

**IN THE MATTER OF AN ARBITRATION UNDER CHAPTER ELEVEN OF THE
NORTH AMERICAN FREE TRADE AGREEMENT
AND THE UNCITRAL ARBITRATION RULES (1976)**

BETWEEN:

ELI LILLY AND COMPANY

Claimant/Investor

AND:

GOVERNMENT OF CANADA

Respondent/Party

(Case No. UNCT/14/2)

EXPERT REPORT OF TIMOTHY R. HOLBROOK

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Trade Law Bureau
Departments of Justice and of Foreign
Affairs, Trade and Development
Lester B. Pearson Building
125 Sussex Drive
Ottawa, Ontario
K1A 0G2
CANADA

I. Background and Qualifications

1. I am Associate Dean of Faculty and Professor of Law at Emory University School of Law. I joined the Emory faculty in 2009. Prior to joining Emory, I was a professor at Chicago-Kent College of Law, Illinois Institute of Technology from 2000-2009. I also served as the Associate Director of the Program in Intellectual Property Law at Chicago-Kent from 2006-2009. I have taught patent law at least once per year every year since entering the academy, as well as teaching advanced classes in International Intellectual Property, International Patent Law, and Patent Litigation. I am the co-author of a casebook, *PATENT LITIGATION AND STRATEGY* (4th Edition 2013), along with the Honorable Kimberly A. Moore, a judge on the U.S. Court of Appeals for the Federal Circuit (“Federal Circuit”), and John F. Murphy, a partner at BakerHostetler. I joined the faculty of Chicago-Kent after being an associate at Wiley Rein & Fielding (now Wiley Rein), a 200+ attorney law firm in Washington, DC, where I specialized in patent and appellate litigation. I associated with Wiley Rein after spending six months working in Budapest, Hungary, with the patent firm Danubia. Prior to my time in Hungary, I served as a law clerk to the Honorable Glenn L. Archer, Jr., of the Federal Circuit while he was Chief Judge, from August 1996 through December 1997, and then while he was Senior Judge, from December 1997 through March 1998. I graduated from Yale Law School with a JD in 1996 and from North Carolina State University in 1993 with a B.S. in Chemical Engineering, where I graduated first in my class and was a valedictorian.

2. Other than preparing this report, I have no ties to Canada or to the Canadian government. The views in this report reflect my considered, independent assessment of the state of U.S. patent law.

II. Introduction

3. The dispute between Eli Lilly & Company and the government of Canada arises over the Canadian rejection of Eli Lilly patents on the basis of lack of utility, as that criteria is interpreted and applied under Canada’s *Patent Act*. In particular, Eli Lilly argues that in adopting certain interpretations of the ‘utility’ requirement under Canada’s *Patent Act*, Canadian courts are ‘out of step’ with the U.S. interpretation of the utility criteria and, by consequence, have violated Canada’s obligations under NAFTA.

4. My report will focus on Claimant’s allegations with regard to the content of U.S. law. In particular, I have been asked to consider the following questions:

- 1) Does U.S. patent law include rules similar to those adopted by Canadian courts through the ‘utility’ requirement? In particular:
 - a. Does Claimant paint an accurate portrait of current U.S. law on utility?
 - b. Does U.S. patent law otherwise address similar considerations to those raised under ‘utility’ in Canada, by other means?

- 2) Is it accurate to argue that U.S. interpretations of its substantive patent rules have remained static since NAFTA came into force in 1994?
- 3) In U.S. patent practice, do U.S. courts defer to the determinations of USPTO regarding proper interpretation of the Patent Act?

I will address each of these issues in turn.

5. Lilly characterizes Canadian rules concerning utility as the “promise utility” doctrine. My understanding is that “promise utility” doctrine is Claimant’s expression and not that of Canadian courts. Moreover, I understand what it characterizes as a single doctrine is in fact a series of specific determinations relevant to several aspects of the overall patent validity analysis, not limited to the mere “threshold” for required utility, notably:

- 1) **What is the invention?** My understanding is that, in Canada, where a patentee has asserted (or “promised”) a certain degree of utility, the applicant will be held to that promised utility. Moreover, courts will construe the patent specification in light of principles of construction to determine whether there is a promise and if so, its content;
- 2) **Has the inventor actually made the asserted invention?** My understanding is that in Canada, a patentee is required to have made its invention, including having some basis for the promised utility of the invention, not later than the filing date. I understand that in Canada this requirement can be fulfilled either on the basis of “demonstration” (i.e. where the applicant has conclusive proof of the utility before filing), or by “sound prediction”. In the latter case, an applicant may file its application on the basis of less than conclusive proof, so long as the utility has at least been soundly predicted as of the filing date. Sound prediction will be particularly helpful for pharmaceutical inventions, allowing companies to file despite lacking conclusive evidence that a new use of a pharmaceutical compound will “work” as promised. A patentee relying on “sound prediction,” must at least possess with a sufficient factual basis, together with a line of reasoning, to predict that the invention will do what the applicant says it will do. Moreover, in Canada I understand that post-filing evidence is typically not admitted to support allegations of ‘sound prediction’ as of the date of filing;
- 3) **Has the patentee properly disclosed the invention?** In the context of utility that is merely “predicted”, my understanding is that Canadian courts require the basis for the sound prediction of utility – in the form of some factual basis and line of reasoning – to be disclosed in the patent specification.

6. My report explores this basic question: does U.S. patent law incorporate any rules that are equivalent to the different concepts found in Canada’s utility requirement, *i.e.* the “promise of the patent”, demonstration versus sound prediction, rules against post-filing

evidence, and appropriate disclosure of the basis of the sound prediction. In applying such rules, my understanding is that Canadian courts are prompted by a number of policy considerations that underlie the above requirements. One concern is speculative, premature patent filings, where an applicant seeks to file an application on an invention that he or she has not yet realized. The application instead reflects unproven speculation as to the efficacy of the invention. Similarly, Canadian utility requirements police against over-claiming, where the applicant seeks broad protection that is not commensurate with the scope of the invention itself or of applicant's disclosure. Canadian disclosure requirements relating to utility also seek to ensure that the public has an adequate teaching regarding the nature of the disclosed invention, including the basis upon which the applicant asserts a promised utility (which in cases such as pharmaceuticals, can be the essence of the invention). In this regard, the equivalent policy question is, does the U.S. system address or concern itself with similar policy issues? My answer, as demonstrated below, is that the United States does have doctrines that implement similar policy concerns.

7. I reach this conclusion by a more appropriate comparative methodology than that of Claimant. The Claimant inappropriately focuses narrowly on a comparison of U.S. and Canadian utility requirements. Such a myopic focus fails to capture the true picture because U.S. law uses other doctrines in addition to utility to police the concerns identified above. As I demonstrate below, U.S. patent law polices concerns of premature filing and overly broad claiming through a patchwork of related yet distinct doctrines: utility, enablement, and written description. Other commentators have noted these similarities and agree that, in the aggregate, these U.S. doctrines address concerns similar to the Canadian approach to utility.¹

8. Claimant's attempted comparative law analysis, therefore, is inherently flawed. A proper comparative analysis considers the functioning of legal systems as a whole. It is unsurprising that two different countries would address similar policy issues using slightly different legal or doctrinal levers. A comparison of a single aspect of a system in isolation, such as focusing solely on a single doctrine or requirement, fails to capture the true similarities between two systems. Once one conducts this proper comparative analysis, it becomes apparent that U.S. patent law addresses the same range of concerns as does Canadian law, within the four corners of Canada's own particular national legal scheme.

1. E. Richard Gold and Michael Shortt, *The Promise of the Patent in Canada and Around the World*, 30:1 Canadian Intellectual Property Review 35, 62-63 (2014) (R-050) ("in order to avoid those difficulties [raising utility arguments], many litigants prefer to reframe utility issues and plead them as failures of 'enablement,' with the result that the doctrine of enablement does much of the work handled by utility in Canada."); Peter Wilcox, *Enablement of Utility: Sound Prediction for the United States?*, 27 Canadian Intellectual Property Review 371, 383 (2011) (R-051) (comparing Canadian "sound prediction" and U.S. enablement doctrine and noting inconsistencies in U.S. law). See also Dmitry Karshedt, *The Completeness Requirement in Patent Law*, 56 Boston College Law Review (forthcoming 2015), draft at 19-25, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2465581 (R-052) (discussing US utility, written description, and patentable subject matter rules as constituting a "completeness" requirement).

9. My report will proceed as follows. I will first explore U.S. doctrines of utility, enablement, and written description, all of which deal with the policy concerns underlying the Canadian approach to utility. With respect to utility, U.S. law is concerned with, and parallels, several issues arising under the Canadian law of utility. To the extent there are differences, Claimant has markedly overstated the ‘settled’ nature of U.S. law on such issues, particularly with respect to the application of the U.S. utility requirement to chemical and pharmaceutical inventions. Second, I will explore the U.S. requirement for an applicant to disclose sufficient information in the patent document so as to enable a person skilled in the art to make and use the claimed invention. As U.S. law makes clear, enablement and utility are closely related and, particularly in the pharmaceutical context, they often overlap. Third, I will elaborate a second disclosure requirement in U.S. patent law, that the applicant provide a written description of the claimed invention. This requirement is also closely related to enablement and requires the applicant to demonstrate within the patent document that he or she was in possession of the invention as of the filing date. As this report explains, these three doctrines are meant to address concerns with premature patenting and overly broad claim scope, as do the Canadian utility requirements. U.S. law simply places these policy concerns in different doctrinal “buckets” than in Canada.

10. With regard to Claimant’s suggestion that NAFTA froze the patent laws of both countries as of its signing, this report also elaborates how U.S. law has evolved and fluctuated over time, either by adding new substantive criteria unknown at the time of NAFTA (such as the written description requirement), by rendering the application of certain doctrines more rigorous (such as non-obviousness), or by invalidating entire classes of inventions (such as the shift in patentable subject matter). The position that the parties to NAFTA somehow “enshrined” patent rules about the application and interpretation of substantive criteria is not supported by the course of U.S. patent law since 1994.

11. Finally, the report explains that the U.S. Patent and Trademark Office (USPTO) lacks substantive rulemaking authority. In other words, the USPTO does not control how the patent laws of the United States are to be interpreted. Interpretation of the substantive provisions of the patent laws is the exclusive domain of the U.S. courts. It is unsurprising, therefore, that a former official of the USPTO would state that the guidelines offered by the agency did not change the law. In part, that is true because the guidelines do not have the force of law until adopted by the courts. Second, it would be quite extraordinary for a former USPTO official to suggest that somehow the agency had exceeded its authority by changing a substantive legal standard. In reality, however, practitioners and academics recognize that the USPTO utility guidelines, subsequently embraced by the Federal Circuit, effectively raised the U.S. utility standard, precluding most patents on gene fragments. Moreover, even if the guidelines merely reflected a return to earlier views of utility, the new guidelines still reflect the oscillation that occurs in U.S. law, belying the argument that the patent laws of both countries were somehow “frozen” by the adoption of NAFTA.

12. It is not my role to opine as to whether I agree with Canadian or U.S. law as a matter of policy. Instead, my focus is on noting parallels between U.S. patent law and Canadian requirements; noting the evolution in the U.S.'s application of patenting criteria since the signing of the NAFTA agreement; and commenting on the hierarchy between USPTO patent grants and U.S. court's interpretation of patent law, which frequently leads to invalidations of such grants.

III. U.S. Patent Law Doctrines of Utility, Enablement, and Written Description Include Rules Similar to Those Found in Canadian Utility Requirement

13. Every patent system in the world has to balance an inherent tension with any patent: providing adequate reward through patent scope to the inventor while ensuring that the patent scope is commensurate with the inventor's actual contribution to the state of the art. Moreover, every patent system is concerned with timing, wanting to award inventors with patents only for inventions that are truly complete as of the application date. A patent should be awarded for an actual invention, not speculation.

14. Canada polices these dynamics in part through rules developed through the application of the "utility" requirement under Canada's *Patent Act*. While the United States does not approach utility in exactly the same way as Canada, overall US courts apply doctrines addressing the same or similar policy concerns to ensure that a patent's scope is properly tailored to what the patentee has actually invented as disclosed within the patent document. Patents should not be awarded for speculative theories or for mere research proposals.

15. Three different, though related, doctrines in U.S. patent law – utility, enablement, and written description – in the aggregate address policy concerns analogous to those policed in Canada under its utility requirement

A. Eli Lilly Fails to Paint an Accurate Picture of the Importance of the Utility Requirement in U.S. Patent Law

16. As in Canada, the utility requirement has played an important role in the United States in ensuring that a patent is awarded only for a completed invention. As the U.S. Supreme Court noted as far back as 1966 while addressing the utility requirement, "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."² The Federal Circuit, which has national appellate jurisdiction over patent law in the United States, has also expressed this role for utility. As that court has noted, "[t]he utility requirement prevents mere ideas from being patented" and "also prevents the patenting of a mere research proposal or an invention that is simply an object of research."³

² *Brenner v. Manson*, 383 U.S. 519, 536 (1966) ("*Brenner*") (R-053).

³ *In re '318 Patent Infringement Litigation*, 583 F.3d 1317, 1324 (Fed. Cir. 2009) ("*In re '318*") (R-054).

17. Utility must be demonstrated *as of the filing date* of the application.⁴ Utility doctrine in the United States, therefore, operates in a manner comparable to that of Canada: ensuring that patents are granted only for inventions that are known to work as of their filing date. In the pharmaceutical context, utility serves to ensure that the inventor has demonstrated the efficacy of the drug, as opposed to merely speculating as to its usefulness. A patent should not be rewarded if the applicant is merely speculating as to the possible usefulness of a compound as a drug.

18. Contrary to Professor Merges' assertions, utility is not a "low bar to patentability,"⁵ in the context of pharmaceutical, chemical, and biological inventions. Professor Merges own casebooks acknowledge that, for these classes of inventions, utility is an important limit on patentability, for very simple reasons: "Chemists often synthesize compounds that they believe might be useful someday for something but for which no particular use is known. When they apply for patents on these compounds, they sometimes run headlong into the utility requirement."⁶ Discussions of utility as a low threshold apply primarily to the more predictable arts, such as mechanical or electronic inventions.⁷ It remains a significant barrier to patentability in the pharmaceutical context.⁸ As the U.S. Supreme Court stated in *Brenner v. Manson*:

⁴ *Id.* at 1326 (R-054) ("The results from the '318 patent's proposed animal tests of galantamine for treating symptoms of Alzheimer's disease were not available at the time of the application.").

⁵ See Expert Report of Robert P. Merges, ¶ 6

⁶ Robert P. Merges, Peter S. Menell, & Mark A. Lemley, *Intellectual property in the New Technological Age* 177 (Wolters Kluwer 6th Ed. 2012) (R-055); see also Robert Patrick Merges & John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials* 223 (LexisNexis, 6th ed. 2013) (R-056) ("[C]hemists often synthesize compounds which they believe might be useful someday for something, but for which no particular use is currently known.").

⁷ See Donald S. Chisum, *Chisum on Patents: A Treatise on the Law of Patentability, Validity and Infringement*, Volume 1§4.01 (2014) (R-057) ("The requirement is easily met with most mechanical devices and processes, but it is a frequent problem with chemical compounds and processes—particularly pharmaceutical compounds (drugs), and with genetic and other biological materials."); F. Scott Kieff, Pauline Newman, Herbert F. Schwartz & Henry E. Smith, *Principles of Patent Law* 690 (Foundation Press, 5th ed. 2011) (R-058) (noting "mechanical and electrical inventions...usually have a specific end result and use in mind..."); Martin J. Adelman, Randall R. Rader, & John R. Thomas, *Patent Law* 132 (3d ed. 2009) (R-059) (noting that, "[o]utside the chemical and biotechnological arts," inventors often "construct a device directed towards a specific application, as say, an electrical engineer does while designing a new circuit..."); Sean B. Seymore, *Making Patents Useful*, 98 Minn. L. Rev. 1046, 1049 (2014) (R-060) ("History reveals that those seeking patents on inventions in nascent technologies, fields which have a poor track record of success, and unpredictable fields like chemistry, biotechnology, and pharmaceuticals have had to fight with the Patent Office and in the courts over utility."); Michael Risch, *A Surprisingly Useful Requirement*, 19 Geo. Mason L. Rev. 57, 58 (2011) (R-061) (describing the level of utility required as "extremely low" except for applications "claiming perpetual-motion machines, chemicals with unknown effects, and other fantastic concepts." (emphasis added)); Sean B. Seymore, *The Enablement Pendulum Swings Back*, 6 Northwestern J. of Tech. and Intell. Prop. 278, 282 (2008) (discussing divide between unpredictable and predictable arts) (R-062).

⁸ The empirical study relied upon by Professor Merges ultimately does not support the broad proposition for which he is stating. The study does not break down the use of utility in litigation based on the nature of the invention. It is unsurprising that utility is not raised frequently across all patent litigation, as it normally is only an issue in biochemical, pharmaceutical and chemical cases. The rest of the study shows that it was raised five times in their data, and it was successful once. But that still yields a success rate of 20%. Moreover, Professor Merges omits the important use of enablement and written description. His study shows that 9.4% of patents were invalidated on the basis of written description or enablement challenges, and, when asserted, such challenges were successful 36.1% of the time (13 out of 36 cases). Indeed, Professor Merges and his co-authors note that written description and

a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. 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. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.⁹

Similarly, the Federal Circuit has said that “where there is ‘no indication that one skilled in [the] art would accept without question statements [as to the effects of the claimed drug products] and *no evidence has been presented to demonstrate that the claimed products do have those effects,*’ an applicant has failed to demonstrate sufficient utility....”¹⁰ Moreover, “[u]tility has served as the basis for rejecting applications at the USPTO or invalidating patents in litigation in a variety of situations involving unpredictable art fields, such patents covering gene fragments known as express sequence tags (ESTs),¹¹ a method of treating Alzheimer’s Disease,¹² and a nutritional composition for the treatment of connective tissue.¹³

19. The U.S. utility requirement has its origins in the U.S. patent statute. Specifically, 35 U.S.C. § 101 requires: “Whoever invents or discovers any new and **useful** process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” An invention, therefore, must be useful to be patent eligible. The statute provides no other guidance, however, leaving it to the courts to elaborate what is sufficient for an invention to be useful.¹⁴

enablement challenges were the fifth most popular way to invalidate a claim. Finally, these are only litigation statistics. It doesn’t measure the applications that were not filed, or that were delayed, because the inventor had not yet discovered a sufficient utility. Utility therefore can be significant barrier to filing a patent application.

⁹ *Brenner* (R-053).

¹⁰ *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1323 (Fed. Cir. 2005) (citing *In re Novak*, 306 F.2d 924, 928 (C.C.P.A. 1962)) (emphasis added) (“*Rasmusson*”) (R-063).

¹¹ *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005) (“*In re Fisher*”) (R-064).

¹² *In re ‘318* (R-054).

¹³ *Petito v. Puritan’s Pride, Inc.*, -- F. Supp. 2d ---, 2014 WL 3804921, at *7-14 (S.D.N.Y. July 31, 2014) (“*Petito*”) (R-065).

¹⁴ *Brenner* (R-053) (“As is so often the case, however, a simple, everyday word can be pregnant with ambiguity when applied to the facts of life.”).

20. The courts have interpreted the utility requirement to contain three distinct criteria: (1) the invention must be operable/have a utility credible to one of ordinary skill in the art;¹⁵ (2) the utility must be specific;¹⁶ and (3) the utility must be substantial.¹⁷ Whether the applicant has satisfied the utility requirement is a factual issue, not a legal one,¹⁸ a decision to which the Federal Circuit must defer on appeal.

1. Operability/Credible Utility

21. The operability aspect of utility deals with the basic question of whether the invention has been proven to work. This aspect also relates to credibility: one of ordinary skill in the art would need to believe the asserted utility is credible, or believable, given the state of the art at the time of the application. Issues of operability involve two distinct classes of inventions: those that will never work and those that have *yet* to be proven to work. The first category involves claims to inventions that are impossible because they violate natural laws. For example, the Federal Circuit affirmed a USPTO rejection of a perpetual motion machine as lacking utility because it violates the laws of thermodynamics.¹⁹ The Federal Circuit also invalidated a claim because the method would violate the principle of conservation of mass.²⁰ Such incredible assertions of utility are easily rejected by the USPTO or courts.

22. The second class of inventions involve those that are not *presently* operable, though subsequent advances in technology may render such inventions operable.²¹ Cures for baldness, for example, were once viewed as being inoperable and thus lacking utility; over time, however, science evolved to the point where the asserted utility was deemed credible.²² Similarly, the Federal Circuit affirmed the USPTO's rejection of a claim directed towards cold fusion as lacking utility because the state of the art made clear that such technology was not yet operational.²³ This aspect of operability deals directly with the issue of timing: an inventor cannot obtain a patent until she knows the invention will actually work. If she files before she has demonstrated the invention's utility, then her application will be denied for want of utility,

¹⁵ *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed. Cir. 1999) (“*Process Control Corp.*”) (**R-066**).

¹⁶ *In re Fisher* (**R-064**).

¹⁷ *In re Fisher* (**R-064**); *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563 (Fed. Cir. 1996) (**R-067**) (“Consequently, it is well established that a patent may not be granted to an invention unless substantial or practical utility for the invention has been discovered and disclosed.”).

¹⁸ *In re Fisher* (**R-064**); *Process Control Corp.* at 1359 (**R-066**); *In re Cortright*, 165 F.3d 1353, 1356 (Fed. Cir. 1999) (“*In re Cortright*”) (**R-068**).

¹⁹ *Newman v. Quigg*, 877 F.2d 1575, 1581 (Fed. Cir. 1989) (**R-069**).

²⁰ *Process Control Corp.* at 1359 (**R-066**).

²¹ See Sean B. Seymore, *Making Patents Useful*, 98 Minn. L. Rev. 1046, (2014), at 1068 (**R-060**).

²² *In re Cortright*, at 1357 (discussing history of utility of treatments for baldness) (**R-068**).

²³ *In re Swartz*, 232 F.3d 862 (Fed. Cir. 2000) (**R-070**).

even if that utility is subsequently demonstrated.²⁴ For example, the USPTO once rejected methods of treating baldness as lacking operability.²⁵ Over time, however, technology has evolved, rendering claims of utility for treating baldness credible.²⁶

23. Utility must be articulated in the patent document, and the articulated utility is presumed to be true "unless [the USPTO] has reason to doubt the objective truth of the statements contained in the written description."²⁷ The USPTO can establish such doubt "when the written description 'suggest[s] an inherently unbelievable undertaking or involve[s] implausible scientific principles.'"²⁸ As the Federal Circuit has explained, "the PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility."²⁹

24. For example, in *In re '318 Patent Infringement Litigation*, the court confronted a patent claiming a method of treating Alzheimer's disease using the molecule galanthamine.³⁰ The court invalidated the patent for want of utility because the patent owner had not

²⁴ *Cre-Agri, Inc. v. Pinnacliffe, Inc.*, No.: 11-CV-6635-LHK, 2013 WL 6673676, at *16 (N.D. Cal. Dec. 18, 2013) ("*Cre-Agri*") (**R-071**) ("an invention will not be considered useful for the purposes of section 101 where, at the time of filing, 'there is a complete absence of data supporting the statements which set forth the desired results of the claimed invention'—even if the invention is later proven useful or operable." (quoting *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325 (Fed. Cir. 2005)), *aff'd without opinion*, No. 2014-1209, 2014 WL 5162378 (Fed. Cir. Oct. 15, 2014). The Federal Circuit affirmed *Cre-Agri* under Rule 36 of the Federal Circuit Rules of Appellate Procedure. The Federal Circuit will summarily affirm a district court's judgment without opinion when the court "determines that any of the following conditions exist and an opinion would have no precedential value:

- a) the judgment, decision, or order of the trial court appealed from is based on findings that are not clearly erroneous
- b) the evidence supporting the jury's verdict is sufficient;
- c) the record supports summary judgment, directed verdict, or judgment on the pleadings;
- d) the decision of an administrative agency warrants affirmance under the standard of review in the statute authorizing the petition for review; or
- e) a judgment or decision has been entered without an error of law.

In *Cre-Agri*, the district court granted summary judgment of invalidity, such that the Federal Circuit must have determined Rule 36(c) applied and that a written decision would have no precedential value.

²⁵ See, e.g., *In re Ferens*, 417 F.2d 1072, 1075 (C.C.P.A. 1969) (**R-072**) ("[W]e are not persuaded that whatever growth of hair the various subjects did experience would necessarily be regarded by those skilled in this particular art as stemming from treatment with appellant's composition and method.").

²⁶ *In re Cortright*, at 1357 (**R-068**).

²⁷ *Id.* at 1357 (**R-068**).

²⁸ *Id.* (quoting *In re Brana*, 51 F.3d 1560,1566 (Fed. Cir. 1995)) (**R-068**).

²⁹ *In re Brana*, 51 F.3d at 1566 ("*Brana*") (**R-073**).

³⁰ *In re '318*, at 1320-21 (**R-054**).

demonstrated that the method would be successful.³¹ The court noted that “neither in vitro test results nor animal test results involving the use of galanthamine to treat Alzheimer-like conditions were provided.”³² The animal testing in the prior art, which was discussed in the patent’s specification, was also insufficient.³³ The court concluded that “at the end of the day, the specification, even read in the light of the knowledge of those skilled in the art, does no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis. That is not sufficient.”³⁴

25. Similarly, in *CreAgri, Inc. v. Pinnacliffe*, the district court invalidated the patent for lacking utility, even though the asserted utility was demonstrated subsequent to the patent application. The court agreed with the argument that “one having ordinary skill in the art would not accept an assertion that [the chemicals at issue] have therapeutic anti-inflammatory qualities,” given the lack of published data on the topic.³⁵ The court also concluded that the specification’s disclosure was inadequate because “the inventor did not know at the time of filing whether the invention was in fact operable and instead rests the invention’s asserted operability on, as the inventor himself conceded, ‘prophe[cy].’”³⁶ The court also faulted the specification because it “provide[d] nothing that could be considered argument or analytic reasoning” to support the asserted utility.³⁷

³¹ *Id.* at 1327 (R-054) (“The ‘318 patent’s description of using galantamine to treat Alzheimer’s disease thus does not satisfy the enablement requirement because the ‘318 patent’s application did not establish utility.”). As discussed below, enablement and utility are related doctrines in U.S. patent law with considerable overlap between the two.

³² *In re ‘318* at 1325 (R-054).

³³ *Id.* (R-054). (“Indeed, both in responding to the examiner’s obviousness rejection and in responding to the obviousness defense at trial, the inventor (Dr. Davis) and Janssen’s witnesses explicitly stated that the utility of the invention could not be inferred from the prior art testing described in the application.”).

³⁴ *Id.* at 1327 (R-054).

³⁵ *Cre-Agri*, at *17 (R-071).

³⁶ *Id.* at *20 (R-071).

³⁷ *Id.* at 21 (R-071).

2. Substantial Utility

26. Whereas operability deals with whether the invention works *at all*, the requirement for a “substantial” utility asks whether the invention’s utility is *sufficient enough* to justify the grant of a patent. “Substantial utility” has been referred to as “practical utility” or “real world” utility.³⁸ The Federal Circuit has described “substantial utility” as one that “provides some immediate benefit to the public.”³⁹ For many inventions, the substantial utility requirement is readily satisfied: the metaphorical “better mousetrap” necessarily catches mice. For others, such as chemical entities and uses of pharmaceuticals for treatment of a medical problem, the requirement for a substantial utility can create a significant burden.⁴⁰ As such, to satisfy the requirement for a “substantial” utility, “an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the ‘substantial’ utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public.”⁴¹

27. For example, in *Brenner v. Manson*, the Supreme Court addressed whether a patent claiming “a chemical process which yields an already known product [steroids] whose utility—other than as a possible object of scientific inquiry—has not yet been evidenced” satisfied the utility requirement.⁴² The Court answered in the negative, concluding that such a process lacked utility. Thus, the fact that the process produced a known chemical was insufficient; the applicant had to disclose a real-world use for the produced chemical as well. As the Court noted, “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”⁴³ We now know, of course, that steroids have considerable clinical efficacy, but such utility was not known at that time, rendering the application premature.

28. Similarly, in *In re Fisher*, the Federal Circuit found claims to express sequence tags (ESTs) to lack substantial utility because “the claimed ESTs act as no more than research intermediates that may help scientists to isolate the particular underlying protein-encoding genes and conduct further experimentation on those genes....Accordingly, the claimed ESTs are, in words of the Supreme Court, mere ‘object[s] of use-testing,’ to wit, objects upon which scientific

³⁸ *In re Fisher*, at 1371 (R-064).

³⁹ *Id.* (R-064) (quoting *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980)).

⁴⁰ *Brenner*, at 529 (R-053); *In re Fisher*, at 1373 (R-064).

⁴¹ *Id.* (R-064).

⁴² *Brenner*, at 529 (R-053).

⁴³ *Id.* at 535 (R-053).

research could be performed with no assurance that anything useful will be discovered in the end.”⁴⁴

3. Specific Utility

29. To satisfy the “specific utility” requirement, “an application must disclose a use which is not so vague as to be meaningless....[A]n asserted use must also show that that claimed invention can be used to provide a well-defined and particular benefit to the public.”⁴⁵ General expressions in the specification of “biological activity” or “biological properties” are generally insufficient to demonstrate specific utility.⁴⁶

30. For example, the Federal Circuit’s predecessor court, the Court of Customs and Patent Appeals (CCPA), rejected claims to specific steroid compounds in *In re Kirk*.⁴⁷ The specification disclosed that “such steroidal materials may be applied to veterinary or medical practice in the form of tablets, elixirs, injections, implants or other pharmaceutical preparations. In other words, the compounds in question are to be used in the manner of other steroid hormones in veterinary or medical compositions.”⁴⁸ The CCPA found such generic, non-specific assertions of utility insufficient.

31. As another example, the Federal Circuit found specific utility to be lacking in the claims to ESTs because “[a]ny EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses.”⁴⁹ The disclosed uses were therefore “general uses for its claimed ESTs, not specific ones that satisfy § 101.”⁵⁰

4. Proof of Utility Must Be Demonstrated As of the Application’s Filing Date

32. Utility is assessed as of the time that the inventor filed her application; if the invention’s usefulness has not been demonstrated at that time, then the application is premature

⁴⁴ *In re Fisher*, at 1373 (quoting *Brenner*, 383 U.S. at 535) (R-064).

⁴⁵ *In re Fisher*, at 1365 (R-064).

⁴⁶ *Id.* at 1371 (R-064); see also *In re Kirk*, 376 F.2d 936, 941 (C.C.P.A. 1967) (“*In re Kirk*”) (R-074) (“It seems to us that the nebulous expressions ‘biological activity’ or ‘biological properties’ appearing in the specification convey no more explicit indication of the usefulness of the compounds and how to use them than did the equally obscure expression ‘useful for ‘technical and pharmaceutical purposes’ unsuccessfully relied upon by the appellant in *In re Diedrich*, 318 F.2d 946, 50 CCPA 1355.”); *In re Diedrich*, 318 F.2d 946, 951 (C.C.P.A. 1963) (“*In re Diedrich*”) (R-075) (“Nowhere in the patent disclosure has appellant mentioned that his compounds possess the property of being opaque to X-ray photographs, the property most crucial to the use for which he now contends.”)

⁴⁷ *In re Kirk*, at 941 (R-074).

⁴⁸ *Id.* (R-074).

⁴⁹ *In re Fisher*, at 1374 (R-064).

⁵⁰ *Id.* (R-064).

and should be rejected. The Federal Circuit has made clear that “an applicant's failure to disclose how to use an invention may support a rejection under ... section 101 for lack of utility ‘when there is a complete absence of data supporting the statements which set forth the desired results of the claimed invention.’”⁵¹ Thus, “an invention will not be considered useful for the purposes of section 101 where, at the time of filing, ‘there is a complete absence of data supporting the statements which set forth the desired results of the claimed invention’—even if the invention is later proven useful or operable.”⁵²

33. Proof of utility can include test results, human trials, animal tests or *in vitro* experiments, depending on the nature of the invention.⁵³ The USPTO theoretically allows proof of utility based on “arguments or reasoning,”⁵⁴ but neither the Federal Circuit nor any federal court so held.⁵⁵ As a result, it is unclear whether this “arguments or reasoning” guideline actually reflects the law. Any such evidence, however, must demonstrate the utility of the invention as of the filing date. Evidence, such as affidavits, cannot be “simply an *ex post facto* affirmation” that merely “attempts to add statements of usefulness to the disclosure of the application as filed.”⁵⁶

34. Evidence of an invention’s utility that is created after the filing date generally should not be considered. Contrary to Professor Merges’ suggestions post-filing information has been allowed in the United States only in narrow circumstances.⁵⁷ The Federal Circuit has permitted post-filing data only when such evidence was redundant with the information available as of the filing date and does not reflect subsequent, post-filing discoveries or innovations.⁵⁸ For example, in *In re Brana*, the Federal Circuit permitted post-application evidence to be admitted and considered, but the court made clear that such post-filing evidence was used “to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification.”⁵⁹ In other words, the court allowed the evidence because it demonstrated the utility of the invention *when the application was filed*.⁶⁰

⁵¹ *In re Cortright*, at 1356 (quoting *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 762 (Fed.Cir.1984)) (**R-068**).

⁵² *Cre-Agri, Inc.*, at *16 (**R-071**) (quoting *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325 (Fed. Cir. 2005)), *aff’d without opinion*, No. 2014-1209, 2014 WL 5162378 (Fed. Cir. Oct. 15, 2014).

⁵³ *In re ‘318*, at 1324-25 (**R-054**); *In re Brana*, at 1566-1567 (**R-073**) (sufficient evidence of specific utility by *in vivo* tests on tumor models).

⁵⁴ Manual of Patent Examining Procedure § 2107.03 (9th Ed. March 2014) (“MPEP 2014”) (**R-076**).

⁵⁵ *In re ‘318 Patent Litigation*, at 1325 (**R-054**) (rejecting such arguments and noting “no case has been called to our attention where utility was established simply by analytic reasoning.”).

⁵⁶ *In re Kirk*, at 941-42 (**R-074**).

⁵⁷ See Expert Report of Professor Robert P. Merges, ¶ 5

⁵⁸ See *Cre-Agri*, at *19 (characterizing use of post-filing data as a “narrow exception”) (**R-071**).

⁵⁹ *In re Brana*, at 1567 n.19 (**R-073**).

⁶⁰ *Id.* (**R-073**).

35. The *Brana* decision is full of various limits and caveats that narrow the scope of the holding. Indeed, much of it could be viewed as non-binding dicta. The Federal Circuit’s primary holding was that the USPTO failed to satisfy its initial burden of challenging the presumptively correct utility because having anti-tumor properties was not an “inherently unbelievable undertaking.”⁶¹ That alone was sufficient to find utility and reverse the USPTO’s decision, rendering consideration of any additional evidence unnecessary. Nevertheless, the court when on, in what is arguably dicta, to explain that, even if the USPTO had satisfied this initial burden, the applicants proffered sufficient evidence to convince the PHOSITA of the invention’s utility.⁶² The applicant submitted the evidence through an affidavit signed and dated June 1991, after the filing date. But, even though the evidence was post-filing, it merely substantiated and confirmed the utility found in the disclosure. Importantly, the claims in *Brana* were directed to compounds, and not particular to methods of treating humans. As such, the broader assertion of utility was sufficient, even though it would be possible that “it may eventually appear that the compound is without value in the treatment in humans.”⁶³

36. It is unsurprising, therefore, that the Federal Circuit and other courts have interpreted *Brana* narrowly. The Federal Circuit has been careful to limit the holding of *Brana*, explaining that “[t]he applicants [in *Brana*] also submitted animal testing results for the claimed compounds to the PTO after the filing date, but our finding of enablement did not depend on these post-application test results. In *Brana*, moreover, unlike the present case, the testing was submitted to the PTO during prosecution.”⁶⁴ Other courts have similarly interpreted *Brana* narrowly:

Read too broadly, however, the *Brana* exception would swallow the rule that ‘[e]nablement, or utility, is determined as of the application filing date.’ Where actual results, garnered post-filing, mirror or otherwise substantiate predicted results, it is plain that those results will pertain to the accuracy of a statement in the specification within the meaning of *Brana*. Here, however, the ’599 Patent makes no assertions whatsoever regarding the outcomes of the proposed studies, so the study designs provided in the specification are not sufficiently prophetic such that later-achieved results can support the utility of the claimed invention.⁶⁵

37. The court of first instance in *Eli Lilly & Co. v. Actavis Elizabeth LLC* rejected Eli Lilly’s patent on the basis of utility because (1) the specification contained no testing data and (2) one of ordinary skill in the art would not have recognized the utility as of the filing date

⁶¹ *Brana*, at 1566 (R-073).

⁶² *Id.* at 1566-67 (R-073).

⁶³ *Id.* at 1567 (quoting *In re Krimmel*, 292 F.2d 948, 953 (CCPA 1961)) (R-073).

⁶⁴ *In re ’318*, at 1325 n.8 (R-054). The Federal Circuit thus recognized that much of the language *Brana* is dicta.

⁶⁵ *Cre-Agri*, at *19 (citations omitted) (R-071). As discussed below, U.S. law permits the applicant to include prophetic examples, which are ones where the applicant did not actually perform but which are “based on predicted results rather than work actually conducted or results actually achieved.” MPEP 2014 § 2164.02 (R-076).

based on the state of the art.⁶⁶ The court concluded that the evidence of utility generated after the filing of the patent application was insufficient to demonstrate that the use of atomoxetine to treat ADHD was known as of the filing date.⁶⁷ The court noted the concern with readily allowing post-filing evidence in: “permitting patents to be filed prior to the establishment (through some means) of enablement/utility cuts off future scientific research in a field “with no assurance that anything useful will be discovered in the end.”⁶⁸

38. Although the Federal Circuit reversed the court’s judgment regarding utility, the Federal Circuit’s non-precedential decision in *Eli Lilly & Co. v. Actavis Elizabeth LLC*⁶⁹ cannot alter preference for evidence contemporaneous with the filing date. (This case is parallel litigation to that in Canada dealing with atomoxetine, in which the Canadian courts rejected the claimed invention for lacking utility.) As a legal matter, the Federal Circuit’s decision is non-precedential, so it does not have the binding effect of precedent, and courts are not bound by its holding. Because it is not binding, if it reflects a misapplication of the law, then future courts need not follow it. Moreover, it is consistent with the narrow exception in *Brana* because the post-filing evidence only confirmed the utility disclosed in the specification, and the Federal Circuit noted that there was no reason to doubt the assertions of utility made in the specification itself. The key aspects of the holding were that:

the norepinephrine relationship was known, safety for antidepressant activity had been established, the specification contained a full description of the utility, experimental verification had been obtained before the patent was granted, and the examiner had not requested additional information. There was no evidence that the disclosure is “on its face, contrary to generally accepted scientific principles.”⁷⁰

The use of post-filing evidence here merely corroborated what was considered the already-sufficient disclosure in the patent application by the court, which is exactly what *Brana* allowed. The case does not represent a change in the basic principle that an invention’s utility must be demonstrated as of the filing date and that post-filing date evidence cannot be used to demonstrate utility in the face of an otherwise insufficient disclosure. To the extent someone reads the case to have a broader holding, this case is an outlier from the actual utility doctrine in the United States.

39. That the U.S. courts and the Canadian courts reached different outcomes on the utility of this invention likely comes from differing views of the factual nature of this inquiry. It

⁶⁶ *Eli Lilly and Co. v. Actavis Elizabeth LLC*, 731 F. Supp. 2d 348, 389 (D.N.J. 2010) (**R-029**).

⁶⁷ *Id.* at 386 (“[T]his Court finds that post-filing date test results are not sufficient, alone, to satisfy the enablement/utility requirement for patentability.”).

⁶⁸ *Id.* at 385.

⁶⁹ *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 Fed. Appx. 917 (Fed. Cir. 2011) (**R-077**).

⁷⁰ *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 Fed. Appx. 917, 926 (Fed. Cir. 2011) (quoting *In re Marzocchi*, 439 F.2d 220, 223 (Ct. Cust. & Pat. App. 1971) (**R-077**)).

is typical for fact-finders to view the evidence differently and to reach inconsistent results. Even the U.S. district court viewed the patent to lack utility, as the Canadian courts did, noting the concern with affording patent protection prematurely.⁷¹ The district court considered the disclosures in the case inadequate to demonstrate utility. As a factual issue, differences about the sufficiency of a single patent disclosure do not reflect systemic, legal inconsistencies between the patent laws of the two countries. Reasonable minds can often disagree on what factual conclusions to draw based on the evidence. Indeed, within the United States, one judge found the disclosure insufficient, while two others disagreed.

40. Overall, what we see in the above narrative is that U.S. courts have indeed addressed many issues relevant to “utility” in a manner analogous to Canadian courts. Notably, they are concerned about speculative patent filing in art fields that are generally unpredictable, like chemistry and pharmaceuticals. They posit that utility must be demonstrated as of the filing date. The utility, particularly in the unpredictable arts, must be founded on real research, conducted as of the date of filing and not years later. Moreover (relevant to a point below), much of the relevant jurisprudence has evolved after the conclusion of NAFTA.

B. Under U.S. Patent Law, Enablement Addresses Utility-Related Issues as Well

41. Utility doctrine is not the only way that U.S. patent law polices concerns of premature patent filings and overly broad patent claims. The enablement requirement of 35 U.S.C. § 112(a)⁷² – that the patent specification shall provide sufficient detail to allow one of ordinary skill in the art to both make and use the claimed invention – also plays a similar role. The Federal Circuit has noted that “[e]nablement is closely related to the requirement for utility.”⁷³ In the United States, “[e]nablement serves the dual function in the patent system of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed invention.”⁷⁴

42. Professor Merges understates the relationship between utility and enablement. Utility is not merely “relevant” to the enablement standard⁷⁵: the courts and the USPTO have

⁷¹ *Eli Lilly and Co. v. Actavis Elizabeth LLC*, 731 F. Supp. 2d 348, 385 (D.N.J. 2010) (**R-029**) (“Although it appears to be a harsh result (as Lilly received positive initial test data months after the filing date), the Court believes that binding precedent requires the enablement/utility requirement to be satisfied at the time the patent application is filed. As Defendants note, and this Court agrees, there is a valid policy for requiring utility to be established at the time of filing: permitting patents to be filed prior to the establishment (through some means) of enablement/utility cuts off future scientific research in a field ‘with no assurance that anything useful will be discovered in the end.’” (quoting *In re Fisher*, 421 F.3d at 1373)).

⁷² In 2011, the Leahy-Smith *America Invents Act* (AIA) went into effect. Before the AIA, the paragraphs of § 112 were not numbered, so the convention was to speak of § 112’s various paragraphs. As such, pre-AIA cases will discuss § 112, paragraph 1. The AIA labeled this section as § 112(a) but did not change the substance of the provision.

⁷³ *In re ‘318*, at 1323 (**R-054**).

⁷⁴ *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1380-81 (“*Magsil Corp.*”) (**R-078**).

⁷⁵ Expert Report of Professor Robert P. Merges, ¶ 16.

made clear that, while not entirely coextensive, the two are inextricably intertwined. The Federal Circuit has noted that “[t]he how to use prong of section 112 *incorporates as a matter of law the requirement of 35 U.S.C. § 101* that the specification disclose as matter of fact a practical utility for the invention. If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112.”⁷⁶ The USPTO similarly recognizes the interrelationship, instructing the examining corps to offer a joint §§ 101/112(a) rejection for lack of enablement and utility:

(2) If no assertion of specific and substantial utility for the claimed invention made by the applicant is credible, and the claimed invention does not have a readily apparent well-established utility, reject the claim(s) under 35 U.S.C. 101 on the grounds that the invention as claimed lacks utility. Also reject the claims under 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, on the basis that the disclosure fails to teach how to use the invention as claimed.⁷⁷

43. This overlap makes sense because, if an invention lacks utility, then the applicant cannot explain how to use it.⁷⁸ As the Federal Circuit has elaborated:

The enablement requirement of 35 U.S.C. § 112, ¶ 1 requires that the specification adequately discloses to one skilled in the relevant art how to make, or in the case of a process, how to carry out, the claimed invention without undue experimentation. The utility requirement of 35 U.S.C. § 101 mandates that any patentable invention be useful and, accordingly, the subject matter of the claim must be operable. If a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement.⁷⁹

44. Enablement performs an important backstop in this context. Whereas § 101 only requires disclosure of a specific, substantial, and credible utility generally, § 112(a) obligates the applicant to ensure that the PHOSITA can employ the full scope of the invention as claimed without “undue experimentation”.⁸⁰ For unpredictable arts, such as the chemical, biological, and pharmaceutical ones, enablement is more difficult to satisfy. Courts gauge “undue experimentation” by considering eight non-exclusive factors, known generally as the *Wand* factors:

(1) the quantity of experimentation necessary,

⁷⁶ *In re Ziegler*, 992 F.2d 1197, 1200-01 (Fed. Cir. 1993) (emphasis added) (R-079).

⁷⁷ MPEP 2014 § 2107 (R-076).

⁷⁸ *See Process Control Corp.*, at 1358 (R-066).

⁷⁹ *Id.* (R-066).

⁸⁰ *In re Wright*, 999 F.3d 1557, 1561 (Fed. Cir. 1993) (“*In re Wright*”) (R-080); *see Seymore, The Enablement Pendulum Swings Back*, at 286-89 (R-062) (discussing requirement that specification enable the full scope of the claimed invention).

- (2) the amount of direction or guidance presented,
- (3) the presence or absence of working examples,
- (4) the nature of the invention,
- (5) the state of the prior art,
- (6) the relative skill of those in the art,
- (7) the predictability or unpredictability of the art, and
- (8) the breadth of the claims⁸¹

45. As Professor Merges correctly notes, there are some differences between the two standards of utility under § 101 and enablement under § 112(a). For example, as the MPEP notes, “if an applicant has claimed a process of treating a certain disease condition with a certain compound and provided a credible basis for asserting that the compound is useful in that regard, but to actually practice the invention as claimed a person skilled in the relevant art would have to engage in an undue amount of experimentation, the claim may be defective under 35 U.S.C. 112, but not 35 U.S.C. 101.”⁸² Although this distinction relates to claim scope, it also involves the concern of premature filing – the applicant has not yet provided an adequate disclosure in the patent specification to support the broad scope of protection claimed. Subsequent investigation and development of the technology, however, may result in an applicant being entitled to broader scope. Nevertheless, the two doctrines remain tightly intertwined, and a failure of utility under § 101 will result in a lack of enablement under § 112(a).

46. As the statute states, it is the patent specification that must contain the enabling information, and the patent document must be enabling as of the filing date.⁸³ Applicants can include working examples in the specification, which are experiments actually performed by the applicant.⁸⁴ Applicant can also include “prophetic” examples, which are ones that the applicant did not actually perform but which are “based on predicted results rather than work actually conducted or results actually achieved.”⁸⁵ It is possible for an inventor to receive a patent without ever having constructed working versions of the invention. For example, Alexander Graham Bell received a patent on the telephone even though he had not constructed a working version prior to filing his patent application.⁸⁶ The patent was granted based solely on predictions. In theory, one could

⁸¹ *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (citing *In re Forman*, 230 U.S.P.Q. 546 (Bd. Pat. App. & Interf. 1986)) (R-081).

⁸² MPEP 2014 § 2107.01 (R-076).

⁸³ See *In re '318*, at 1325 (R-054) (“In this case, however, neither in vitro test results nor animal test results involving the use of galantamine to treat Alzheimer’s-like conditions were provided. The results from the ‘318 patent’s proposed animal tests of galantamine for treating symptoms of Alzheimer’s disease were not available at the time of the application, and the district court properly held that they could not be used to establish enablement.”).

⁸⁴ MPEP 2014 § 2164.02 (R-076).

⁸⁵ *Id.* (R-076); see also *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1189-90 (Fed. Cir. 2014) (R-082).

obtain a patent based solely on prophetic extrapolations, but whether such a disclosure is sufficiently enabling would depend on the nature of the art. Unpredictable art fields, therefore, generally require greater disclosures and may require actual, working examples.⁸⁷

47. Enablement also acts as a limit on the permissible scope of a claim. For example, an inventor who develops a vaccine for a particular RNA virus is not necessarily entitled to claim vaccines on all RNA viruses, which would include the HIV viruses.⁸⁸ The Supreme Court has long viewed enablement as a way of policing claim scope. In *Consolidated Elec. Light Co. v. McKeesport Light Co.*, the Court invalidated a claim covering all fibrous and textile materials for an incandescent light, even though the inventors had only utilized carbonized paper. The Court reasoned:

If the patentees had discovered in fibrous and textile substances a quality common to them all, or to them generally, as distinguishing them from other materials, such as minerals, etc., and such quality or characteristic adapted them peculiarly to incandescent conductors, such claim might not be too broad.... Sawyer and Man supposed they had discovered in carbonized paper the best material for an incandescent conductor. Instead of confining themselves to carbonized paper, as they might properly have done, and in fact did in their third claim, they made a broad claim for every fibrous or textile material, when in fact an examination of over 6,000 vegetable growths showed that none of them possessed the peculiar qualities that fitted them for that purpose. Was everybody, then, precluded by this broad claim from making further investigation? We think not.

The injustice of so holding is manifest in view of the experiments made, and continued for several months, by Mr. Edison and his assistants, among the

⁸⁶ See *The Telephone Cases*, 126 U.S. 1, 535-36 (1888) (**R-083**) (“But it is insisted that the claim cannot be sustained because, when the patent was issued, Bell had not in fact completed his discovery. While it is conceded that he was acting on the right principle, and had adopted that true theory, it is claimed that the discovery lacked that practical development which was necessary to make it patentable...in his specification he did describe accurately, and with admirable clearness, his process,-that is to say, the exact electrical condition that must be created to accomplish his purpose,-and he also described, with sufficient precision to enable one of ordinary skill in such matters to make it, a form of apparatus which, if used in the way pointed out, would produce the required effect, receive the words, and carry them to and deliver them at the appointed place.); see also *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 62 (1998) (**R-084**) (“In 1888, this Court upheld a patent issued to Alexander Graham Bell even though he had filed his application before constructing a working telephone.”).

⁸⁷ See, e.g., *In re Goodman*, 11 F.3d 1046, 1050-52 (Fed. Cir. 1993) (**R-085**) (affirming enablement rejection because single working example did not enable the full scope of the claims); *In re Colianni*, 561 F.2d 220, 224 (C.C.P.A. 1977) (**R-086**) (Miller, J., concurring) (noting one factor in assessing enablement is “the presence or absence of working examples” and concurring that claim is not enabled where “[n]ot a single working example has been disclosed.”). See also Seymore, *The Enablement Pendulum Swings Back*, at 289 (noting need to disclose various versions of the invention as having “long been the rule in the unpredictable arts.”) (**R-062**).

⁸⁸ See *In re Wright*, at 1562-64 (**R-080**).

different species of vegetable growth, for the purpose of ascertaining the one best adapted to an incandescent conductor.⁸⁹

48. Just as with utility, enablement poses a considerable challenge for patent applicants in the chemical and biochemical arts because those areas tend to be unpredictable: minor changes in a chemical structure can have profound impacts on how a drug or biologic operates. A more robust disclosure is often required in order to obtain broad claims because one of skill in the art would be unable to extrapolate from a narrow description.⁹⁰ For example, in *Wyeth and Cordis Corp. v. Abbott Labs.*, the Federal Circuit invalidated a patent method for treating restenosis using rapamycin, a class of chemical compounds. As the Federal Circuit noted with respect to this invention:

Here, the specification similarly discloses only a starting point for further iterative research in an unpredictable and poorly understood field. Synthesizing candidate compounds derived from sirolimus could, itself, require a complicated and lengthy series of experiments in synthetic organic chemistry. Even putting the challenges of synthesis aside, one of ordinary skill would need to assay each of at least tens of thousands of candidates. Wyeth's expert conceded that it would take technicians weeks to complete each of these assays. The specification offers no guidance or predictions about particular substitutions that might preserve the immunosuppressive and antirestenotic effects observed in sirolimus. The resulting need to engage in a systematic screening process for each of the many rapamycin candidate compounds is excessive experimentation. We thus hold that there is no genuine dispute that practicing the full scope of the claims, measured at the filing date, required undue experimentation.⁹¹

Thus, while the specification would have satisfied § 101's utility requirement because the specification disclosed a credible, substantial, and specific one – the treatment of restenosis -- the claim was invalid for lack of enablement because the specification's disclosure was insufficient to support the full scope of the claim. One of ordinary skill would have to experiment extensively to discern which compounds that fell within the scope of the generic claim actually would work to treat restenosis.

49. “In the context of determining whether sufficient ‘utility as a drug, medicant, and the like in human therapy’ has been alleged, ‘it is proper for the examiner to ask for substantiating evidence unless one with ordinary skill in the art would accept the allegations as obviously correct.’”⁹² Mere plausibility is insufficient to demonstrate

⁸⁹ *Consolidated Elec. Light Co. v. McKeesport Light Co.*, 159 U.S. 465, 472-7316 S. Ct. 75, 77-78 (1895) (**R-087**).

⁹⁰ *In re Marzocchi*, 439 F.2d 220, 223 (C.C.P.A. 1971) (**R-088**) (“In the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim.”).

⁹¹ *Wyeth and Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1386 (Fed. Cir. 2013) (**R-089**).

⁹² *Rasmusson*, at 1323 (quoting *In re Jolles*, 628 F.2d 1322, 1325 (Cust. & Pat.App.1980)) (**R-063**).

enablement. Enablement must be demonstrated as of the filing date. As the Federal Circuit has explained:

If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to “inventions” consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses *later proved true*, the “inventor” would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis.⁹³

50. The Federal Circuit has emphasized that enablement must be assessed as of the filing date; post-filing evidence that represents advances in the state of the art cannot inform the analysis. The court has explained:

this field of art has advanced vastly after the filing of the claimed invention. The specification containing these broad claims, however, does not contain sufficient disclosure to present even a remote possibility that an ordinarily skilled artisan could have achieved the modern dimensions of this art. Thus, the specification enabled a marginal advance over the prior art, but did not enable at the time of filing a tunnel junction of resistive changes reaching even up to 20%, let alone the more recent achievements above 600%.⁹⁴

51. In recent years, the Federal Circuit has tightened the enablement requirement, emphasizing the importance of disclosures in the patent document itself. In *Genentech, Inc. v. Novo Nordisk A/S*, the Federal Circuit bemoaned the dearth of disclosure in the specification:

It is true, as Genentech argues, that a specification need not disclose what is well known in the art. However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge

⁹³ *Id.* at 1325 (**R-063**). See also *In re Kirk*, at 942 (Ct. Cust. & Pat. App. 1967) (“*In re Kirk*”) (**R-074**) (“Thus we agree with the solicitor that appellants’ affidavit is simply an ex post facto affirmation irrelevant to the issue of adequacy of the original disclosure inasmuch as it attempts to add statements of usefulness to the disclosure of the application as filed. . . . ‘We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.’” (quoting *In re Diedrich*, 318 F.3d 946, 949 (C.C.P.A. 1963)).

⁹⁴ *MagSil Corp.*, at 1382 (Fed. Cir. 2012) (**R-078**).

of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research.⁹⁵

The emphasis on the disclosure, and the discounting of the knowledge of one of ordinary skill has continued. In particular, the Federal Circuit has limited the ability of applicants to use broad claims that cover various versions of an invention, when the specification only provides few, or even one, example. Patent claims can cover multiple versions of an invention, called embodiments. For example, a claim may require a “board,” which could include boards made of wood, plastic, or other materials. A wood board would be one embodiment of the invention. When the patent specification only discloses one or very few embodiments, the Federal Circuit has invalidated claims that attempt to cover a large number of embodiments.

52. For example, the Federal Circuit has held that a particular embodiment covered by the claims is not enabled when the specification actually teaches against the use of a particular embodiment by suggesting that version of the invention is inferior or otherwise defective.⁹⁶ The court has extended this reason more recently to situations where a thin disclosure will not support claims directed to alternative embodiments, even absent the above scenario where the specification denigrates that variant. If the claim covers two or more embodiments, but the specification only adequately discloses one, then the Federal Circuit has found those broad claims invalid for lack of an enabling disclosure.⁹⁷ For example, in *Automotive Technologies International, Inc. v. BMW of North America, Inc.*, the Federal Circuit invalidated a claim that

⁹⁵ *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (**R-090**).

⁹⁶ *Liebel-Florsheim Co. v. Medrad Inc.*, 481 F.3d 1371, 1379 (Fed. Cir. 2007) (“*Liebel-Florsheim*”) (**R-091**) (finding claims covering both jacketed and jacketless syringes lacking enablement because the specification had suggested problems with jacketless embodiments; court reasons “where the specification teaches against a purported aspect of an invention, such a teaching ‘is itself evidence that at least a significant amount of experimentation would have been necessary to practice the claimed invention.’”) (quoting *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003)); *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d at 1244 (**R-092**) (“We conclude that the specification is inadequate as a matter of law in that regard primarily because it expressly teaches against it. Worse than being silent as to that aspect of the invention, the specification clearly and strongly warns that such an embodiment would not wet well. In particular, the specification warns that silicon content above 0.5% in the aluminum coating causes coating problems. Such a statement discourages experimentation with coatings having more than 0.5% silicon, undue or otherwise. It tells the public that higher amounts of silicon will not work. Nothing further need be said about the matter.”).

⁹⁷ *ALZA Corp. v. Andrx Pharmaceuticals, LLC*, 603 F.3d 935, 940-41 (Fed. Cir. 2010) (“*Alza Corp.*”) (**R-093**) (claim covering both osmotic and non-osmotic versions of drug not enabled because, “[t]o satisfy the plain language of § 112, ¶ 1, ALZA was required to provide an adequate enabling disclosure in the specification; it cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification.”); *Sitrick v. Dreamworks*, 516 F.3d 993, 1000 (Fed. Cir. 2008) (“*Sitrick*”) (**R-094**) (claim covering both video games and movies was not enabled because “[n]either patent specification in this case teaches how the substitution and integration of a user image would be accomplished in movies.”); *Automotive Technologies International, Inc. v. BMW of North America, Inc.*, 501 F.3d 1274, 1283 (Fed. Cir. 2007) (“*Automotive Technologies*”) (**R-095**) (finding claims covering both mechanical and electronic sensors invalid for lack of enabling disclosure with respect to the electronic sensors, reasoning “ATI argues that despite this limited disclosure, the knowledge of one skilled in the art was sufficient to supply the missing information. We do not agree.... Although the knowledge of one skilled in the art is indeed relevant, the novel aspect of an invention must be enabled in the patent. The novel aspect of this invention is using a velocity-type sensor for side impact sensing.”).

required a “sensor.”⁹⁸ The term sensor covered both mechanical and electronic sensors, but the specification had a minimal description of the electronic sensor. Given the lack of support in the patent document, the court invalidated the claim for failure to enable the use of an electronic sensor.⁹⁹

53. These cases show a trend in the case law of elevating the importance of the patent’s disclosure to determine enablement. I personally disagree with this line of cases. Whether a claim is enabled is traditionally assessed by combining the knowledge of the person of ordinary skill in the art with the patent’s disclosure to determine whether that person could practice the invention as claimed without undue experimentation. By placing such emphasis on the patent disclosure, the cases, in my view, inappropriately discount the knowledge and views of technologists in the field, creating risks that the court will make mistakes based on erroneous views of the technology.¹⁰⁰ Nevertheless, the cases clearly demonstrate that the Federal Circuit has ratcheted up the U.S. disclosure requirements.¹⁰¹ U.S. patent specifications need more robust disclosures in order to ensure that the full scope of a given claim is enabled.

54. Because enablement acts as a check on the scope of a patent’s claims, necessarily the interpretation of those claims can become very important. Patentees can find themselves in a catch-22, arguing for a broader claim construction to cover the device or method accused of infringing, only to have the claim invalidated for lack of enablement because the claim, as construed, is not supported by the specification. This situation arose *Liebel-Florsheim Co. v. Medrad, Inc.*, where the Federal Circuit specifically noted:

The irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled, a challenge it could not meet. The motto, “beware of what one asks for,” might be applicable here.¹⁰²

Other cases have presented this same problem for patent holders.¹⁰³ The link between enablement and claim construction is clear from these cases, as other district court cases also confirm.¹⁰⁴

⁹⁸ *Automotive Technologies International*, at 1283 (R-095).

⁹⁹ *Id.* (R-095).

¹⁰⁰ Timothy R. Holbrook, *Patents, Presumptions, and Public Notice*, 86 IND. L.J. 779, 792-803 (2011) (R-096).

¹⁰¹ Sean B. Seymore, *The Enablement Pendulum Swings Back*, at 289-92 (discussing elevated enablement requirements) (R-062).

¹⁰² *Liebel-Florsheim Co. v. Medrad Inc.*, 481 F.3d 1371, 1380 (Fed. Cir. 2007) (“*Liebel-Florsheim*”) (R-091). *But see* Timothy R. Holbrook, *Patents, Presumptions, and Public Notice*, 86 Ind. L.J. (2011) at 802-03 (criticizing outcome and suggesting courts should narrowly construe claims to preserve validity) (R-096).

¹⁰³ *MagSil Corp. I*, at 1384 (R-078) (“MagSil’s difficulty in enabling the asserted claims is a problem of its own making” due to its position on claim construction); *ALZA Corp. v. Andrx Pharmaceuticals, LLC.*, 603 F.3d at 943 (“*Alza Corp.*”) (R-093) (“ALZA successfully argued to the district court that the claims encompassed both osmotic and non-osmotic dosage forms. However, ALZA’s patent specification does not enable the full scope of the claims, namely non-osmotic oral dosage forms with ascending release rates.”); Sitrick, at 999-1000 (R-094) (“The district court construed the asserted claims to include both video games and movies....Because the asserted claims are

55. This review demonstrates how the enablement doctrine in the United States operates in a manner comparable to the ‘utility’ requirements in Canadian patent law. Indeed, within the United States, enablement and utility have considerable overlap. The requirement for an enabling disclosure in the United States acts as a constraint on claims when the applicant has not made a sufficient contribution to the state of the art to permit the practice of the full scope of the claims. Applicants are allowed to offer predictions, through prophetic examples, of how the invention may work, but these examples still must be predictive, permitting the person of ordinary skill in the art to practice the invention without undue experimentation. This standard can be difficult to satisfy in the unpredictable arts, like pharmaceuticals, suggesting that such patents must be narrowly circumscribed or risk invalidation for lack of enablement.

C. The United States Patent Law’s Written Description Requirement Also Ensures that the Claims of the Patent Reflect what the Inventor Actually Created

56. U.S. patent law also uses another doctrine – written description – to police issues similar to those of the Canadian utility doctrine. Section 112(a) requires “[t]he specification shall contain a written description of the invention.” Enablement and the written description requirement are distinct but “closely related” requirements.¹⁰⁵ Indeed, the Federal Circuit has noted that they “usually rise and fall together.”¹⁰⁶ Another court noted that the written description and utility requirements are also closely related.¹⁰⁷ Utility, enablement, and written description, therefore are all tightly woven together, which is unsurprising because they police similar policy concerns of premature patent filings and undue patent claim scope. Interestingly, the courts introduced this variation of the written description requirement after NAFTA was negotiated, at the express behest of Eli Lilly, as a means to prevent patenting on upstream or premature patent applications.¹⁰⁸

broad enough to cover both movies and video games, the patents must enable both embodiments.”); *Automotive Technologies*, at 1285 (R-095) (“ATI sought to have the scope of the claims of the ’253 patent include both mechanical and electronic side impact sensors. It succeeded, but then was unable to demonstrate that the claim was fully enabled. Claims must be enabled to correspond to their scope.”).

¹⁰⁴ See, e.g., *Bradford Co. v. Afco Mfg.*, No. 1:05-CV-449, 2008 WL 974043, at *7 (S.D. Ohio April 8, 2008) (R-097) (noting case is “mirror image of *Liebel-Flarsheim* and finding claim enabled under narrower construction); *LG Elecs., Inc. v. Hitachi, Ltd.*, No. 5:07-CV-90(DF), 2008 WL 5784208, at *23 (E.D. Tex. Dec. 8, 2008) (noting link between enablement and claim construction) (R-098).

¹⁰⁵ *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc) (“*Ariad*”) (R-099); *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1344-45 (Fed. Cir. 2005) (R-100).

¹⁰⁶ *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1344-45 (Fed. Cir. 2005), at 1345 (R-100) (“Those two requirements usually rise and fall together. That is, a recitation of how to make and use the invention across the full breadth of the claim is ordinarily sufficient to demonstrate that the inventor possesses the full scope of the invention, and vice versa.”).

¹⁰⁷ *Petito*, at *15 (R-065) (“[t]he case law does support that where an invention fails the utility requirement, it often will fail the written description requirement.”).

¹⁰⁸ *Regents of the University of California V. Eli Lilly & Co.*, 119 F.3d 1559, 1566-69 (Fed. Cir. 1997) (“*University of California*”) (R-101).

57. To satisfy the written description requirement, the specification must demonstrate that the inventor was “in possession” of the invention as claimed at the time she filed the patent application.¹⁰⁹ In other words, “the description must clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.”¹¹⁰ The proof that the inventor possessed the full scope of the claims must be within the four corners of the patent document itself.¹¹¹ The applicant cannot resort to evidence other than the specification, such as proof that she actually built the device, to satisfy the requirement.¹¹² If there is inadequate support in the patent’s specification for the breadth of the claim, then the claim is invalid.

58. The purpose of the written requirement is primarily to combat speculative, overly broad claims that cover subject matter not actually invented by the patent applicant. In this way, the written description requirement works to protect against the premature patenting of an invention. Eli Lilly has itself characterized this requirement as avoiding “the patenting of the hypothetical results of broad, prophetic research plans.”¹¹³ The level of disclosure required will vary “depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology,”¹¹⁴ in a manner akin to enablement. For broad, generic claims, the court has “set forth a number of factors for evaluating the adequacy of the disclosure, including ‘the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.’”¹¹⁵

59. The Federal Circuit has “held that a sufficient description of a genus ... requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.”¹¹⁶ The court has eschewed the use of any bright-line rules, however, as to when structural details must be disclosed and when functional claiming is sufficient.¹¹⁷ Because the inquiry is anchored to the PHOSITA, necessarily the

¹⁰⁹ *Ariad*, at 1352 (R-099); *Carnegie Mellon University. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed.Cir.2008) (“*Carnegie Mellon University*”) (R-102).

¹¹⁰ *Carnegie Mellon Univ.* (quoting *In re Alton*, 76 F.3d 1168, 1172 (Fed.Cir.1996)) (R-102).

¹¹¹ *Ariad*, at 1351 (R-099).

¹¹² *Id.* at 1352 (R-099) (“Conversely, we have repeatedly stated that actual “possession” or reduction to practice outside of the specification is not enough. Rather, as stated above, it is the specification itself that must demonstrate possession.”).

¹¹³ Brief of Appellant-Petitioner Eli Lilly & Co., *Ariad v. Eli Lilly & Co.*, No. 2008-1248, 2009 U.S. Fed. Cir. Briefs LEXIS 345 at 3 (Nov. 9, 2009) (R-XXX); see also *id.* at 5-6 (R-099) (“This Court has observed that identification of a function to be performed or a research plan for achieving it is not a conception but an attempt to preempt the future before it has arrived.”).

¹¹⁴ *Id.* at 1351 (R-099).

¹¹⁵ *Id.* (quoting *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005)) (R-099).

¹¹⁶ *Id.* at 1350 (R-099).

¹¹⁷ *Id.* at 1351 (R-099) (“The law must be applied to each invention at the time it enters the patent process, for each patented advance has a novel relationship with the state of the art from which it emerges. Thus, we do not try here to predict and adjudicate all the factual scenarios to which the written description requirement could be applied. Nor do

sufficiency of a disclosure will evolve over time just as the state of the art does. Although the Federal Circuit has rejected the idea that the written description requirement is a biotechnology-specific doctrine,¹¹⁸ the courts have applied it primarily in the context of chemical, pharmaceutical, and biotech inventions.¹¹⁹

60. Just as with enablement, the written description requirement is also closely tied to claim construction, as the assessment of the adequacy of the disclosure depends on the scope of the claim.¹²⁰ A patent owner may argue for a broader interpretation of a claim to ensure that the device accused of infringing is covered. The result may be, however, that the claim is invalid for a lack of adequate written description in the specification.

61. Written description law in the United States, therefore, deals with similar policy concerns as do aspects of the Canadian utility requirements. If the inventor has not demonstrated in the specification that she was in possession of the invention as of the filing date, then the claim is invalid. The focus in the analysis is on the patent disclosure, and there should be little resort to evidence outside of the patent document itself. Moreover, the issue of what is adequate disclosure is closely linked to construction of the patent specification.

IV. U.S. Patent Law has not remained “frozen” since NAFTA was adopted; it has continued to evolve over time.

62. Eli Lilly suggests that the NAFTA in some way froze patent law doctrine in both countries.¹²¹ Thus Canada’s introduction of new interpretations or applications of the ‘utility’ criteria under the Patent Act, if adopted by Canadian courts after NAFTA was signed, would violate the treaty. The United States’ own activities belie that view. U.S. patent law has not remained stagnant since the early 1990s. The courts in the United States have continued to

we set out any bright-line rules governing, for example, the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field.”)

¹¹⁸ *Id.* at 1352 (**R-099**) (“We also reject the characterization, cited by Ariad, of the court’s written description doctrine as a ‘super enablement’ standard for chemical and biotechnology inventions.”)

¹¹⁹ *See, e.g., AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014) (**R-103**) (invalidating claims as to antibodies associated with overproduction of naturally occurring protein for want of written description); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) (“*Enzo Biochem*”) (**R-104**); *University of California*, at 1567 (**R-101**).

¹²⁰ *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1322-23 (Fed. Cir. 2003) (“*Moba*”) (**R-105**) (Rader, J., concurring) (“Each time a claim encompasses more than the preferred embodiment of the invention described in the specification, a defendant can assert that the patent is invalid for failure to describe the entire invention. Under the expanded written description doctrine, every claim construction argument could conceivably give rise to a validity challenge as well.”); *see, e.g., Lochner Techs., LLC v. Vizio, Inc.*, 567 Fed. Appx. 931, 932 (Fed. Cir. 2014) (**R-106**) (“We conclude that the district court erred in its claim construction analysis. Because its written description and “regards as invention” analyses were predicated on this flawed analysis, we vacate the district court’s judgment of invalidity and remand for further proceedings.”)

¹²¹ Claimant’s Memorial, paras 7, 207-212.

adjust their application of various patentability requirements over time. This is quite typical and expected, as no country's law remains stagnant; it can be seen in U.S. patent law in a variety of contexts.¹²²

63. Recent activity at the U.S. Supreme Court in the law of subject matter eligibility is a good example. The U.S. Supreme Court has decided four cases since 2010 dealing with what subject matter should be viewed as eligible for patent protection.¹²³ In the process, they have rejected approaches articulated by the Federal Circuit, including the test that an invention merely have a concrete, tangible, and useful result to be patent eligible,¹²⁴ or that, to be eligible, the invention must be tied to a particular machine or transform a particle into a different state or thing.¹²⁵ One commentator has suggested that the Supreme Court's 2014 decision in *Alice v. CLS Bank* will result in the invalidation of "a majority of the software patents being litigated right now."¹²⁶ Such doctrinal chaos is telling because it shows that U.S. patent law has not been stable post-NAFTA and that patent applicants should not have reasonable expectations that the law will not change or evolve. The following section focuses on other key aspects of U.S. law that have changed or oscillated over time: utility, written description, and obviousness.

A. Utility Doctrine in the U.S. Has Oscillated Over Time

64. Contrary to Professor Merges' assertion that utility law has been stable, the law of utility has oscillated over time, with a recent uptick in its application that is far more consistent with the Supreme Court's decision in *Brenner v. Manson*. The Federal Circuit seemingly

¹²² David L. Schwartz, *Retroactivity at the Federal Circuit*, 89 Ind. L.J. 1547, 1558-70 (2014) (R-107) (delineating changes in U.S. patent doctrine, including the written description requirement, and the retroactive impact of those decisions).

¹²³ See *Alice Corp. Pty. Ltd. V. CLS Bank Int'l*, 134 S. Ct. 2347 (2014) (R-108); *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 21707 (2013) ("Molecular Pathology") (R-109); *Mayo Collaborative Services. V. Prometheus Laboratories., Inc.*, 132 S. Ct. 1289 (2012) (R-110); *Bilski v. Kappos*, 561 U.S. 593 (2010) (R-111).

¹²⁴ *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998) (R-112). The Federal Circuit rejected this approach in *In re Bilski*, 545 F.3d 943, 960-61 (Fed. Cir. 2008) (en banc) (R-113) ("we also conclude that the "useful, concrete and tangible result" inquiry *960 is inadequate and reaffirm that the machine-or-transformation test outlined by the Supreme Court is the proper test to apply."). The Supreme Court also rejected this approach in *Bilski v. Kappos*. See *Bilski v. Kappos*, 561 U.S. at 612 (R-111) ("And nothing in today's opinion should be read as endorsing interpretations of § 101 that the Court of Appeals for the Federal Circuit has used in the past." (citing *State Street*)); see also *id.* at 660 (R-111) (Breyer, J., concurring) ("To the extent that the Federal Circuit's decision in this case rejected [the *State Street*] approach, nothing in today's decision should be taken as disapproving of that determination.").

¹²⁵ *In re Bilski*, 545 F.3d at 954 (R-113). The Supreme Court rejected this approach in its decision reviewing the Federal Circuit's reasoning. *Bilski v. Kappos*, 561 U.S. at 604 (R-111) ("The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible 'process.'").

¹²⁶). *The Ramifications of Alice: A Conversation with Mark Lemley*, IP Watchdog, available at <http://www.ipwatchdog.com/2014/09/04/the-ramifications-of-alice-a-conversation-with-mark-lemley/id=51023/> (R-114).

stepped away from *Brenner*'s mandate with a seemingly more lax standard in *In re Brana*.¹²⁷ The Federal Circuit in *Brana* concluded that the USPTO had not demonstrated a lack of utility in the face of evidence from *in vivo* animal tumor models showing antitumor activity.¹²⁸ Subsequently, as discussed above, the Federal Circuit embraced the USPTO's utility guidelines, requiring that an invention have a specific, substantial, and credible utility, which represent a return to a more strict approach to utility consistent with *Brenner*. The USPTO adopted these guidelines in large part to combat the deluge of patents covering various gene fragments. Contrary to Mr. Kunin's assertion, the 2001 Guidelines were not adopted merely to provide "additional guidance" to the examiners; instead, they were in response to the signals by the USPTO itself to the patent bar that it was going to issue such patents.¹²⁹ In an article in *Science*, John J. Doll, then a part of the USPTO and eventually the acting Director of the USPTO, signaled the intent of the USPTO to issue patents on gene fragments, noting that they satisfied the utility requirement.¹³⁰ The USPTO then retreated from this position in the face of the controversy by issuing the 2001 Utility Guidelines.

65. Once the USPTO adopted the guidelines, it began to reject patent applications as to gene fragments, as demonstrated by the *Fisher* case itself. While the USPTO and the Federal Circuit contend that the standard was not heightened, commentators have noted that *Fisher* did effect a heightening of the utility standard.¹³¹ Indeed, even Mr. Kunin characterized the new guidelines as being "a more stringent test for utility than [the USPTO's] earlier set of guidelines...."¹³²

¹²⁷ *In re Brana* (R-073). Somewhat surprisingly and conspicuously, the Federal Circuit never even cited *Brenner* in its *Brana* analysis.

¹²⁸ *Id.* at 1566-67(R-073).

¹²⁹ Robert Cook-Deegan and Christopher Heany, *Patents in Genomics and Human Genetics*, 11 Annual Rev. Genomics Hum. Genet. 383-425 (2010), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2935940/pdf/nihms218000.pdf> (R-115) ("The EST patent controversy quieted down for several years when NIH abandoned its EST patent applications in 1994 but then roared back to life three years later when the U.S. patent office signaled it was about to grant patents on ESTs. The announcement came at a symposium on gene patents in February 1997.").

¹³⁰ John J. Doll, *The Patenting of DNA*, 280 *Science* 689-90 (May 1, 1998) (R-116).

¹³¹ See, e.g., Tashica T. Williams, *In re Fisher: Raising the Utility Hurdle for Express Sequence Tags*, 21 *Berkley Tech. L.J.* 123, 137 (2006) (R-117); see also Robert P. Merges, Peter S. Menell, & Mark A. Lemley, *Intellectual property in the New Technological Age* (Wolters Kluwer 6th Ed. 2012) 187 (R-055) ("While [the USPTO utility guidelines] do not take explicit notice of the academic debate [regarding fragmented ownership interests], the guidelines reflect a similar concern. It is clear that the *reason* 'throwaway' utilities are not acceptable is that they permit patents to issue on inventions whose greatest value has yet to be realized."); William F. Lee, et. Al., *Limits on Patentability in Life Sciences: Claims Covering Expressed Sequence Tags*, 6 *Sedona Conf. J.* 95, 96 (2005) (R-118) ("In 2001, however, the U.S. Patent and Trademark Office (PTO) placed itself at the center of the EST debate by issuing Utility Examination Guidelines that announced a new heightened standard for utility under 35 U.S.C. Section 101. On its face, the new, more stringent standard purports to apply to all inventions. In practice, however, the PTO has applied a heightened utility standard to EST patent applications, while continuing to judge the utility of other inventions under a more lenient test.").

¹³² Stephen J. Kunin, *Written Description Guidelines and Utility Guidelines*, 82 *J. Pat. & Trademark Off. Soc'y* 77, 100 (2000) (R-119).

66. Moreover, assuming that the *Fisher* decision marks a *return* to the utility requirement as articulated in *Brenner*, then the variability that *Fisher* arguably corrected demonstrates that the law of utility had not been locked into place pursuant to NAFTA.¹³³ Whether a new standard or a return to a former standard, the law of the utility has been in flux and has changed since NAFTA came into force.

B. The Enablement Requirement has Changed Since NAFTA Came into Force

67. As detailed above, the Federal Circuit has ratcheted up the enablement requirement in two ways. The court has emphasized the need for the applicant to disclose more information and minimized the ability of applicants to rely upon the knowledge of the person of ordinary skill in the art. Additionally, as detailed by Professor Sean Seymore, the Federal Circuit now requires the full scope of the claim to be enabled in both the predictable and unpredictable arts.¹³⁴ He has even described the change in the law as “the court’s new enablement standard.”¹³⁵ Consequently, the enablement requirement – the only disclosure obligation required in all patent systems pursuant to TRIPS – has fluctuated considerably within the U.S. post-NAFTA.

C. Written description Doctrine In Its Current Form is a Dramatic Change in U.S. Law

68. Due in large part to Eli Lilly’s own efforts,¹³⁶ the law of written description in the United States has evolved into a doctrine distinct from enablement that assesses the adequacy of a patent disclosure, even as to originally filed claims. Although the majority at the Federal Circuit contended that application of the written description test in this way is not new, the dissenting members of the Federal Circuit disagreed strongly with this view.¹³⁷ Although the

¹³³ See, e.g., Janice Mueller, Patent Law 330 (Wolters Kluwer, 4th ed. 2013) (R-120) (“In the wake of the USPTO’s promulgation of the *Utility Examination Guidelines*..., a test case was brought to clarify the standards for applying the §101 utility requirement to patent claims reciting ESTs (expressed sequence tags). The result in *In re Fisher* was a return by the Federal Circuit in 2005 to the rigorous utility criteria announced almost 40 years earlier by the Supreme Court in *Brenner v. Manson*.”).

¹³⁴ See Sean Seymore, *The Enablement Pendulum Swings Back*, at 291 (R-062) (“It appears that the Federal Circuit’s adoption of the full scope enablement standard mitigates the historical dichotomy between the predictable and unpredictable arts and moves the court toward a unitary adjudicatory framework. At a minimum, the court’s new enablement standard vitiates old doctrines and raises new questions about the adequacy of disclosure and the proper scope of claims.” (emphasis added)).

¹³⁵ *Id.* (R-062).

¹³⁶ *Ariad*, at 1344 (en banc) (R-099); *University of California*, at 1566-69 (R-101).

¹³⁷ *Ariad*, at 1361 (R-099) (Rader, J., dissenting-in-part) (“These earlier writings document the embarrassingly thin (perhaps even mistaken) justifications for *the minting of this new description doctrine in 1997* and the extensive academic criticism of this product of judicial imagination.” (emphasis added)); *id.* at 1366-67 (R-099) (Rader, J., dissenting) (“If this court perceives a need for renewed attention to description requirements, it should strengthen its enablement jurisprudence *instead of making new rules*.”); *id.* at 1369 (R-099) (Linn, J., dissenting-in-part,

Federal Circuit majority suggested that this requirement has always existed, the dissenting judges and commentators confirm that, in fact, this is an additional requirement that came into being after the adoption of NAFTA.¹³⁸ It is ironic, then, that Eli Lilly is arguing that NAFTA froze patent law in both countries when it was a key, if not the primary, advocate for a significant change in U.S. patent law post-NAFTA.

69. Regardless of whether one views the Federal Circuit's post-*Lilly* articulation of the written description requirement as "new" or as merely a return to previous law, the adoption of this form of the written description requirement demonstrates that the law in the United States did not enter a state of stasis when NAFTA was adopted, with the standard fluctuating over time.

D. The U.S. Supreme Court Has Changed the Standard for Non-obviousness Standard Since NAFTA Came Into Force

70. The US patent law requires that an invention, to be eligible for patent protection, must be non-obvious in light of the prior art. 35 U.S.C. § 103. The standard for assessing obviousness, however, has not been consistent since the adoption of NAFTA.

71. The seminal case for obviousness is the Supreme Court's 1966 decision in *Graham v. John Deere Co.*, where it elaborated four factors for assessing the obviousness of invention: the scope and content of the prior art; the differences between the prior art and the claims at issue; the level of ordinary skill in the pertinent art; and any secondary considerations that bear on non-obviousness, such as the commercial success of the invention, long felt but unsolved needs, and the failure of others.¹³⁹

concurring-in-part) ("I cannot accept the majority's conclusion that the current written description doctrine adopted in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed.Cir.1997), was created not by the Federal Circuit in 1997, but by the Supreme Court as early as the 19th century, and therefore carries weighty stare decisis effect.")

¹³⁸ See, e.g., *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 433 F.3d 1373 (Fed.Cir.2005) (**R-121**) (plethora of opinions dissenting and concurring from declining en banc reconsideration); *University of Rochester v. G.D. Searle & Co., Inc.*, 375 F.3d 1303, (Fed. Cir. 2004) (same) (**R-122**); *Enzo Biochem*, at 970-89 (same) (**R-104**). See also *Moba*, at 1322-28 (**R-105**) (Rader, J. and Bryson, J., concurring) (debating written description doctrine and its tension with claim construction). The judges opposed to this doctrine called out their colleagues for adopting a new requirement that did not exist before (and certainly did not exist before NAFTA).

Commentators also view the post-*Lilly* written description doctrine as new or as a change in the law. Janice M. Mueller, Patent Law 153-54 (Wolters Kluwer, 4th ed. 2013) (**R-120**) ("Beginning in 1997 with *Regents of the Univ. of Cal. V. Eli Lilly & Co.*, the Federal Circuit has expanded the written description of the invention analysis to consider the validity of un-amended, originally filed claims....In the view of this author, this is an anomalous application of written description principles, contrary to binding precedent."); Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 Wake Forest L. Rev. 827, 834 (1999) (**R-123**) ("the CAFC broke new ground by applying the written description requirement not only to later-filed claims but also to claims filed in the original patent.").

¹³⁹ *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966) (**R-124**). The Federal Circuit has identified several other secondary considerations. See *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349-54 (Fed. Cir. 2012) (discussing copying, licensing, industry skepticism, and industry praise) (**R-125**).

72. The Federal Circuit in the years after NAFTA changed the standard for obviousness by elevating another factor to have near determinative significance – whether the prior art provided a teaching, suggestion, or motivation to combine various pieces of prior art to yield the claimed invention.¹⁴⁰ Absence of such a teaching would render the claimed invention non-obvious and thus eligible for patent protection. Commentators argued that the Federal Circuit, by adopting this requirement, had lowered the standard for patentability.¹⁴¹ The Federal Circuit had also made clear that the obviousness standard could not be satisfied if it was merely “obvious to try” the claimed invention.¹⁴²

73. The law of obviousness, however, changed dramatically when the Supreme Court decided *KSR International Co. v. Teleflex, Inc.* in 2007.¹⁴³ The Court rejected the Federal Circuit’s strict application of the “teaching, suggestion, or motivation to combine” test.¹⁴⁴ Moreover, it resuscitated the “obvious to try” doctrine as an appropriate measure of obviousness.¹⁴⁵

74. It is clear that, post-*KSR*, the Federal Circuit has both loosened the relevance of a teaching, suggestion, or motivation to combine the prior art¹⁴⁶ and has permitted obviousness to

¹⁴⁰ See, e.g., *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) (**R-126**); *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998) (**R-127**).

¹⁴¹ See Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law & Policy Ch. 4, p. 15 (**R-128**) (“Requiring concrete suggestions or motivations beyond those actually needed by a person of ordinary skill in the art, and failing to give weight to the suggestions implicit from the prior art as a whole, suggestions from the nature of the problem to be solved, and the ability and knowledge of one of ordinary skill in the art, errs on the side of issuing patents on obvious inventions and is likely to be unnecessarily detrimental to competition.”)

¹⁴² *In re Deuel*, 51 F.3d 1552, 1569 (Fed. Cir. 1995) (**R-129**) (“‘Obvious to try’ has long been held not to constitute obviousness.”).

¹⁴³ *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007) (**R-130**).

¹⁴⁴ See *id.* at 415 (**R-130**) (“We begin by rejecting the rigid approach of the Court of Appeals. Throughout this Court’s engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM test here.”).

¹⁴⁵ See *id.* at 421 (**R-130**) (“The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was “[o]bvious to try.” When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.” (citation omitted)).

¹⁴⁶ *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008) (**R-131**) (“The TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence—teachings, suggestions (a tellingly broad term), or motivations (an equally broad term)—that arise before the time of invention as the statute requires. As *KSR* requires, those teachings, suggestions, or motivations need not always be written references but may be found within the knowledge and creativity of ordinarily skilled artisans.”), *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1260 (Fed. Cir. 2007) (**R-132**) (“as the Supreme Court suggests, a flexible approach to the TSM test prevents hindsight and focuses on evidence before the time of invention without unduly

be demonstrated when it would be obvious to try the claimed invention.¹⁴⁷ By altering the obviousness inquiry in at least these two ways, the Supreme Court made it more difficult for applicants to demonstrate that their inventions were non-obvious.¹⁴⁸ These changes all occurred post-NAFTA. Regardless of whether viewed as a new, heightened standard of obviousness, or as a return to previous standard of non-obviousness, it is clear that the legal doctrine has not been static since NAFTA was adopted.

75. The variations in obviousness can be seen in the changes the USPTO has made to the MPEP over time. For example, prior to *KSR*, the USPTO noted that “[o]bviousness *can only be established* by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so *found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.*”¹⁴⁹ The current edition of the MPEP no longer contains such strict language and acknowledges “[o]bviousness *can be established* by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so.”¹⁵⁰ Similarly, the MPEP used to list “obvious to try” as an improper rationale for combining references.¹⁵¹ “Obvious to try” is now listed as an exemplary rationale for establishing a *prima facie* case of obviousness.¹⁵² While these do not have the force of law, the changes in the MPEP demonstrate the fluctuations in the law of obviousness that have arisen over time and belie any suggestion that applicants are entitled to rely on any particular articulation of substantive patent law standards by the courts or patent offices.

V. GIVEN THE LACK OF SUBSTANTIVE RULEMAKING AUTHORITY BY THE USPTO, NO SOPHISTICATED PATENT ACTOR WOULD RELY UPON ANY PATENT OFFICE DETERMINATION

constraining the breadth of knowledge available to one of ordinary skill in the art during the obviousness analysis.” (citation omitted))

¹⁴⁷ *In re Kubin*, 561 F.3d 1351, 1358 (Fed. Cir. 2009) (R-133) (“Insofar as *Deuel* implies the obviousness inquiry cannot consider that the combination of the claim's constituent elements was ‘obvious to try,’ the Supreme Court in *KSR* unambiguously discredited that holding. In fact, the Supreme Court expressly invoked *Deuel* as a source of the discredited ‘obvious to try’ doctrine.”); see also *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Litigation*, 676 F.3d 1063, 1072-73 (Fed. Cir. 2012) (R-134); *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1361 (Fed. Cir. 2011) (R-135).

¹⁴⁸ See generally Jason Rantanen, *The Federal Circuit's New Obviousness Jurisprudence: An Empirical Study*, 16 Stan. Tech. L. Rev. 709, 733-34 (2013) (R-136).

¹⁴⁹ MPEP 2014 § 2143.01 (7th ed., rev. 1, February 2000) (R-076); see also *id.* § 2143 (R-076) (“First, there *must be* some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.”).

¹⁵⁰ MPEP 2014 § 2143.01 (9th Ed. March 2014) (R-076).

¹⁵¹ Manual of Patent Examining Procedure § 2145(X)(B) (7th ed., rev. 1, February 2000) (R-0137).

¹⁵² MPEP 2014 § 2143(I)(E) (R-076); see also *id.* § 2145(X)(B) (R-076) (noting “‘obvious to try’ rationale may support a conclusion that a claim would have been obvious...”).

76. Lilly suggests that it reasonably relied upon the Canadian Intellectual Property Office, the Manual of Patent Office Practice, and various doctrines in assuming that the validity of its two patents would be upheld. Given the fluidity of patent doctrine, particularly within the United States itself, such reliance seems misplaced. Indeed, the USPTO has no authority to set U.S. substantive patent law, so any reliance on USPTO guidance would be misplaced.

77. The relationship between the U.S. courts and the USPTO differs from other court-agency relationships. Unlike most agencies, the USPTO does not possess substantive rule making authority.¹⁵³ The USPTO is free to determine its procedural rules, to which courts will defer, but it has no ability to define with any binding precedent the substantive content of the US patent laws. For example, the USPTO can only offer guidance as to what the appropriate standard for non-obviousness under 35 U.S.C. § 103 should be. When issues reach the courts from the USPTO, the courts are required to defer only to any fact-finding done by the agency under the “substantial evidence” standard.¹⁵⁴ Any legal conclusions reached by the USPTO, such as whether a patent claim is obvious, are reviewed *de novo*, with no deference required.¹⁵⁵

78. This dynamic can be seen in the case *In re Fisher*. Prior to the decision, the USPTO had offered its examination guidelines as to the proper standard for utility, particularly in the face of claims to gene fragments. On appeal, the Federal Circuit was free to disregard the USPTO’s approach although, in that case, the Federal Circuit embraced the guidelines. Similarly, the Federal Circuit agreed with the USPTO’s written description guidelines in *Enzo Biochem*.¹⁵⁶ The Federal Circuit, in other contexts, has rejected rules promulgated by the USPTO, such as the standard for “materiality” in determining whether a party has committed inequitable conduct before the USPTO.¹⁵⁷

79. As to substantive patent law, the courts are the ultimate arbiters of the interpretation of the Patent Act. For example, the string of U.S. Supreme Court cases interpreting patentable subject matter under 35 U.S.C. § 101 demonstrates that the courts, not the USPTO, define what constitutes eligible subject matter. In three of the cases mentioned above, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*¹⁵⁸, *Association for Molecular*

¹⁵³ See *Enzo Biochem*, at 964 (R-104) (“The Guidelines, like the Manual of Patent Examining Procedure (“MPEP”), are not binding on this court, but may be given judicial notice to the extent they do not conflict with the statute.”); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) (“*Merck*”) (R-138) (“the broadest of the PTO’s rulemaking powers—35 U.S.C. § 6(a)—authorizes the Commissioner to promulgate regulations directed only to ‘the conduct of proceedings in the [PTO]’; it does not grant the Commissioner the authority to issue substantive rules.”).

¹⁵⁴ *In re Gartside*, 203 F.3d 1305, 1311-15 (Fed. Cir. 2000) (“*In re Gartside*”) (R-139).

¹⁵⁵ *Merck*, at 1449 (R-138); *In re Gartside*, at 1316 (reviewing legal determination of obviousness *de novo*) (R-139).

¹⁵⁶ See *Enzo Biochem*, at 964 (R-104) (“We are persuaded by the Guidelines on this point and adopt the PTO’s applicable standard for determining compliance with the written description requirement.”).

¹⁵⁷ *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1293-94 (Fed. Cir. 2011) (en banc) (R-140) (“This court does not adopt the definition of materiality in PTO Rule 56. As an initial matter, this court is not bound by the definition of materiality in PTO rules.”).

¹⁵⁸ *Mayo Collaborative Services. V. Prometheus Laboratories., Inc.*, 132 S. Ct. 1289 (2012) (R-110).

*Pathology v. Myriad Genetics, Inc.*¹⁵⁹, and *Alice Corp. v. CLS Bank International*¹⁶⁰, the appeals came from litigation involving patents already issued by the USPTO. At no point did the Supreme Court defer to the interpretation offered by the USPTO as to what constitutes eligible subject matter; instead, it offered its own authoritative interpretation of the statute. Indeed, the *Myriad* case was a lawsuit directed *against* the USPTO, challenging the agency’s decision to allow patents to issue on isolated DNA and complementary DNA. The Court expressly rejected the argument that “the PTO’s past practice of awarding gene patents is entitled to deference.”¹⁶¹ The Court even rejected Myriad’s argument that the Supreme Court “should uphold [Myriad’s] patents so as not to disturb the reliance interest of patent holders like itself.”¹⁶² The Court responded that “[c]oncerns about reliance interest arising from PTO determinations, insofar as they are relevant, are better directed to Congress.”¹⁶³

80. As such, interpretations provided by the USPTO as to substantive patent law matters, such as utility, enablement, and written description, do not have the force of binding law. They are merely guidelines which the courts are free to ignore. Reliance upon such guidelines would be misplaced, and any actor in the U.S. system would know as such.

81. The USPTO can occasionally shape the law, if the courts allow it. For example, when it issued its 2001 Guidelines, it signaled to patentees that applications for gene fragments needed to be specific, substantial and credible utility. The courts embraced the heightened standard of utility, bringing back the standard from *Brenner*. However, the courts, as the final arbitrators of the law, are not bound by MPEP or the USPTO. More typically, the MPEP reflects changes made to the law by the judiciary. Therefore, when Professor Kunin reviews the changes to the MPEP made from 1992-2014 and concludes that there have been no substantive changes to the utility standard, he is wrong. As I have explained in detail above, there have been changes to the utility standard over this time period. Further, his assessment is internally inconsistent. He admits, for example, that the 1995 Utility Guidelines reflected the Federal Court’s position that the USPTO was being too strict in applying the standard.¹⁶⁴ Ultimately, there would be no basis for a party to rely upon a set standard for utility given the fluctuation in the standard demonstrated by the changes in the Guidelines.

Signed at: San Antonio, TX on: 26 Jan 2015

[signed]

Timothy R. Holbrook

¹⁵⁹ *Molecular Pathology* (R-109).

¹⁶⁰ *Alice Corp. Pty. Ltd. V. CLS Bank Int’l*, 134 S. Ct. 2347 (2014) (R-108).

¹⁶¹ *Molecular Pathology*, at 2118 (R-109).

¹⁶² *Molecular Pathology*, at 2119 n.7 (R-109).

¹⁶³ *Id.*

¹⁶⁴ See Professor Kunin’s Expert Report, para. 28.

Timothy R. Holbrook

Associate Dean of Faculty and Professor of Law

Emory University School of Law

1301 Clifton Road, NE

Atlanta, GA 30322

(o) (404) 712-0353

(f) (404) 727-6820

tholbrook@emory.edu

ACADEMIC POSITIONS

Permanent Appointments

Emory University School of Law, Atlanta, GA

Associate Dean of Faculty

7/12-present

Professor of Law

7/09-present

Teach courses in patent law, international intellectual property, patent litigation, trademark law, and property. Research interests include patent law, international patent law, biosciences and the law, and trademark law.

Chicago-Kent College of Law, Illinois Institute of Technology, Chicago, IL

Associate Professor of Law (with tenure)

7/06-7/09

Associate Director, Program in Intellectual Property Law

7/06-7/09

Assistant Professor of Law

8/01-7/06

Visiting Associate Professor of Law

6/00-8/01

Visiting and Other Positions

Central European University, Budapest, Hungary

Visiting Professor

9/10

Taught International Intellectual Property in
Department of Legal Studies

Scholar-in Residence

Spring 2006

Center for Communication and Media Studies

University of Denver, Sturm College of Law, Denver, CO

Visiting Associate Professor of Law

Spring 2009

Stanford Law School, Palo Alto, CA

Edwin A. Heafey, Jr. Visiting Professor of Law

Fall 2007

Lund University and Suffolk University School of Law, Lund, Sweden

Professor in Summer Program

Summer 2005

Washington University School of Law, St. Louis, MO.
Visiting Professor

Spring 2004

EDUCATION

Yale Law School, New Haven, CT

J.D., June 1996

Activities *Yale Journal on Regulation*, Lead Editor and Publications Director
Class of 1996 Student Representative

Barristers' Union Mock Trial – Board Member and Treasurer

Alumnus YLS Association of Chicago – Coordinating Committee
Member (2003-2009)

Yale Law School Executive Committee (2013-present)

North Carolina State University, Raleigh, NC

B.S. in Chemical Engineering, May 1993. GPA: 4.00/4.00

Valedictorian, *summa cum laude*

Honors National Merit and John T. Caldwell Alumni Scholar
North Carolina Fellows Leadership Development Program
Phi Kappa Phi and Tau Beta Pi Honor Societies

Activities Phi Delta Theta Fraternity – Secretary and Alumni Chair
NC State Student Senate – Athletics and Operations Chairs
Chancellor's Aide

North Carolina State University Study Abroad Program, Oxford,
University, Oxford, UK Summer 1990

Alumnus John T. Caldwell Alumni Scholarship Review Committee
Featured Speaker at Caldwell-Fellows Dinner

JUDICIAL CLERKSHIP

U.S. Court of Appeals for the Federal Circuit

Law Clerk to the Honorable Glenn L. Archer, Jr.

As Chief Judge

8/96-12/97

As Senior Circuit Judge

12/97-3/98

LEGAL EXPERIENCE

Wiley, Rein & Fielding, Washington, DC

Associate

9/98-4/00

Practiced primarily in patent litigation with some general appellate litigation.

Responsibilities included drafting briefs to the Federal Circuit, summary judgment motions, and claim construction motions; preparation of witnesses for deposition; drafting *amicus* briefs before the Massachusetts Supreme Judicial Court; pro bono work for the Whitman-Walker Clinic in Washington, DC, representing persons with HIV and AIDS.

Danubia, Budapest, Hungary

Language Advisor and Legal Assistant 3/98-8/98
Served as the English Language Editor for the journal *Proceedings of the Hungarian Group*, International Association for the Protection of Industrial Property; assisted Danubia, a Hungarian patent law firm, in preparing English versions of patent applications and response letters; performed research on American patent law; tutored Hungarian attorneys in both American patent law and English grammar.

Summer Associate Positions

<i>Foley & Larder</i> , Washington, DC	Summer 96
<i>Kenyon & Kenyon</i> , New York, NY and Washington, DC	Summer 95
<i>Womble, Carlyle, Sandridge, & Rice</i> , Raleigh, NC	Summer 94
<i>Bell, Seltzer, Park & Gibson</i> , Charlotte, NC	Summer 94

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Is the Supreme Court About to Rule that Software is Ineligible for Patent Protection?, FORBES, March 16, 2014, <http://www.forbes.com/sites/realspin/2014/03/16/is-the-supreme-court-about-to-rule-that-software-is-ineligible-for-patent-protection/>

Not All Patent Trolls are Demons, CNN OPINION, Feb. 21, 2014, <http://www.cnn.com/2014/02/21/opinion/holbrook-patent-trolls-demons/>

Forget Invisibility: Visibility is the New Superpower, HUFFINGTON POST, Jan. 1, 2014, http://www.huffingtonpost.com/timothy-holbrook/forget-invisibility-visibility-is-the-new-superpower_b_4532824.html

Where are the Gay Federal Appellate Judges?, HUFFINGTON POST, Oct. 13, 2013,
http://www.huffingtonpost.com/timothy-holbrook/where-are-the-gay-federal-appellate-judges_b_4118795.html.

Why Being a Gay Christian Isn't an Oxymoron, TALKING POINTS MEMO (TPM), Oct. 4, 2013, <http://talkingpointsmemo.com/cafe/why-being-a-gay-christian-isn-t-an-oxymoron>

HONORS AND AWARDS

- Outstanding Service to the Community Award, Stonewall Bar Association of Georgia (LGBT bar association), 2014.
- Friends in Faculty Award, Division of Campus Life, Emory University, 2014.
- Professor of the Year, Emory's Black Law Students Association, 2014.
- Public Voices Fellow in the Op-Ed Project, Emory University, 2014-16.
- The Linn Inn Alliance Distinguished Service Medal, March 22, 2013.
- Elected Member, American Law Institute (ALI), March 19, 2013.

RESEARCH GRANT

Lori Andrews, Lori Rosenow, Timothy R. Holbrook, *Complex Genetic Disorders and Intellectual Property Rights*, #DE-FG02-02ER63460, from the Office of Biological and Environmental Research, the Office of Science, U.S. Department of Energy (DOE) and The Robert Wood Johnson Foundation Investigator Awards in Health Policy Research Program. Two year grant to study the implications of intellectual property rights on research on complex genetic disorders.

PRESENTATIONS AND WORKSHOPS

Explaining the Supreme Court's Interest in Patent Law, Emory Law @ Work, Orrick, Herrington & Sutcliffe, San Francisco, CA, Dec. 4, 2014.

IP at the Supreme Court: Guidance or Garbage, 8th Annual Evil Twin Debate, Intellectual Property Institute of the University of Richmond School of Law, Nov. 21, 2014 (debate with Prof. John Golden of University of Texas School of Law)

Patent Anticipation and Obviousness as Possession, Faculty Colloquium, Notre Dame School, South Bend, IN, Oct. 30, 2014.

Explaining the Supreme Court's Interest in Patent Law, Atlanta Intellectual Property Inn of Court, Atlanta, GA, Oct. 15, 2014.

Patent Anticipation and Obviousness as Possession, Faculty Workshop, William and Mary Law School, Williamsburg, VA, Oct. 2, 2014.

Moderator, *Mock Oral Arguments with Judges from the US Court of Appeals for the Federal Circuit*, Georgia Intellectual Property Institute, Amelia Island, FL, Sept. 20, 2014.

- Panelist, *A Matter of Perspective: Current Trademark Issues Examined from the Academic, In-House, and Private Practice Viewpoints*, Georgia Intellectual Property Institute, Amelia Island, FL, Sept. 20, 2014.
- Panelist, *Limelight v. Akamai* and *Medtronic v. Mirowski*, Supreme Court Intellectual Property Review, IIT Chicago-Kent College of Law, Chicago, IL, Sept. 12, 2014.
- Commentator, Junior IP Scholars Workshop, Vanderbilt Law School, Nashville, TN, April 25, 2014.
- The Federal Circuit is No Longer the “Supreme Court” of Patent Law: Patent Year in Review*, 16th Annual Sughrue Symposium, University of Akron School of Law, Akron, OH, March 10, 2014.
- The Supreme Court and Patent Law*, Naples Midwinter Patent Law Experts conference, Naples, FL. Feb. 11, 2014.
- Panelist, *A Comparative Look at Obviousness*, Naples Midwinter Patent Law Experts conference, Naples, FL. Feb. 10, 2014.
- Patentable Subject Matter and Audience*, Patents 101: Eligibility from Computer Code to Genetic Codes Symposium, Vanderbilt Law School, Nashville, TN, Jan. 24, 2014.
- Patent Anticipation and Obviousness as Possession*, Emory University School of Law Faculty Workshop, Emory University, Atlanta, GA, Jan. 8, 2014.
- The Smart Phone Wars*, Emory Law “Point Nine,” Miami, FL, Nov. 19, 2013.
- Panelist, *Crystal Balls and Groundhogs—Predicting the Future of Emerging Entertainment and IP Issues*, 25th Annual North American Entertainment, Sports, and Intellectual Property Conference, Montego Bay, Jamaica, Nov. 9, 2013.
- Explaining the Supreme Court’s Interest in Patent Law*, Alston & Bird IP Retreat, Callaway Gardens, GA, Aug. 24, 2013.
- A Possession-Based Approach to Patent Validity*, Thirteenth Annual Intellectual Property Scholars Conference, Cardozo School of Law, Yeshiva University, New York, NY, Aug. 9, 2013.
- Commentator on Paul Gugliuzza, Patent Law Federalism*, Thirteenth Annual Intellectual Property Scholars Conference, Cardozo School of Law, Yeshiva University, New York, NY, Aug. 8, 2013.
- A Possession-Based Approach to Patent Validity*, Emory/University of Georgia Joint Faculty Workshop, Athens, GA, July 17, 2013.

Perry and Windsor: *An Introduction*, The Supreme Court's Marriage Cases: What Do We Do Now?, Stonewall Bar Association of Georgia, Atlanta, GA, July 10, 2013.

Mid-Year Patent Law Review, American Intellectual Property Law Association Mid-Year Meeting, Seattle, WA, May 3, 2013.

Panelist, *LGBT Diversity in IP Profession*, American Intellectual Property Law Association Mid-Year Meeting, Seattle, WA, May 1, 2013.

The Written Description Gap, Patents, Innovation and Freedom to Use Ideas, Loyola University Chicago Law Journal Symposium, Loyola University Chicago School of Law, Chicago, IL, April 11, 2013.

The Smart Phone Wars, Kiwanis Club of North Druid Hills, Atlanta, GA, March 25, 2013.

As If the AIA Wasn't Enough: Continued Judicial Activity in Patent Law, 2012-13, 15th Annual Sughrue Symposium, University of Akron School of Law, Akron, OH, March 4, 2013.

Panelist, *Software Skirmishes: Is Patent Stockpiling Trampling Innovation?*, Vanderbilt University School of Law, Feb, 25, 2013.

Panelist, *Copyright and Patent Law*, American Law Institute, Washington, DC, Feb. 21, 2013.

Explaining the Supreme Court's Interest in Patent Law, Naples Midwinter Patent Law Experts Conference, University of Akron School of Law, Naples, FL, Feb. 4-5, 2013.

The Smart Phone Wars, Emory Alumni Association Back to Class, Coral Gables, FL, Jan. 26, 2013.

Panelist, *A Discussion of the Recent Federal Circuit Rulings on Joint Infringement in McKesson Technologies and Akamai Technologies*, Emory Law Alumni Intellectual Property Society, Atlanta, GA, Nov. 15, 2012.

Panelist, *Trans-border Infringement: Latest Developments and Outlook*, IPO IP Chat Channel, Nov. 14, 2012.

Panelist, *Patent Indirect Infringement*, 24th Annual North American Entertainment, Sports, and Intellectual Property Law Conference, Cancun, Mexico, Nov. 7-11, 2012.

The Internationalization of U.S. Patent Law, Corporate IP Institute, Georgia State University, Atlanta, GA, Oct. 25, 2012.

Moderator, *Cease and Desist Letters: The Law and Tactics*, Patent Perspectives from the Inside, Sitting of the US Court of Appeals for the Federal Circuit at the University of Denver Sturm College of Law, Denver, CO, Oct. 4, 2012.

Explaining the Supreme Court's Interest in Intellectual Property, The State of Patent Litigation: A Conversation with the Federal Circuit, Indiana University Maurer School of Law, Bloomington, IN, Sept. 24, 2012.

Explaining the Supreme Court's Interest in Intellectual Property, IP Law Summit, Las Vegas, NV, Sept. 14, 2012.

Extraterritoriality in U.S. Patent Law, Brown Bag Lunch Workshop, United States Patent and Trademark Office, Alexandria, VA, July 10, 2012.

Panelist, *Court 101* (discussing proper appellate strategy), IP SpringPosium, IP Section of the Atlanta Bar Association, Barnsley Gardens, GA, April 13, 2012.

Patent Law Developments, 14th Annual Richard C. Sughrue Symposium on Intellectual Property and Policy, University of Akron School of Law, Akron, OH, March 19, 2012.

Should Foreign Patent Law Matter?, The New Global Convergence: Intellectual Property, Increasing Prosperity, and Economic Networks in the Twenty-First Century, Campbell University Norman Adrian Wiggins School of Law, Raleigh, NC, March 16, 2012.

The America Invents (work for patent attorneys) Act, 3rd Annual Intellectual Property Law Symposium of The Florida Bar, Orlando, FL, March 2, 2012.

Explaining the Supreme Court's Renewed Interest in Patent Law, 56th Annual Intellectual Property Law Conference, John Marshall Law School, Chicago, IL, Feb. 24, 2012.

Panelist, *International Dispute Resolution*, Anticipating Dissension: When Legal Frameworks, U.S. Commerce and Foreign Markets Intersect, Joint Symposium by N.C. Journal of International Law and N.C. Journal of Law and Technology, University of North Carolina School of Law, Chapel Hill, NC, Jan. 27, 2012.

Panelist, *ETHICS – Therasense, Best Mode + Supplemental Examination from the AIA*, IPO Educational Foundation PTO Day, Washington, DC, Dec. 5, 2011.

Patent Law's Audience, Distinguished Professor Lecture, John Marshall Law School, Chicago, IL, Nov. 18, 2011.

Moderator, A View from the Bench—Federal Circuit Court of Appeals, (panel with Judges Clevenger and Prost of the U.S. Court of Appeals for the Federal Circuit), North American Entertainment, Sports, and Intellectual Property Law Conference, Cabo San Lucas, Mexico, Nov. 10-12, 2011.

Explaining the Supreme Court's Interest in IP, Emory IP Alumni Society, Emory University School of Law, Atlanta, GA, October 3, 2011.

The Supreme Court's Shocking, Continuing Interest in IP, Carolina Patent, Copyright and Trademark Law Association, Fall Seminar, Charleston, SC, September 24, 2011.

Panelist, *The America Invents Act: First to File versus First to Invent? (Podcast)*, The Federalist Society, June 20, 2011.

Moderator, *Therasense - Inequitable Conduct and Ethical Considerations in IP Practice*, 7th Annual SpringPosium IP CLE Conference, Barnsley Gardens Resort, Adairsville, Georgia, April 29-30, 2011.

Panelist with the Honorable Sharon Prost, U.S. Court of Appeals for the Federal Circuit, *IP Advice from the Federal Bench*, 7th Annual SpringPosium IP CLE Conference, Barnsley Gardens Resort, Adairsville, Georgia, April 29-30, 2011.

The Supreme Court and IP: Patent and Copyright, Yes; Trademark, No, Emory IP Law Society Advisory Board CLE, Alston & Bird, Atlanta, GA, March 2, 2011.

Panelist, Patent Unrest Symposium, Vanderbilt University Law School, Nashville, TN, Feb. 24, 2011.

Commentator, Panel 1: Compulsory Licensing and TRIPS Compliance, 15 Years of TRIPS Implementation, University of Georgia School of Law, Athens, GA, Jan. 28, 2011.

Patent Law's Audience, Fordham University School of Law Intellectual Property and Innovation Colloquium, New York, NY, Jan. 24, 2011.

2009-10 Patent Law Year in (P)Review, PLI Patent Litigation 2010, Atlanta, GA, Nov. 8, 2010.

Panelist, *The Extraterritorial Reach of U.S. Patent Law After Transocean*, IPO Chat Channel on-line seminar, Oct. 13, 2010.

Patents, Presumptions, and Public Notice, IP Workshop at the George Washington University School of Law, Washington, DC, Sept. 9, 2010.

The Road to Bilski...and the Path Afterwards, Technology Association of Georgia, Atlanta, GA, Aug. 17, 2010.

Speaker and Panelist, *Ariad v. Lilly and the Role of Doctrine in Policing Patent Claim Scope*, Southeastern Association of Law Schools 2010 Annual Conference, Palm Beach, FL, July 31, 2010.

Moderator and Speaker, *Ethics and Inequitable Conduct*, 6th Annual SpringPosium IP CLE Seminar, Barnsley Gardens, Adairsville, GA, May 8, 2010.

Speaker, *Patent Law's Written Description Requirement*, Georgia IP Bar Association, Atlanta, GA, April 20, 2010.

Moot Court Judge, Washington and Lee Law School, IP Practicum Course, Lexington, VA, April 12, 2010.

Speaker and Panelist, *The Year in Patent Law*, American Bar Association, Section of Intellectual Property, 25th Annual Intellectual Property Conference, Arlington, VA, April 9, 2010.

Speaker and Panelist, *Implications of ACLU-Myriad on the Patentability of Genes*, The Future of Genetic Disease Diagnosis and Treatment: Do Patents Matter?, University of Maryland School of Law, Baltimore, MD, April 2, 2010.

The Expressive Dimension of Patent Law, Indiana Intellectual Property Colloquium, Indiana University Maurer School of Law, Bloomington, IN, Jan. 28, 2009.

Panelist, *Opinions of Counsel Post-Seagate*, 15th Annual Georgia Intellectual Property Institute Conference, Punta Cana, Dominican Republic, Nov. 13, 2009.

Speaker and Panelist, *The Future of the Patent System*, Symposium for the U.S. Court of Appeals Sitting in Houston, University of Houston Law Center, Nov. 4, 2009.

Panelist, *Developments in Section 112 Law: The Enablement and Written Description Requirements As Applied to Pharma and Biotech Patents*, Developments in Pharmaceutical and Biotech Patent Law 2009, Practising Law Institute, New York, NY, Sept. 17, 2009 and San Francisco, CA, Oct. 14, 2009.

Equivalency and Patent Law's Possession Paradox, Faculty Workshop, Washington and Lee University School of Law, Lexington, VA, Sept. 14, 2009.

Panelist, *Short-Term Patents & Post-Grant Opposition - Does Europe Have the Answer? and What Can Congress Do to End the Plague of Inequitable Conduct?*, at *Pushing the Envelope on IP Reform*, 2nd Annual Quad City IP Symposium, University of Dayton School of Law, Dayton, OH, July 16-17, 2009.

Patent Non-Economics, Faculty Workshop, University of Denver Sturm College of Law, Denver, CO, Feb. 13, 2009.

The World Trade Organization and World Intellectual Property Organization as Institutions of Innovation, Academic Panel on Institutions Promoting Innovation, Exploring the Obvious: The Evolution of Intellectual Property Law, Texas Intellectual Property Law Journal University of Texas School of Law 10th Annual Intellectual Property Law Symposium, Austin, TX, Feb. 6, 2009.

Equivalency and Patent Law's Possession Paradox, Faculty Workshop, Emory Law School, Atlanta, GA, Dec. 16, 2008.

Panelist, *Successful Strategies at the Federal Circuit, Patent Law Symposium 2008, Intellectual Property Law Association of Chicago (IPLAC), Chicago, IL, Oct. 10, 2008.*

Claim Construction Update: What's the Latest Trend?, Minnesota State Bar Association Continuing Legal Education, Minneapolis, MN, May 2, 2008.

Panelist, *The Pendulum Swings Back: The Impact of Recent SCOTUS and Federal Circuit Cases, Northwestern Journal of Technology and Intellectual Property 3rd Annual Symposium, Northwestern University School of Law, Chicago, IL, April 18, 2008.*

Moderator, *What Patent Law Reform Really Means For You, American Bar Association, Section of Intellectual Property, 23rd Annual Intellectual Property Conference, Arlington, VA, April 10, 2008.*

Conference Fellow, *A Symposium on PATENT FAILURE, University of Georgia, Athens, GA, March 29, 2008.*

Commentator, *MSU IP & Communications Workshop, Michigan State University College of Law, East Lansing, MI, Feb. 15-16, 2008.*

Panelist, *Patent Reform – Motivations, Impact and Controversy, Northwestern School of Law IP Law Week, Northwestern University School of Law, Chicago, IL, Jan. 14, 2008.*

Equivalency and Patent Law's Possession Paradox, Faculty Workshop, Santa Clara University School of Law, Nov. 27, 2007.

Patent Law: The Year in Review (aka the Aftermath of the Supreme Court), On-Line Seminar: Patent, Trademark and Copyright: Hot Topics from 2007, American Intellectual Property Law Association (AIPLA), Nov. 7, 2007.

Equivalency and Patent Law's Possession Paradox, Stanford Law School Faculty Workshop, Stanford, CA, Oct. 24, 2007.

Patent Law: The Year in Review (aka the Aftermath of the Supreme Court), Annual Meeting of the American Intellectual Property Law Association (AIPLA), Washington, DC, Oct. 20, 2007.

Moderator for Enablement and Written Description Discussion, Federal Circuit Reform Roundtable, Berkeley Center for Law and Technology, UC Berkeley School of Law, Berkeley, CA, Sept. 26, 2007.

Extraterritoriality in U.S. Patent Law, Thomas Jefferson School of Law Faculty Workshop, San Diego, CA, Sept. 7, 2007.

Equivalency and Patent Law's Possession Paradox, 7th Annual Intellectual Property Scholars Conference, DePaul University School of Law, Chicago, IL, August 9-10, 2007.

Equivalency and Patent Law's Possession Paradox, II Conference on High-Technology Law, University of Gdansk, Gdansk, Poland, May 11-12, 2007.

What if US Patents and Applications Were Not Published?, What Ifs and Other Alternative Intellectual Property and Cyberlaw Stories, Fourth Annual Intellectual Property & Communications Law Program Symposium, Michigan State University College of Law, March 30-31, 2007.

Extraterritoriality in U.S. Patent Law, Patents and Progress: Reflections in the Midst of Change, 7th Annual CIPLIT Symposium, DePaul College of Law, Chicago, IL, March 15-16, 2007.

Commentator on *Revising TRIPS Art. 30: Clarifying the Scope of Exceptions to Patent Rights in WTO Countries* by Toshiko Takenaka, *Modest Proposals 3.0*, Benjamin N. Cardozo School of Law, Yeshiva University, New York, NY, Feb. 20, 2007.

Panelist, *Academics and the Courts*, Richard Linn Inn of Court, Chicago, IL, February 15, 2007.

Moderator, *IP Day in Chicago – The Supreme Court and Intellectual Property*, Chicago Intellectual Property Alliance, Loyola University Chicago School of Law, Chicago, IL, February 7, 2007.

2006: A Year of Supreme Court Action and Federal Circuit Inaction, American Intellectual Property Law Association (AIPLA) Mid-Winter Meeting, New Orleans, LA, January 25, 2007.

Patents, Identity, and the Specter of Privatized Eugenics, Patenting People, Conference at Benjamin N. Cardozo School of Law, Yeshiva University, New York, NY, November 12-13, 2006.

Contrasting the Extraterritorial Enforcement of Trademark and Patent Rights, American Intellectual Property Law Association (AIPLA) Annual Meeting, Washington, DC, October 20, 2006.

The Failed Promise of Phillips, presented at Phillips v. AWH Corp.: *Are We Still Baffled?*, Chicago Bar Association, Chicago, IL, September 20, 2006.

Extraterritoriality in Patent Law, Graduate Seminar in International Intellectual Property Law, Chicago-Kent College of Law, Chicago, IL, September 12, 2006.

Making Infringers Pay: IP Roundtable Discussion of eBay Inc. v. MercExchange L.L.C., Chicago-Kent College of Law, Chicago, IL, September 5, 2006.

Panel on Access to Patented Toxicogenomics Applications, Intellectual Property Concerns for Toxicogenomics, The National Academies, Committee on Emerging Issues and Data on Environmental Contaminants, Washington, DC, June 29, 2006.

Laboratory Corp. v. Metabolite Laboratories: Implications for Gene Patents, Patients, and Beyond, Teleconference for National Constitution Center, June 27, 2006.

The Return of the Supreme Court to Patent Law: 2005 in Review and 2006 in Preview, the Richard C. Sughrue Symposium on Intellectual Property Law and Policy, Akron, OH, March 13, 2006.

Panel Discussion on Patent Reform, Panelist, the Richard C. Sughrue Symposium on Intellectual Property Law and Policy, Akron, OH, March 13, 2006.

Curing Heterosexuality? Moral Signals and the Potential for Expressive Impacts in Patent Law, Forum for Research on Law, Politics, and the Humanities, University of Illinois at Chicago, Chicago, IL, November 16, 2005.

The Enablement/Written Description Debate of Patent Law, Panelist, John Marshall Law School, November 7, 2006 (in conjunction with the Federal Circuit's sitting in Chicago; panel included Chief Judge Michel and Judge Linn of the Federal Circuit and Judges Kennelly and Holderman of the Northern District of Illinois).

Possession in Patent Law, Faculty Workshop, Marquette University Law School, Milwaukee, WI, October 18, 2005.

Patent Trolls and International Compulsory License Obligations, the Markey Symposium, *Innovation and its Discontents: Patents and Innovation Policy in the 21st Century*, John Marshall Law School, Chicago, IL, October 14, 2005.

Commentator on Charles W. Adams, *A Brief History of Indirect Liability for Patent Infringement*, Third-Party Liability in Intellectual Property Law, Santa Clara University School of Law, October 7, 2005.

Possession in Patent Law, Faculty Workshop, Santa Clara University School of Law, October 6, 2005.

Possession in Patent Law, Chicago-Kent Junior Faculty Workshop, Chicago-Kent College of Law, September 30, 2005.

Implications of MGM v. Grokster, Chicago-Kent IP Roundtable, Chicago-Kent College of Law, August 30, 2005.

Enabling Enablement in Patent Law, Fifth Annual Intellectual Property Scholars Conference, Cardozo School of Law, Yeshiva University, New York, NY, August 11, 2005.

In the Shadow of Phillips: the Year in Patent Law, Twentieth Annual Intellectual Property Law Conference, American Bar Association Section of Intellectual Property Law, Washington, DC, April 14, 2005.

The Solomon Amendment: Must Law Schools Welcome Military Recruiters Despite DoD's "Don't Ask, Don't Tell" Policy?, a debate sponsored by Chicago-Kent Chapters of the Federalist Society and the National Lawyers Guild, Chicago, IL, April 7, 2005.

Curing Heterosexuality? Moral Signals and the Potential for Expressive Impacts in Patent Law, Loyola University Chicago School of Law, IP Brown Bag Lunch Series, March 22, 2005.

Commentator on *Constitutionalizing Patents* by Craig Allen Nard and Andrew P. Morriss, Where IP Meets IT: Technology and the Law Symposium, University of Pittsburgh School of Law, Pittsburgh, PA, March 18, 2005

The Calm Before the Storm—A Quiet Year in Patent Law . . . or Not?, University of Akron Law School, the Richard C. Sughrue Symposium on Intellectual Property Law and Policy, Akron, OH, March 7, 2005.

Panel Discussion on Claim Construction and Phillips v. AWH Corp., University of Akron Law School, Panel Member, the Richard C. Sughrue Symposium on Intellectual Property Law and Policy, Akron, OH, March 7, 2005.

Curing Heterosexuality? Moral Signals and the Potential for Expressive Impacts in Patent Law, University of Houston Law Center, Colloquium: Reenvisioning Law, January 27, 2005.

Google, Key Words and Pop-Up Ads: The Future of Trademarks on the Internet, discussion with Professor G. Dinwoodie, DC-area Chicago-Kent Alumni Luncheon, Washington, DC, October 15, 2004.

Procedural versus Substantive Formalism in Claim Construction, presented at the Tenth Annual Lewis & Clark Law School Fall Business Law Forum, entitled *Markman v. Westview Instruments: Lessons from a Decade of Experience*, Portland, OR, October 8, 2004.

Does the Patent System Need Fixing? Panel Discussion on the Federal Trade Commission Report "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy," Panel Member, Federal Bar Association, Chicago, IL, September 15, 2004.

Curing Heterosexuality? Moral Signals and the Potential for Expressive Impacts in Patent Law, DePaul University College of Law, Edward Manzo Patent Seminar, August 30, 2004.

P2P File Sharing and Copyright Law: Implications of the Grokster Decision, Chicago-Kent IP Program Roundtable, Chicago-Kent College of Law, August 25, 2004.

Patent Law and Its Potential Impact on Research Labor Markets, National Research Council, National Materials Advisory Board Committee on Globalization of Materials Research and Development, Chicago, IL, May 12, 2004.

Curing Heterosexuality? Moral Signals and the Potential for Expressive Impacts in Patent Law, Washington University (St. Louis) School of Law Faculty Workshop, April 21, 2004.

Curing Heterosexuality? Moral Signals and the Potential for Expressive Impacts in Patent Law, University of San Francisco, McCarthy Institute for Intellectual Property and Technology Law Scholarship Workshop Series, March 17, 2004.

Of Mice and Sprouts...and Other Things: The 2002 Review of Patent Cases, The Federal Circuit Bar Association's Fifth Bench and Bar Conference, Amelia Island, FL, May 22, 2003.

Give and Take - Implications of Patent Rights in Developing Countries, Northwestern University School of Law, Northwestern University School of Law Intellectual Property Society, April 2003.

Curing Heterosexuality? Moral Signals and the Potential for Expressive Impacts in Patent Law, University of Cincinnati College of Law Faculty Workshop, February 10, 2003.

Curing Heterosexuality? Moral Signals and the Potential for Expressive Impacts in Patent Law, Chicago-Kent College of Law Faculty Workshop, November 26, 2002.

The Treaty Power and the Patent Clause: Are There Limits on the United States' Ability to Harmonize?, Symposium: Patent Law, Social Policy, and Public Interest: The Search for a Balanced Global System, Cardozo Law School, November 7, 2002.

The Impact of the Supreme Court's Decision in Festo, Chicago Bar Association, Patent, Copyright and Trademark Committee, Sept. 24, 2002.

International Implications of Patent Infringement via Offers to Sell, Second Annual Intellectual Property Scholars Conference, Benjamin N. Cardozo School of Law/Yeshiva University, August 8-9, 2003.

Equivalents After Festo II: Point/Counterpoint, Seminar at IIT-Rice Campus, July 18, 2002.

Why Can Genes Be Patented, and Who Owns Them?, Chicago Bar Association, Young Lawyers Section, Committee on Intellectual Property, Feb. 6, 2002.

Issues in Gene Patenting, University of Chicago Hillel Shabbat Dinner in conjunction with the Chicago Center for Jewish Genetic Disorders, May 2001.

Patenting Genes: Pros and Cons, discussion with Professor F. Scott Kieff at Northwestern University School of Law for the Northwestern Intellectual Property Society, April 5, 2001.

Equivalents After Festo: Point/Counterpoint, Seminar at IIT-Rice Campus, March 1, 2001.

The State of American Patent Law With Respect to Patenting Genes, presented at International Symposium on Ethics, Intellectual Property and Genomics, UNESCO Headquarters, Paris, January 30, 2001.

BAR MEMBERSHIP, BAR ASSOCIATIONS, AND OTHER ACTIVITIES

- Member of the New York, District of Columbia, Supreme Court, and Federal Circuit Bars
- American Intellectual Property Law Association, Education Committee Vice Chair (2014-15); Annual Meeting Planning Subcommittee (2013-14); Amicus Brief Committee (2010-2013)
- Atlanta Intellectual Property Inn of Court, Founder, Master (2012-present), Past President (2012-2014); First President (2010-2012)
- Sedona Conference Working Group 10 (2013-14)
- American Bar Association, Book Board, IP Section (2010-12)
- Richard Linn Inn of Court (IP-specific Inn of Court), Founder, Program Chair (2006-2009)
- Board of Directors, AIDS Legal Council of Chicago (2004-07)
- Chicago Intellectual Property Alliance (CIPA), Chair of IP Day Committee (2006-07)
- English Language Editor, *Proceedings of the Hungarian Group*, International Association for the Protection of Industrial Property (1998-2005)

INTERESTS AND HOBBIES

Hungarian language and culture; reading, particularly in the history of religion; beach and indoor volleyball; triathlons; running.