelty inquiry. The novelty inquiry ordinarily asks whether an invention is new to society as measured against the prior art.⁶⁰ In theory, one could ask not only whether the invention is new, but whether the invention is new to the inventor, that is, whether the inventor actually invented it.

[¶47] Such a concept would make novelty more analogous to the copyright originality requirement, in which we ask whether the work has both sufficient creativity and whether the author independently created the work.⁶¹ The question of whether an inventor sufficiently possessed something that is later claimed would then manifest as a variant of the idea that the work must be the inventor's work rather than someone else's work. In this case, the "someone else" would be someone who has come later or perhaps has not come at all.⁶²

[¶48] Novelty inquiries, however, generally focus on a different set of issues. As currently conceptualized, novelty presupposes that the inventor actually gave us something. The task of novelty, then, is one of weighing and measuring what the inventor has given against what has come before.

⁶⁰ See 35 U.S.C. § 102 (2005) (noting the novelty requirement); JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 93-94 (2003) (describing novelty).

⁶¹ See *Feist Publ'ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 345 (1991) (defining copyright originality as requiring independent creation and a modicum of creativity). Note, however, that the creativity requirement in copyright is a far easier standard to meet than the novelty requirement in patent. See, e.g., *id.* ("To be sure, the requisite level of creativity is extremely low; even a slight amount will suffice. The vast majority of works make the grade quite easily, as they possess some creative spark, 'no matter how crude, humble or obvious' it might be."); see also 1 M. NIMMER & D. NIMMER, COPYRIGHT §§ 2.01[A], [B] (2005) (explaining that the originality requirement is lower than that of novelty so that even if a work is substantially similar to another, it will be worthy of copyright protection as long as it was independently created).

⁶² Cf. *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1314 (Fed. Cir. 2004) (raising the possibility that the written description question in *Rochester* could be characterized as a § 102(f) problem).

[¶49] The novelty language of the Patent Act § 102(f) does contain a provision denying patentability if the inventor “did not himself invent the subject matter sought to be patented.”⁶³ This language is broad enough to cover the notion that the invention did not properly exist through the work of this inventor but rather was created later, when someone else came along. Section 102(f) inquiries, however, generally concern more mundane issues, such as whether the wrong name has been listed as the inventor or whether the inventor told someone else about the invention and the other person raced off to the patent office.⁶⁴

[¶50] The question of whether an inventor sufficiently possessed something that is later claimed also could be part of a utility inquiry. The patent statute requires that an invention must be both “new and useful.”⁶⁵ Following this language, inventors are required to demonstrate a use for their invention beyond that of “a mere curiosity, a scientific process exciting wonder yet not producing physical results . . . not aiding in the progress nor increasing the physical possession of the human race.”⁶⁶

[¶51] In theory, utility could include not only the notion that the invention must do something, but also that the invention must do what the inventor says it does. In other words, utility could include the concept that the invention actually works. There are certainly strains of this concept in some patent cases. For example, in 1989, the Federal

⁶³ 35 U.S.C. § 102(f) (2005).

⁶⁴ See, e.g., *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321 (Fed. Cir. 2000); *Davis v. Reddy*, 620 F.2d 885, 889 (C.C.P.A. 1980); Timothy R. Holbrook, *Territoriality Waning? Patent Infringement for Offering in the United States to Sell an Invention Abroad*, 37 U.C. DAVIS L. REV. 701, 712 (2004) (explaining that under § 102(f), if the inventor stole something, he cannot patent it); Anna Martina Tyreus, *Note, H.R. 2391: Protecting Universities in Collaborative Research*, 82 WASH U. L.Q. 557, 564 (2004); Jennifer Gordon, *Preparing and Prosecuting a Patent that Holds up in Litigation*, 766 PLI/PAT 873, 887 (2003) (explaining § 102(f) in conjunction with incorrect inventorship or dishonesty with respect to naming inventors); Mark A. Lemley & Colleen V. Chen, *Are the U.S. Patent Priority Rules Really Necessary?*, 54 HASTINGS L.J. 1299, 1326 n.84 (2003) (noting that § 102(f) prevents one party from taking an idea from another).

⁶⁵ 35 U.S.C. § 101 (2005).

⁶⁶ 1 WILLIAM ROBINSON, TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS 463 (1890).

Circuit upheld denial of a patent for a perpetual motion machine.⁶⁷ Among other grounds, the Federal Circuit agreed with the lower court that the application failed the utility standard because it did not work.⁶⁸ Similarly, in 1985, the Federal Circuit denied rights to an inventor who claimed to be able to improve the flavor of beverages by passing them through a magnetic field.⁶⁹ The court was unimpressed with an affidavit from a food science professor who had conducted taste tests.

[¶52] One way of thinking about the question of whether the invention works is whether we could achieve the results the inventor claims if we follow what the inventor tells us. This is another way of getting at the issue of whether the inventor has given us enough that we will grant a patent right.

[¶53] The possibility of framing in a utility context the question of whether an inventor has made a sufficient contribution is evident in the Patent and Trademark Office Guidelines on Utility. The guidelines require, for example, that meeting the utility requirements for an expressed sequence tag, essentially a sub portion of a gene sequence, requires demonstrating not just a general use as a probe for fishing out a gene but rather a specific use such as one associated with a particular disease process. Through this approach, utility becomes a way of approaching the question of whether the inventor has given enough to receive a grant of rights.

[¶54] Despite potential analysis as a utility or novelty question, the question of whether an inventor possessed something to a sufficient extent that the inventor could

⁶⁷ *Newman v. Quigg*, 877 F.2d 1575 (Fed. Cir. 1989), *cert. denied*, 495 U.S. 932 (1990).

⁶⁸ *Id.* at 1581; *see also* ROBERT P. MERGES, PETER S. MENELL & MARK A. LEMLEY, *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 163-64 (2d ed. 2000) (describing the *Newman* case).

⁶⁹ *Fregeau v. Mossinghoff*, 776 F.2d 1034 (Fed. Cir. 1985).

claim rights in that thing has been channeled primarily into the disclosure inquiry.⁷⁰

Locating the possession question in a disclosure inquiry fits logically with the theory of disclosure. As described above, disclosure is the quid pro quo, an inventor's contribution to society in exchange for the patent rights. We evaluate whether you have satisfied your disclosure obligation by asking whether you have delivered your contribution. One can think of possession as a threshold question for an inventor's ability to satisfy the quid pro quo. If you never had it, you could not have given it to us, and you could not have satisfied your end of the bargain. The ability to give to society begins with actual possession of something to give.

[¶55] One could conceptualize the analysis of the inventor's contribution in two different ways, as a patentability question or as a scope question. On the one hand, one could frame the question as "did the inventor give society enough to secure rights." This is essentially a patentability question which asks whether you fulfilled your end of the bargain sufficiently that you will receive a patent.

[¶56] On the other hand, one could frame the question as "how much should the inventor receive based on what the inventor gave." This is essentially a question of

⁷⁰ See *Moba v. Diamond Automation*, 325 F.3d 1306, 1320 (Fed. Cir. 2003) ("The test for compliance with § 112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing."); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1329 (Fed. Cir. 2002) ("The purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." (citations omitted)); *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) ("The written description requirement and its corollary, the new matter prohibition of 35 U.S.C. § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date."); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) ("The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.'" (citation omitted)). *But cf. In re Brana*, 51 F.3d 1560, 1563 n.9 (Fed. Cir. 1995) (citing the patent examiner's comment in the briefs that the patent's failure to satisfy disclosure, which stemmed from a failure to demonstrate that the compound actually reduced tumors as claimed, could also be characterized as a utility problem).

scope. Perhaps you have not given us enough from your end of the bargain that we will give you all that you have asked for in your claims, but we will give you something less.

[¶57] The analysis of the inventor's contribution, therefore, can be conceptualized either as a question of whether the inventor gave enough to receive rights or as a question of the scope of rights that the inventor will receive. Both conceptualizations are aspects of weighing the inventor's contribution, as measured by the disclosure. Both ask whether the inventor's contribution is sufficient to receive the requested rights.⁷¹

[¶58] In sum, the modern written description requirement focuses on questions related to whether an inventor originally possessed something that is later claimed. Although some critics would limit the inquiry to priority cases, the question of whether an inventor initially possessed something added while the patent was pending involves the same issues as the question of whether the inventor initially possessed something that the inventor tries to reach after the patent was granted. Both questions concern the inventor's ability to provide a sufficient contribution. This question properly resides in the disclosure inquiry, the vehicle by which we measure an inventor's ability to satisfy his end of the patent bargain with a sufficient contribution.

III. Information Unknowable at the Time of the Invention

⁷¹ See *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 969 (Fed. Cir. 2002) [hereinafter, *Enzo II*], in which Judge Lourie suggested a more narrow interpretation of what would satisfy possession. The opinion suggested that the possession inquiry might be satisfied simply by producing an affidavit. Judge Lourie argued that written description surely must encompass more than that and therefore must involve more than a possession inquiry.

I agree with Judge Lourie that the concepts embodied in the written description inquiry certainly could not be satisfied so simply. This is true, however, not because written description necessarily extends beyond possession but because the concept of possession reaches to broader theoretical ground.

[¶59] As described in the section above, the modern written description requirement asks whether an inventor had possession of something that the inventor tries to reach after the initial application. The answer would be much easier if we never allowed an inventor to reach beyond what the inventor actually did. If that were the case, disclosure would be a matter of asking whether you told us enough about what you did. Measuring the inventor's contribution, however, is vastly complicated by the fact that the patent system allows an inventor to reach to far more than what the inventor has actually done.

[¶60] In particular, under classic patent doctrine, one who invents a product may exclude others from the full spectrum of the product, including any use of the product and a range of other embodiments of the product. A patent holder need only identify a single use and a single embodiment for the product to receive rights to a wide range of embodiments and all uses.⁷²

⁷² See, e.g., *Schering Corp. v. Gilbert*, 153 F.2d 428 (2d Cir. 1946); *Maurer v. Dickerson*, 113 F. 870, 874 (3d Cir. 1902) (finding that “the claim is not restricted to the product made by the described process, but covers the chemical individual, however produced”); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1335 (Fed. Cir. 2003) (noting that “the law makes clear that the specification need teach only one mode of making and using a claimed composition”); *Utility Examination Guidelines*, 66 Fed. Reg. 1092, 1095 (Jan. 5, 2001) (noting that a patent on a composition gives exclusive rights to the composition for a limited time, even if the inventor disclosed only a single use); Symposium, *The Human Genome Project, DNA Science and the Law: the American Legal System's Response to Breakthroughs in Genetic Science*, 51 AM. U. L. REV. 371, 392 (2002) (noting that the law extends patent rights to unknown embodiments with unknown utilities when the inventor has disclosed one embodiment with one utility); Ellen P. Winner, *Enablement in Rapidly Developing Arts – Biotechnology*, 70 J. PAT. & TRADEMARK OFF. SOC'Y 608, 611 (Sept. 1988) (noting that “[a] claim to the composition of matter is not limited to the method of making and using ... taught by the inventor”); Robin C. Feldman, *Rethinking Rights in Biospace* (manuscript on file with author) (describing the one embodiment doctrine); see also *Chiron Corp. v. Genentech, Inc.* 363 F.3d 1247, 1254 (Fed. Cir. 2004) (noting that an inventor need not enable technology that arises after the invention); *Continuous Curve Contact Lenses, Inc. v. Nat. Patent Dev. Corp.*, 214 U.S.P.Q. 86, 113 (C.D. Cal. 1982) (noting it is well established that product claims without process limitations cover the product no matter how it is produced); *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991) (noting that it is not necessary that a patent application test all embodiments of an invention); *In re Angstadt*, 537 F.2d 498, 502 (C.C.P.A. 1976) (same); *In re Hogan*, 559 F.2d 595, 606 (C.C.P.A. 1977) (holding that a patent applicant need not enable later developed technology). But see 3 CHISUM, *supra* note 11, at § 7.05[1] (noting early cases with contrary results).

¶61] The one embodiment doctrine has the potential to conflict with efforts to identify whether a patent holder possessed something for the purposes of satisfying disclosure. If an inventor can reach beyond what the inventor actually has, how do we make sense out of the question of whether the inventor possessed something?

¶62] In theory, one could rationalize the possession inquiry and the one embodiment doctrine by saying that we are asking whether the inventor possessed enough to count as a single embodiment, after which the inventor will get all. This formulation, however, cannot answer the question of whether an individual invention should be interpreted to include a larger group. In that case, it is clear that the inventor has described a single embodiment. The question is whether the single embodiment can reach to the larger group. That is precisely the reach that courts have been attempting to limit by stressing the possession requirement in the context of applying the disclosure doctrines. Questions related to whether a single embodiment can reach to the larger group bring the possession inquiry directly into conflict with the one embodiment doctrine.

¶63] Moreover, even issues related to defining what counts as a single invention can be characterized both as a problem of identifying a relevant group and as a simple issue of different embodiments of the same product. Recall, for example, that in *Lilly*, the Federal Circuit used possession to restrict an inventor of the rat form of insulin-encoding DNA from reaching to the full mammal group. The court viewed the question in the case as whether the rat inventor could reach to the larger mammalian group.

¶64] One could also characterize the issue, however, as a question of different embodiments of the same invention. From this perspective, the human form of insulin-

encoding DNA is just the rat form made out of a different material. The material may have slightly different properties and may be appropriate in different settings and uses, but that is equally true of doorknobs made out of glass as opposed to wood. Just as glass doorknobs may break too frequently or cause safety problems in a pre-school, so rat insulin may be inappropriate for use in humans. One might assume that the term “doorknob” or “chair” connotes a single invention for which we then grant different embodiments. On the contrary, the notion of defining a chair is always a question of delineating the proper group, just as the criticism that an inventor is reaching too widely to a group can be reframed in terms of whether the inventor is simply asking for a different embodiment.

[¶65] The comparison of DNA to doorknobs is not a perfect one, but it does expose the underlying conflict between requiring possession and allowing one embodiment to bring all rights. If we allow an inventor to reach beyond what an inventor actually has, how do we frame the question of whether the inventor has something in hand?

[¶66] As a result of this conflict, attempts to clamp down on an inventor’s reach by requiring possession inevitably clash with the notion that one embodiment gets all. Current case law has failed to recognize the contradiction. Rather, courts find themselves on the one hand, saying, “you have to describe everything with great precision” and on the other hand saying, “no, you don’t.”⁷³ Efforts to navigate the conflict have created a chaotic set of inconsistent doctrines.

⁷³ Compare *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1328 (Fed. Cir. 2003) (holding that patent holder can reach to embodiments that could not have been known at the time of the invention and therefore need not describe those embodiments) with *Chiron v. Genentech*, 363 F.3d 1247, 1254 (Fed. Cir. 2004) (holding that patent holder cannot reach to embodiments that could not have been known at the time of the invention because those embodiments were not described).

¶67] The conflict is not irresolvable. The solution requires separating the difficult disclosure problems into two categories: 1) the inventor didn't initially describe what is at issue because no one could have known it given the state of the art; and 2) the inventor didn't initially describe what is at issue because the inventor did not appreciate it, but it could have been known given the state of the art.⁷⁴ In other words, the cases can be separated according to whether the information omitted could have been known at the time of the application. In both of these categories, the problems can be solved without resorting to a separate written description doctrine.

¶68] Consider first circumstances in which the inventor did not initially describe what is at issue because of information that could not have been known at the time of the invention. Examples of this include the case of *Amgen v. Hoechst*, which concerned rights to the protein erythropoietin ("EPO"). EPO is a naturally occurring human hormone that controls the formation of red blood cells and has proven extremely useful in the treatment of anemia.⁷⁵

¶69] The patent holder in *Hoechst* obtained EPO using traditional recombinant DNA techniques.⁷⁶ The patent holder identified and isolated the human gene that is used to produce the protein EPO, created the reverse transcript of the gene, transferred that segment into a circular piece of carrier DNA, transferred the carrier DNA into a host cell (in this case Chinese hamster ovary cells), and induced the host cell to use its own

⁷⁴ For example, in *Spero v. Ringold*, the court concluded that although the inventor did not know of the configuration, those skilled in the art would have known. *See Spero v. Ringold*, 377 F.2d 652 (C.C.P.A. 1967).

⁷⁵ *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1319 (Fed. Cir. 2003).

⁷⁶ *See id.* at 1321. For a description of the technology in the case, see Feldman, *supra* note 72.

transcription machinery to produce EPO.⁷⁷ Based on this work, the inventor then received a patent including claims to all “non-naturally occurring EPO.”⁷⁸

[¶70] The inventor of the accused product also began with the isolated human gene that controls the production of EPO. In contrast to traditional recombinant DNA techniques, the second inventor essentially determined how to spike the start mechanism of the isolated gene, thereby inducing it to create large amounts of EPO that could be administered to patients.⁷⁹

[¶71] The second invention easily could have been considered outside the reach of the patent. At the very least, the second invention was created with technology that could not have been known at the time of the invention.⁸⁰ The common ancestor of all of Amgen’s patents in question was filed in 1984. The technological underpinnings that would lead to the Hoechst patent were not reported in the scientific literature until 1988 at the earliest.⁸¹

[¶72] In addition, one could argue that the EPO produced is not precisely the same in both inventions. Not only are they produced from different source materials, hamster cells as opposed to human cells, the final products themselves may vary slightly in composition. For example, the *Hoechst* court noted that there are differences in glycosylation, that is, the sugar residues, in the EPO produced from human cells as

⁷⁷ See sources cited at note 76.

⁷⁸ See *Amgen v. Hoechst*, 314 F.3d at 1327-28.

⁷⁹ See *id.* at 1325-26.

⁸⁰ See *id.* at 1335 (describing the accused product as after-developed technology).

⁸¹ See Suzanne L. Mansour et al., *Disruption of the Proto-oncogene int-2 in Mouse Embryo-derived Stem Cells: A General Strategy for Targeting Mutations to Non-selectable Genes*, NATURE 336, 348 (1988); E. G. Shesely et al., *Correction of a Human Beta S-globin Gene by Gene Targeting*, 88 PROC. NATL. ACAD. SCI. 4294 (1991); Mario R. Capecchi, *The New Mouse Genetics: Altering the Genome by Gene Targeting*, 5 TRENDS IN GENETICS 70 (1989).

opposed to the EPO produced from hamster cells.⁸² Glycosylation can affect the behavior of proteins.

[¶73] Nevertheless, trapped by the broad one embodiment doctrine, the *Hoechst* court ruled that the original patent properly reached all EPO other than the way nature intended it. The court held that this applied regardless of the source, the materials or the method used to create it. From the court's perspective, the second inventor merely created a different embodiment of the patented product. Under the one embodiment doctrine, a patent holder has the right to all embodiments of the patented product. Most importantly, the *Hoechst* court held that, for the purposes of the disclosure inquiry, a patent holder need neither describe nor enable things that could not have been known at the time of the application.⁸³

[¶74] The court in *Chiron v. Genentech*⁸⁴ reached precisely the opposite conclusion. The *Chiron* case concerned a type of antibody used in the treatment and diagnosis of breast cancer.⁸⁵ Antibodies are Y-shaped proteins consisting of a tail region and two arm regions.⁸⁶ The patent holder claimed rights to all monoclonal antibodies that bind to the human breast cancer antigen Her2.⁸⁷ In support of this claim, the patent holder described antibodies produced using genetic coding material derived from mice.⁸⁸

[¶75] At the time of the application, antibody populations for treating, diagnosing, and studying many types of diseases were produced using cells from one species,

⁸² *See, e.g.*, *Amgen v. Hoechst*, 314 F.3d at 1321-22 (noting differences in glycosylation, that is, sugar residues, in the EPO produced from human cells as opposed to the EPO produced from hamster cells).

⁸³ *See id.* at 1335, 1338-39.

⁸⁴ *Chiron v. Genentech*, 363 F.3d 1247 (Fed. Cir. 2004).

⁸⁵ *See id.* at 1250; for a detailed description of the technology in the case, see Feldman, *supra* at note 72.

⁸⁶ *See* ALBERTS, *supra* note 29, at 1375-76.

⁸⁷ *See Chiron v. Genentech*, 363 F.3d at 1250.

⁸⁸ *See id.* at 1251-52 (detailing both the antibodies described in the original application and those added in later versions of the application).

frequently mice cells. Antibody populations produced using mice cells could not be administered on a long-term basis to human patients without triggering a human immune system response that could lead to toxic shock or death.⁸⁹ Over time, however, the state of the art advanced such that scientists began to create antibodies by using genetic coding materials from different species for different parts of the antibody.

[¶76] For example, the arms of the antibody could be created using genetic coding material derived from mouse DNA while the tail could be created using genetic coding material derived from human DNA. Antibodies made in this combined fashion are known as “chimeric” antibodies.⁹⁰ Antibodies created predominantly from coding materials derived from human DNA are called “humanized” antibodies.⁹¹

[¶77] The fact that scientists have found methods to create chimeric and humanized antibodies for treatment and investigation of certain diseases does not guarantee that such antibodies can be created for any disease. Developing a chimeric or humanized antibody is a difficult process, involving tremendous experimentation, skill, and insight by scientists.⁹²

[¶78] The accused product in the *Chiron* case was a humanized antibody that could bind to the human breast cancer antigen Her2 and was being used in the long-term treatment of breast cancer.⁹³ At the time of the *Chiron* patent holder’s application,

⁸⁹ See *id.* at 1251.

⁹⁰ See *id.* at 1250-51.

⁹¹ See *id.*

⁹² See Sherie Morrison, *Genetically Engineered Antibodies: Progress & Prospects*, 12 (3,4) CRITICAL REVIEWS IN IMMUNOLOGY 125, 139-43 (detailing the state of humanized antibody technology in the late 1980s); Man Sung Co and Cary Queen, *Humanized Antibodies for Therapy*, 351 NATURE 501 (1991). The difficulty and desire to create humanized antibodies has even lead to the development of a mouse in which the genes responsible for antibody production have been replaced with their human counterpart – an enormous technical feat. See L.L. Green et al., *Antigen-Specific Human Monoclonal Antibodies from Mice Engineered with Human Ig Heavy and Light Chain YACs*, 7 NAT. GENET. 13 (1994).

⁹³ See *Chiron v. Genentech* at 1252.

chimeric and humanized antibodies did not exist at all in the science of antibody production.⁹⁴

[¶79] Although the *Chiron* patent holder argued that the humanized antibodies were simply a different embodiment of the mouse antibodies in the patent application, the *Chiron* court disagreed. Following the *Lilly* line of cases, the court noted the existence of a separate written description test⁹⁵ and ruled against the patent holder for failing to describe the later-developed technology.⁹⁶ In particular, the court noted that the patent holder could not possibly have described something that did not exist at the time of the application.⁹⁷

[¶80] As a practical matter, no inventor could ever adequately describe something that did not exist at the time of the invention. Thus, the *Chiron* opinion had the effect of ruling that patent holders cannot reach to embodiments arising after the time of the invention, despite the fact that those embodiments might survive enablement. This opinion is in direct conflict with the *Hoechst* case ruling that patent holders have no need to describe or enable embodiments arising after the time of the invention.⁹⁸

[¶81] The *Chiron* court may have been animated by concerns that patent holders were over reaching, stretching beyond the boundaries of their own inventions. For example, the defendant suggested during oral argument that allowing the patent holder to reach after-developed technology is like allowing the Wright Brothers to control jet

⁹⁴ *See id.* at 1254.

⁹⁵ *See id.* at 1253 (noting that the Federal Circuit has interpreted the relevant portion of § 112 as setting forth two requirements, enablement and written description).

⁹⁶ *See id.* at 1255.

⁹⁷ *See id.*

⁹⁸ *Compare* *Chiron v. Genentech*, 363 F.3d at 1255 *with* *Amgen v. Hoechst*, 314 F.3d at 1335, 1338-39.

engines. In a similar vein, the dissenting judge on the *Hoechst* panel argued the following:

[¶82] A cell, as employed in the patents in suit, is nothing more than a biological machine for making EPO. Even in more predictable arts, one who is first to make a machine is not entitled as a matter of law to claim any or all machines so long as they perform the same function.⁹⁹

[¶83] In short, faced with the clash of the one embodiment doctrine and the instinct to restrain patent holders from reaching into after-developed technology, the *Chiron* court used the separate written description doctrine to impose a limit on patent holders.¹⁰⁰ This approach, however, creates tremendous confusion. The *Chiron* written description rule on after-developed technology now stands in direct conflict with the *Hoechst* written description rule on after-developed technology. Most importantly, preventing patent holders from reaching after-developed technology through written description just adds to the cacophony of doctrines in which the one embodiment notion conflicts with efforts to restrain patent holders.¹⁰¹

[¶84] Using the separate written description doctrine to tackle the problem of after-developed technology is entirely unnecessary. I have argued that the definition of an invention can and should be limited to the state of the art at the time of the invention.¹⁰² This approach resolves inconsistencies across a broad range of doctrines. In addition, under this approach, the court can accommodate its instincts to restrain patent holders

⁹⁹ See *Amgen v. Hoechst*, 314 F.3d at 1360 (Clevenger, J. dissenting in part).

¹⁰⁰ Judge Bryson notes in the concurrence: “What must be guarded against, in my view, is to interpret *Hogan* to hold that claims that are enabled by the original application may be construed broadly enough to encompass technology that is not developed until later and was not enabled by the original application.” See *Chiron v. Genentech*, 363 F.3d at 1262.

¹⁰¹ For an explanation of the inconsistencies across five doctrines, see Feldman, *supra* note 72.

¹⁰² See Feldman, *supra* note 72.

from reaching into tomorrow's technology without resorting to a separate written description doctrine. Patent holders in cases such as *Chiron* would be unable to reach the later-developed technologies, but the result could be accomplished without distorting the disclosure doctrines.

IV. Information Knowable at the Time of the Invention

[¶85] The more difficult cases exist when the inventor did not initially describe what is at issue because the inventor did not appreciate it, but it was knowable given the state of the art. *Gentry Gallery*¹⁰³ is an example of this type of case. The case concerned an invention related to "L" shaped sectional sofas.¹⁰⁴ Such sofas normally include two individual seats that can recline.¹⁰⁵ Presumably, this design allows the two members of a couple to each recline in comfort.

[¶86] Under the state of the art prior at the time of the invention, the only way to allow each occupant to recline independently was to place the two recliners at opposite ends of the L.¹⁰⁶ This had the distinct disadvantage of creating an absence of intimate conversation, not to mention conflict over placement of the television set. The patent holder solved the problem by placing the two recliners next to each other with a console table between them.¹⁰⁷ Two sets of controls could be placed on the console, and the recliners could move independently while still facing the same direction.

¹⁰³ *Gentry Gallery, Inc. v. Berklene Corp.*, 134 F.3d 1473 (Fed. Cir. 1998).

¹⁰⁴ *Id.* at 1474.

¹⁰⁵ *Id.* at 1474-75.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* at 1475.

[¶87] The specification in the original application described a console that “accommodates the controls.”¹⁰⁸ The patent holder later added a claim including “a pair of control means mounted on the double reclining sofa seat section” rather than mounted on the console table. This claim was added to cover a competitor’s product that had entered the market. The question for the case concerned whether the original disclosure could be expanded by amendment to include control buttons located on a fold down middle seat which could serve as the equivalent of a console rather than only on a permanent console table. Unlike the *Chiron* and *Hoechst* cases, there was no concern here that locating the controls on a fold down sofa section required technological innovation that did not exist at the time. Thus, the case is not an example of after-developed technology in which the embodiment could not have existed at the time of the patent application.

[¶88] Similarly, *In re Ruschig*¹⁰⁹ falls within the category of cases in which the inventor didn’t initially describe what is at issue but it was knowable given the state of the art. As described above, the original application disclosed a formula that could encompass a half a million compounds, although the patent holder argued that indicators in the original application would have led one skilled in the art to significantly narrow the field.¹¹⁰ The court found the disclosure insufficient, arguing that even considering the state of the art and the narrowed category, the patent holder still did not provide enough “blaze marks” to find one’s way through the woods.¹¹¹

¹⁰⁸ *Id.*

¹⁰⁹ See *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967); see *supra* text accompanying notes 55-57 (describing the case).

¹¹⁰ See *Ruschig*, 379 F.2d at 993-94.

¹¹¹ See *id.* at 994-95.

[¶89] The *Ruschig* case concerned a patent holder's failure to sufficiently narrow the field. The patent holder failed to communicate, and probably failed to appreciate, which members of the group were of particular use. The case, however, did not concern after-developed technology that allowed the particular chemical to come to light. It concerned an inventor who had not yet engaged in the effort of working through the various members of the group to determine which ones were relevant. The question for this type of case is whether that effort was necessary in order to obtain patent rights or whether some contribution short of that effort would suffice. The answer should turn on what is required to obtain the additional information. One should ask whether the step necessary to go from the information provided to the additional information is simply a routine step easily and normally performed by one skilled in the art, or whether the step requires creativity, imagination or experimentation to derive. If the step is routine, something that anyone in the field would naturally do and could easily accomplish, requiring inventors to disclose that information adds nothing to society's store of knowledge. There is no need to use patent incentives to motivate the inventor to contribute something society already has at its reach.

[¶90] This perspective suggests that the *Lilly* decision, which required patent holders to identify the nucleotide sequence of a genetic invention in order to meet the disclosure requirements, is unwarranted today. In the current scientific environment, sequencing is inexpensive and routine. Researchers can sequence DNA for about a penny a nucleotide with results in 1-2 days.¹¹² Thus, the *Lilly* rule would make little

¹¹² See DNA Sequencing Service By Automated Fluorescence Technology, available at <http://www.genegateway.com/DNAsequencing.htm> (last visited 6/21/2005).

sense today, given the state of the art, regardless of any merit at the time of the decision.¹¹³

[¶91] One could argue that without the *Lilly* requirement, there is little incentive for anyone to get the sequence. The patent holder does not need to press further, having already obtained patent rights. Other scientists may be deterred from moving forward to obtain the sequence because they cannot obtain any additional credit in the patent system for taking that step. If the step is truly routine, however, there is little need to create incentives to engage in it. The inventor has given us the information that was difficult to obtain and unavailable. This is the type of contribution with which we should be concerned.

[¶92] The choice not to require disclosure of information or embodiments that can be routinely obtained is consistent with other patent requirements. Patent law does not, for example, require inventors to start from scratch and teach every aspect of every technology used.¹¹⁴ An inventor of a new machine does not need to teach how to assemble the hammer that will be used in construction of the machine if that hammer is available in the art.¹¹⁵ Similarly, although inventors are required to identify the best

¹¹³ For a discussion of how different commentators view the state of the art at the time of *Lilly* versus the state of the art today, see Eli A. Loots, *The 2001 USPTO Written Description Guidelines and Gene Claims*, 17 BERKELEY TECH. L.J. 117, 130, 2002 (noting that some commentators believe the level of skill in the art at the time of the filing of the *Lilly* application was sufficiently high that to allow the description in the patent to communicate adequate information to those in the art).

¹¹⁴ See, e.g., *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1334 (Fed. Cir. 2003) (“The specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without ‘undue experimentation.’”); 3 CHISUM, supra note 11, at §7.03[2][a] (explaining that the hypothetical person having ordinary skills in the art is presumed to know all the prior art in the relevant field).

¹¹⁵ *Id.*

mode of practicing their invention, the best mode requirement is not violated by the unintentional omission of information that is readily known in the art.¹¹⁶

[¶93] To the extent that reaching to embodiments or to the entire group requires creativity, imagination or experimentation, however, this expense should not be within the inventor's reach. Granting an inventor rights to something that requires additional creativity or experimentation essentially grants an inventor rights that extend into someone else's contribution. When an inventor stops short, leaving some inventive work to those who come after, the inventor's contribution is too small.

[¶94] The logic is consistent with what the court was struggling to articulate in *Ruschig* when it noted the following:

[¶95] Specific claims to single compounds require reasonably specific supporting disclosure and while we agree with the appellants, as the board did, that Naming [the particular compound] is not essential, something more than the disclosure of a class of 1000, or 100, or even 48, compounds is required. Surely, given time, a chemist could name (especially with the aid of a computer) all of the half million compounds This does not constitute support for each compound individually when separately claimed.¹¹⁷

[¶96] In other words, although an inventor can reach beyond what is provided, the extent of that reach is not measured by evaluating the size of the group the inventor is trying to reach, but rather the state of the art in sorting through the group. Is the journey routine or does it require creativity and experimentation?

¹¹⁶ See *High Concrete Structures, Inc. v. New Enter. Stone & Lime Co.*, 377 F.3d 1379 1948 (Fed. Cir. 2004).

¹¹⁷ *In re Ruschig*, 379 F.2d at 994.

[¶97] There may be times when the sheer number of items in the group may help convince a court that finding the answer requires experimentation. The court is not engaged in a quantitative inquiry, however, but a qualitative one. Most importantly, the inquiry cannot be answered in the abstract. It is intimately tied to an examination of the practices in the art at the particular moment of the original application.

[¶98] When an inventor didn't initially describe what is at issue, but it was knowable given the state of the art, the question of whether disclosure is sufficient should turn on whether the omitted information is routine in the art or would require significant trial and creativity to accomplish. This rule could be applied to questions of whether the inventor should be able to narrow an overly large group or whether an inventor should be able to expand the examples provided to include a larger group. For narrowing cases, where information is omitted that would indicate the proper choice among a large group, the question is whether this narrowing process is routine in the art. For expansion cases, where information is omitted that would describe other embodiments or other members of a larger group, the question is whether the embodiment can be accomplished routinely given the state of the art.

[¶99] Patent law, however, already has the tools to answer this question without a separate written description requirement. These tools reside in the undue experimentation rule that exists within the traditional enablement requirement. Long before any discussion of a separate written description requirement, courts ruled that to satisfy the enablement requirement of § 112, an inventor's disclosure must enable one skilled in the art to practice the invention without undue experimentation.¹¹⁸ For

¹¹⁸ See, e.g., *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 271 (1916) (finding that the description, while leaving something to the skill of persons applying the invention is clearly sufficiently definite to

example, the Supreme Court as early as 1881 found that the disclosure need not include that which is common and well known to persons skilled in the relevant art.¹¹⁹ Rather, the relevant inquiry concerns whether one trying to practice the invention would have to engage in experimentation that is unreasonable given the state of the art.¹²⁰ This undue experimentation requirement not only has a long pedigree; it is also a vibrant doctrine in modern cases, including cases after *Lilly*.¹²¹

[¶100] Thus, the inquiry concerning whether what is omitted in a disclosure is routine in the art or would require significant trial and creativity already resides in the traditional enablement inquiry. There is no need to create a separate written description requirement to address it. Once again, the problems can be solved without resorting to the creation of a separate written description requirement.¹²²

[¶101] Asking whether the omitted information is purely routine rather than something requiring experimentation and creativity has the indirect effect of measuring the inventive leap of the accused product. When an inventor adds claims during the application process in response to other products on the market and when an inventor files an infringement suit claiming that a product on the market is simply another

guide those skilled in the art); *Fruit Treating Corp. v. Food Machinery Corp.*, 112 F.2d 119 (5th Cir. 1940), *cert. denied*, 311 U.S. 679 (1940) (finding that patent disclosing a solvent percentage of 1% to 50% to enhance the color of oranges was not adequate because it would require undue experimentation); *see also* 3 CHISUM, *supra* note 11, at §§ 7.03[1], 7.03[4] (describing the undue experimentation doctrine in enablement).

¹¹⁹ *See* *Webster Loom Co. v. Higgens*, 105 U.S. 580, 586 (1882)

¹²⁰ *See, e.g.*, *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 271 (1916); *Amgen, Inc v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1212 (1991) (noting that some experimentation does not constitute a lack of enablement as long as the amount of experimentation is not unduly extensive); 3-7 CHISUM, *supra* note 11, at §§ 7.03[1], 7.03[4].

¹²¹ *See, e.g.* *Enzo Biochem, Inc. v. Calgene, Inc.* 188 F.3d 1362 (Fed. Cir. 1999); *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988); *United States v. Electronics, Inc.*, 857 F.2d 778 (Fed. Cir. 1988); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

¹²² For an interesting angle on the problem, see *Janis, supra* note 47 at pp. 62-63 (exploring but ultimately rejecting the possibility that any redundancies between written description and enablement might prove useful for patent law by giving judges additional discretion in difficult cases).

embodiment of the invention, one must essentially evaluate the leap that it will take to get from what the inventor actually disclosed to the product that the inventor is trying to reach. This is true with existing applications of the undue experimentation doctrine as well as with potential applications of the doctrine to modern problems.

[¶102] In theory, a court is not supposed to consider the accused product when evaluating the meaning of the claims and the validity of the patent. In reality, however, the question appears in an indirect fashion, in the undue experimentation inquiry performed during the process of measuring the amount of experimentation necessary to move to the accused product as it is captured in what the inventor tries to reach.

[¶103] Although perhaps not faithful to pure doctrinal notions of separating evaluation of the patent from comparison of the products, from a theoretical standpoint, this is not a bad inquiry. The definition of an invention flows not from some scientifically precise notion of an object but rather from the legal boundaries with which we endow the object. It is those boundaries that must be at issue in defining the claims and determining whether the invention is patentable, and the boundaries do not exist in pure isolation from the accused product. When inventors ask for a particular boundary but give only disclosure that will require the addition of creativity, they have failed to make a sufficient contribution for the rights desired.

[¶104] Perhaps the most important aspect of placing the possession inquiry in the undue experimentation test is that undue experimentation is grounded in an examination of the practices in the art at the particular moment of the original application. Framing the inquiry in this manner leads away from the kind of rigid, formulaic rules that the

court adopted in *Lilly*.¹²³ Although the judicial instinct to reach for rules in an effort to restrain inventors is understandable, such rules are quickly outpaced by the science, particularly in rapidly evolving fields of knowledge.¹²⁴

[¶105] For example, recall the *Lilly* court ruling that possession of the amino acid sequence of the protein is insufficient to claim the related DNA invention because knowledge of amino acid sequences does not directly yield the nucleotide sequence of the DNA. Suppose that the science of determining the relevant DNA sequence given the amino acid sequence of the protein becomes quite simple, even routine. Under those circumstances, having the protein's amino acid sequence should be at least as significant a contribution as the DNA sequence. Such technological advancement is more than merely fantastic. At time of the *Lilly* case, taking an isolated piece of DNA and determining the nucleotide sequence was itself a time-consuming and expensive process, although it is one that would be considered quick, inexpensive, and routine today.

[¶106] A rigid rule based on particular requirements rather than a standard based on the state of the underlying science offers insufficient flexibility as the science advances. Even in the context of the science at the time, the rule is wrongly focused. The question of whether information about a subset of the group translates into information about the group as a whole is a complex question that may not be easily solved by requiring common nucleotides, for example. At the time of the *Lilly* decision, one might have argued that requiring nucleotide sequencing made little sense if the path was time-consuming and expensive although possible to accomplish given the state of the art.

¹²³ See text accompanying notes 27-32, *supra* (describing the *Lilly* case).

¹²⁴ Cf. *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1375 (recognizing that in view of the rapid advances in science, what may be unpredictable at one point in time may become predictable at a later time).

Asking inventors to delay applications while they engage in such a process may be inappropriate. The question is not “do you have the nucleotide sequence” or even “how long would it take to get it” but rather, “how routine is the process of getting to it from where you are.” Requiring inventors to engage in a lengthy but routine process does not require any greater contribution to society, although it could serve as a trap for the unwary for those who received patents before the requirement is announced.

[¶107] The insufficient contribution in *Lilly* is not best defined as a problem of “lack of nucleotide sequence” but by the difficulties of translating rat DNA into human DNA. The difficulty of the work that lay ahead for the inventor should have been the focus of whether the application constituted an insufficient contribution.

[¶108] This is not to suggest that placing the possession inquiry within undue experimentation will eliminate all disputes and provide clarity for courts and parties alike. In particular, there is always the problem of hindsight interpretation when one is examining the state of the art in the past.¹²⁵ Problems related to hindsight interpretation, however, are endemic to patent law. In a variety of contexts, courts are asked to determine the state of knowledge of those skilled in the art at a particular moment in the past.¹²⁶ The inquiry required here is no different from others throughout patent law.

¹²⁵ See Rebecca S. Eisenberg, Symposium: *Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA*, 19 BERKELEY TECH. L.J. 885 (2004).

¹²⁶ *Id.* at 1454. *Cf.*, *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437 (Fed. Cir. 1984):
What controls the patentability of the fruits of the inventor's labors are the statutory conditions of novelty, utility, and unobviousness “to a person having ordinary skill in the art to which said subject matter pertains” as stated in § 103. It should be clear that that hypothetical person is not the inventor, but an imaginary being possessing “ordinary skill in the art” created by Congress to provide a *standard of patentability*.

[¶109] One presumably could argue that patent holders should not be able to reach at all beyond the precise information they have provided.¹²⁷ From this perspective, patent holders could not reach to information or embodiments that are routine in the art in addition to being unable to reach to those that require undue experimentation. Rather, anything requested must be described.

[¶110] One could think of this as a form of an evidentiary test. If the information really is routine, if the embodiment is well known in the art, one would expect an inventor to mention it. If the inventor fails to mention it, perhaps we have less confidence in the evidence suggesting that it was routine in the art at the time.

[¶111] Such a rule would enhance the notice function of patents.¹²⁸ If inventors can reach only what they describe with precision, rather than what is known in the art, other inventors will have more precise notice of what is covered by the invention and what is fair game.¹²⁹

[¶112] Alternatively, one could think of this as a fool's rule. If you, or more likely your patent counsel, do not know what is common knowledge in the field, we will limit your reward. Patent law, however, is designed to encourage inventors to create and reveal new ideas. One could argue, therefore, that the reward should be based on whether the idea is new, not on how much the inventor knows about existing ideas.

¹²⁷ See Robert P. Merges & Richard R. Nelson, *ON THE COMPLEX ECONOMICS OF PATENT SCOPE*, 90 COLUM. L. REV. 839, 845 (1990) (noting that although the argument makes sense at first blush, such an ultra-narrow enablement principle would soon render patents useless).

¹²⁸ See *Id.*

¹²⁹ For arguments on whether under modern patent statutes, the notice function resides in the claims only or more broadly, see Janis, *supra* note 47, at 62-64; *Univ of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1310-11 (Rader, J. dissenting from denial of hearing en banc). *But see* Eli A. Loots, *The 2001 USPTO Written Guidelines and Gene Claims*, 17 BERKELEY TECH L.J. 117, 118 (emphasizing the potential notice function inherent in the broad written description requirement).

[¶113] Moreover, implementing a fool’s rule would require that we apply hyper-technical interpretation to patent disclosure. Even in the case of something that everyone clearly knows about, if you don’t say it precisely, you are out of luck. This is an inefficient rule that would raise the costs of applying for patents and the costs of defending patents.

[¶114] Such a rule certainly would be justified if one thought that there were more fools in the patent system than there are diligent patent holders struggling against clever litigation counsel who can argue that words have many meanings and should be interpreted narrowly in a particular case. I suspect that the fools are not the problem.

[¶115] Most importantly, placing such strict requirements on inventors would necessitate a shift in the fundamental design of patent law. Patent law does not require that inventors describe information that is known in the art.¹³⁰ Nor does patent law require that inventors think through, test, and describe all possible embodiments of their invention.¹³¹ Requiring that inventors describe all possible embodiments would interfere with patent law’s design to encourage inventors to bring forth information to the public as quickly as possible, rather than stopping along the way to test and describe every possible permutation.¹³² Moreover, requiring that inventors describe all possible permutations of the invention would require complete elimination of the one embodiment doctrine, which

¹³⁰ See, e.g., *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (noting that the specification need not describe what is well known in the art).

¹³¹ See, e.g., *Atlas Powder v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569 (Fed. Cir. 1984) (holding that the claims were not limited to the precise embodiments tested by the patent owner); Sheila R. Arriola, *Biotechnology Patents After Festo: Rethinking Heightened Enablement and Written Description Requirements*, 11 FED. CIR. B.J. 919, 932 (2002) (citing *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), for the proposition that even a considerable amount of experimentation is permissible if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed).

¹³² See 3 CHISUM, *supra* note 11, at §10.08[1] (“A major purpose of the patent system is to induce persons not only to make useful new inventions but also to disclose them so that the public may have the long-term benefit of the technology”).

holds that inventors must only provide a single embodiment and a single use of their inventions. Although this piece suggests limiting the one embodiment doctrine to embodiments that could have been created at the time, this is not the same as eliminating one embodiment altogether.

[¶116] Finally, there must be some reach and flexibility in patent law. One who patents the idea of a doorknob and discloses an embodiment of pine wood should be able to broadly claim wooden doorknobs and to reach doorknobs made of oak. Problems occur when the doorknob inventor claims essentially “a mechanism for opening doors by the human hand” and attempts to reach computerized pushbutton key systems.¹³³ Such problems, however, can be addressed by limiting the reach of inventions to what could be known at the time of the invention as well as properly applying the undue experimentation test. They do not require a separate written description test.

V. Disclosure Without Written Description

[¶117] A number of troublesome issues arise in deciding whether an inventor has provided sufficient disclosure to constitute the necessary contribution. These issues can be addressed without resorting to a separate written description requirement. In particular, the disclosure issues perplexing modern courts can be separated according to whether the information could have been known at the time of the application.

Information that could not have been known at the time of the application should be

¹³³ Although simple mechanical inventions must be claimed by structure, not by function, for the type of biotech patents referenced in the analogy here, function can play a larger role. *See, e.g.,* Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1330 (Fed. Cir. 2002) (holding that structural details may not be necessary where sufficient information exists concerning the link between function and structure of the group).

beyond the reach of the inventor. This approach requires interpreting the one embodiment notion to focus on what could have been created given the state of the art.

[¶118] For information that *could* have been known at the time of the application, the rule should be that the inventor can reach those things that would be routine in the art but not those that would require creativity and undue experimentation. Such questions can be resolved by proper application of the undue experimentation test in the existing enablement doctrine.¹³⁴ In short, the disclosure issues facing modern courts can be resolved by proper interpretation of current doctrines and without development of a separate written description doctrine. The confusion and controversies spawned by the separate written description requirement are simply unnecessary.

A. Metabolites: An Example

[¶119] Separating disclosure issues in this way has the potential to resolve certain other difficult issues as well. For example, courts and commentators have expressed concerns about drug patent holders who try to refresh their patents by applying for separate patents on the metabolite of the drug.¹³⁵ A metabolite is a chemical compound formed in a patient's body when the patient takes a particular medicine.¹³⁶ In other words, it is a form that the drug goes through in the body in the process of digestion. By filing for a patent on the metabolite in the years after receiving a patent on the drug, the drug patent holder could effectively extend control over the drug.

¹³⁴ See Stephen J. Burdick, *supra* note 47 (discussing the *Moba* case and arguing that the written description requirement was redundant as applied in *Lilly* and unnecessary in the cases that have used it).

¹³⁵ See Robin C. Feldman, *Rethinking Rights in Biospace* (forthcoming SOUTHERN CAL. L. REV.).

¹³⁶ See, *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1375 (Fed. Cir. 2003).

[¶120] The question can be framed in the following manner: Does the language of the original drug patent reach the metabolite of the drug, even if that metabolite is not identified in the patent? After all, we are asking here whether the drug, as described in the earlier patent, should be defined to include the metabolite, even though the metabolite is not disclosed or even mentioned at all in the patent.

[¶121] The Federal Circuit appears to have shut down this potential form of abuse in the *Geneva* case, which held that the patent on the metabolite was invalid in light of the prior art of the drug.¹³⁷ The relief has come, however, at the expense of creating additional chaos in the doctrines.¹³⁸

[¶122] The metabolite problem can be solved by applying the two-prong disclosure analysis described above: Where the inventor fails to describe something because it is beyond the state of the art, the invention cannot reach that far. Where the inventor fails to describe something that could have been known given the state of the art, the question turns on how much effort it takes to get from one invention to the other.

[¶123] For example, suppose the knowledge that metabolites exist or the ability to isolate and identify particular metabolites is beyond the state of the art at the time of the drug invention. In that case, the earlier drug patent would not cover the metabolite. One who later isolated and identified the metabolite could apply for a patent.

[¶124] In contrast, suppose we all know that drug metabolites exist, and we know how to find the metabolite given a particular drug. In that case, the question should turn on how much experimentation is necessary to move from the drug to the metabolite. If

¹³⁷ See Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165, 221 (2005) (noting that the *Schering* case will eliminate some types of metabolite claims); see also *Schering Corp v. Geneva Pharms., Inc.*, 339 F.3d 1373 (Fed. Cir. 2003).

¹³⁸ See Feldman, *Rethinking Rights in Biospace*, *supra* note 135.

moving from the drug to the metabolite is routine, then the drug inventor can reach that far. If it will take extensive experimentation to move from the drug to the metabolite, the drug patent holder cannot reach that far with the original patent, and the metabolite is fair game for later patents.

[¶125] With this approach, we are spared the outrage of allowing a drug patent holder to get a new patent by identifying something that should be accessible in a routine fashion. Nevertheless, we can reward second-comers who find things that are difficult to know about or to isolate.

B. Potential Convergence of the Two Categories

[¶126] As described above, the approach in this article contemplates two categories, one in which the inventor did not disclose the information because it could not have been known at the time of the invention and one in which the inventor did not disclose the information at the time of the invention although the information could have been known given the state of the art. In theory, there is a point at which the two categories, information unknowable and information unappreciated, could converge. What is the difference, for example, between something that could not have been known without undue experimentation and something that simply could not have been known at all? At some point, experimentation that is undue crosses over to something that cannot be known at all. Similarly, one could argue that anything that has not been done by the inventor is after-developed technology, assuming it has not been done precisely in the art.

[¶127] Although by no means a precise line, the difference can be understood when the question is more fully articulated in terms of applying the relevant art. When an

inventor has failed to disclose an embodiment, for example, what does it take to reach from the inventor's disclosure to the undisclosed embodiment? Is it a question of working with technology that exists, adapting, experimenting, and using the type of skill and creativity that those in the art would have to find the proper path through to the new embodiment? This would be something that is knowable given the state of the art, although by no means routine. In contrast, would getting to the undisclosed embodiment require fundamentally new technology or concepts that were unavailable in the art at the time?

[¶128] Consider an inventor who has successfully created one member of a group and wishes to claim the entire group or species. The *Lilly* case, in which the inventor explained how to obtain the segment of rat DNA that coded for rat insulin and thereby claimed human segments of DNA that code for human insulin, provides a good example. Imagine that, given the state of the art, scientists could have taken the information provided by the rat DNA and used it to find and manipulate the proper segments of human DNA. Obtaining and manipulating the human DNA given the rat DNA information might have required extensive adaptation and creativity to account for the differences in human and rat biology. The amount of adaptation needed, however, is a question of whether the necessary experimentation constitutes undue experimentation.¹³⁹ In contrast, if differences between rats and humans were such that moving from a rat invention to its human counterpart seemed beyond the state of the art, perhaps requiring insights or technology not yet developed, that would be a problem of after-developed technology, not a matter of measuring the amount of experimentation.

¹³⁹ See Burdick, *supra* note 47, at 146 (arguing that the Federal Circuit could have come to the same conclusion in *Lilly* using the undue experimentation test of the enablement requirement).

[¶129] Most importantly, any convergence of the categories becomes far less important under the approach outlined in this piece because the results would be consistent no matter which of the two categories is chosen. At the point at which one would worry about whether information should be properly categorized as requiring undue experimentation, as opposed to requiring information that could not have been known at the time of the invention, the answer would be the same. Experimentation so great as to almost rise to the level of after-developed technology would surely constitute experimentation that is undue. Thus, regardless of whether the missing elements were analyzed as information that could have been known or information that could not have been known, the patent holder would be unable to reach it.

[¶130] Problems at the intersection of undue experimentation and after-developed technology are most troublesome when the doctrines involving each would create different results. That is precisely the problem with the current system. If the gap is characterized as undue experimentation, the patent holder is prevented from reaching it. If the gap is characterized as after-developed technology, however, the patent holder may be permitted to reach it, at least under broad interpretations of the one embodiment doctrine.¹⁴⁰ With the approach outlined in this piece, undue experimentation and after-developed technology yield consistent results, making the intersection less troubling.

C. Uncertainty in the Law

[¶131] To some extent, the cases described suggest that when inventors do not include information that could have been known, the inventor simply did not appreciate

¹⁴⁰ See *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004) (patent holder not required to describe or enable technologies that could not have existed at the time of the invention).

its importance. There is, however, another possibility. An inventor may not have described the invention because of lack of clarity concerning what the law required.

[¶132] Placing information in a patent application is not risk-free. Consider an inventor who chooses to disclose information in the general description of the invention intending to use that information in one of the claims. Information disclosed but not claimed, however, is considered to have entered the public domain.¹⁴¹ Thus, if the patent holder later removes that claim to satisfy the patent examiner, the effect may be to dedicate information to the public that might have been kept as a trade secret or developed further to the point of a patentable invention.

[¶133] Choosing which information to include in a patent application is a delicate dance. One cannot necessarily assume that failure to disclose constitutes failure to appreciate. An unfortunate consequence of our inability to resolve disclosure requirements is that inventors must navigate these risks without clear guidance on what the law requires. Resolving the written description conundrum offers inventors some hope of being able to navigate the law's dictates.

VI. Conclusion

[¶134] In sum, creating a written description doctrine separate from enablement has resulted in a set of doctrines that are simply unworkable – clashing with each other, with additional areas of patent law, and with the evolving science. Although the separate written description has spawned chaos and confusion, the solution is not to excise the

¹⁴¹ This is known as “the dedication rule.” See 2-6 CHISUM, *supra* note 11, at §6.03[3]. For cases applying this rule, see, e.g. Maxwell v. J. Baker, Inc., 86 F.3d 1098, 1107 (Fed. Cir. 1996), *cert. denied*, 520 U.S. 1115 (1997) (“subject matter disclosed in the specification, but not claimed, is dedicated to the public” and cannot be deemed an infringement under the doctrine of equivalents); Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1562-63 (Fed. Cir. 1991) (“subject matter disclosed but not claimed in a patent application is dedicated to the public.”); Mahn v. Harwood, 112 U.S. 354, 361 (1884) (“The public has the undoubted right to use, and it is to be presumed does use, what is not specifically claimed in the patent.”).

issues that have been incorporated into the new written description requirement. Those issues reflect a legitimate inquiry regarding the inventor's contribution, an inquiry that properly resides in the disclosure analysis. The key to resolving tensions in the disclosure doctrine lies first in harmonizing disclosure with other doctrines of patent law and second in properly applying the traditional disclosure doctrines. In particular, information that could *not* have been known at the time of the application should be beyond the reach of the invention. Information that *could* have been known should be reachable only if it is routine in that art and does not require undue experimentation.

[¶135] Despite the impasse and frustration at the Federal Circuit level, the problems plaguing modern courts as they struggle to define the nature of the inventor's contribution can be resolved without resorting to a separate written description requirement.