

**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)

SECOND EXPERT REPORT OF TIMOTHY R. HOLBROOK

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A. Introduction

1. I have been requested by the government of Canada to review and consider the opinions expressed by Professor Robert Merges and Mr. Stephen Kunin in the additional reports they submitted in support of Eli Lilly & Company's Reply and in response to my first report. This second report contains my responses. To be clear, if I have not provided a response herein, it is because I believe that my first report adequately addressed Professors Merges' and Mr. Kunin's argument. I fully endorse and reiterate all the opinions in my first report.
2. I have attached an updated C.V. to this Report for the convenience of the Tribunal and the parties. The only significant change is that I stepped down as the Associate Dean of Faculty at Emory University School of Law on August 1, 2015.
3. Professor Merges, Mr. Kunin and I actually agree on a number of critical issues:
 - Professor Merges, Mr. Kunin, and I all agree that the United States utility standard generally is not a high threshold.
 - Professor Merges, Mr. Kunin, and I agree that the utility threshold does not vary across technological fields, notwithstanding Professor Merges inaccurate suggestion that I have argued to the contrary.
 - Professor Merges, Mr. Kunin, and I agree that the utility requirement is of particular relevance in the chemical, pharmaceutical, and biotechnological fields
4. However, I do not agree with the way Professor Merges and Mr Kunin characterize the U.S. utility requirement. Conclusions drawn from the examples cited by Professor Merges¹ and statistics referred to by Mr. Kunin² are misleading because they

¹ Professor Merges' description of the utility doctrine in the United States is inaccurate. His examples involving apparatuses are inapposite because, as we all agree, the utility doctrine plays little role for those technologies.

² Mr. Kunin's report refers to statistics suggesting that utility was raised by examiners to reject applications in only 1% of all Patent Trial and Appeal Board cases from 1998-2008. Those data represent all technologies, and for most technologies, utility is easy to establish. As such, the low number is not surprising.

seem to imply that establishing or challenging utility with respect to any type of invention will entail the same degree of evidence.

5. Professor Merges also fails to provide an appropriate comparison between Canadian and United States' law. As I noted in my first expert report, a proper comparative analysis does not myopically focus on a utility-to-utility doctrine comparison.³ Because countries have flexibility in how they implement various policy options, the proper comparison is a holistic one. In this case, the proper comparison necessarily includes comparison to the doctrines of enablement and written description in the United States. As the U.S. Courts themselves have stated expressly, these doctrines are related and often intertwined with the concept of utility.⁴ This proper comparative analysis demonstrates that the laws between the two countries are not particularly divergent.

6. Additionally, Professor Merges' suggestion that technical evidence generated after filing the patent application to support utility or enablement is routinely admitted is incorrect. Precision is important here. Post-filing evidence that a patent lacks utility or is not enabled of course is relevant: if the invention lacks utility or is not enabled as of a later date, then of course it would fail these tests as of the earlier filing date. Moreover, affidavits created after the filing date *that explain what happened prior to the filing date* are admissible. Such evidence only explains what happened prior to the filing date.⁵ Evidence generated after the filing date – such as scientific references or laboratory experiments to confirm utility or enablement – are generally excluded, subject only to a minor exception. In none of the cases that Professor Merges cites did the court find the specification inadequate but then allowed evidence generated post-filing to correct it.

³ Holbrook First Report, at paras. 7-8.

⁴ See Holbrook First Report, at pp. 6-25.

⁵ Many of Professor Merges' examples relate to post-filing evidence of a lack utility or enablement, which is consistent with my position. Other examples he cites confirm that post-filing evidence in support of utility or enablement is only permitted, if at all, in limited circumstances. In each case where such evidence was admitted, the courts made clear that such evidence was merely supplementary: the specification alone sufficiently disclosed the invention's utility and how to make and use the invention.

7. Finally, Professor Merges' suggestion that changes in United States patent law since NAFTA have been "subtle" is inaccurate.⁶ In particular, the U.S. Supreme Court's recent decisions regarding what subject matter is patentable has dramatically altered patent law within the United States. Similarly, the Federal Circuit's expansion of the written description requirement as an independent basis for invalidating patents represents a significant shift in patent law. These two changes alone, which I addressed in my first report⁷ and to which neither Professor Merges nor Mr. Kunin respond, have dramatically altered the state of United States patent law, making it more difficult to obtain and protect innovations through patent protection. Notwithstanding the issuance of a patent, its validity is often uncertain before it is tested in litigation.

B. Professor Merges, Mr. Kunin, and I Notably Agree on Three Key Points

1) The utility requirement is a low bar under United States patent law

8. Professor Merges, Mr. Kunin, and I all agree that, speaking generally and without regard to particular technologies, the utility requirement in the United States is low. The record is replete with cases and commentary, including my own, recognizing that fact.

2) There is one utility standard for all technologies

9. We also all agree that there is a singular utility standard that applies to all inventions.

10. Professor Merges and Mr. Kunin both suggest that I have articulated that the utility standard is different for chemical and pharmaceutical inventions than for other technologies. I have made no such assertion, and that is not my view. My report and prior academic writings are all consistent: there is a single utility standard that applies across all technologies. The excerpts of my writing that Professor Merges quotes in footnotes confirm that, contrary to his assertion in the body of his report, I view there to be a single utility requirement applicable to all inventions in the United States.

⁶ Merges Second Report, at para. 51.

⁷ Holbrook First Report, pp. 27-31.

3) *The utility requirement has “greater relevance” in the chemical and pharmaceutical contexts*

11. Professor Merges’ and Mr. Kunin’s confusion with respect to my views appears to arise from my statements that utility remains a significant barrier in the context of chemical and pharmaceutical inventions. My report and prior writings are all specific in noting that the uniform utility threshold is less easy to establish with respect to pharmaceutical and chemical inventions than with other technologies. Contrary to Professor Merges’ intimations, there is nothing inconsistent between my first report⁸ and my prior writings.

12. Professor Merges’ and Mr. Kunin’s apparent misunderstanding of my first report is surprising because we all appear to agree that the nature of an invention can make it more difficult to establish utility, and that this is the case with chemical and pharmaceutical inventions.⁹ Professor Merges characterizes this dynamic as utility having “greater relevance in the pharmaceutical field”¹⁰ and that “the use requirement is more salient”¹¹ in these areas. Leaving aside a debate over rhetoric and terminology, his conclusion is the same as mine: even though the utility threshold is the same for all technologies, utility has more “bite” in the context of pharmaceutical, chemical, and biological inventions. Indeed, while Professor Merges takes snippets of my scholarly writing out of context to imply otherwise, the quoted passages in footnote 6 of his second report confirm our agreement. Such agreement is unsurprising. It is well accepted that, while patent law is technology-neutral in theory, it is technology-specific in application.¹²

⁸ Holbrook First Report, at pp. 6-13.

⁹ The reality that different technologies will encounter the same utility requirement in different ways makes Mr. Kunin’s data suspect. He notes that, according to his analysis of cases at the USPTO from 1998-2008, examiners issued utility rejections in only 1% of the cases. These data are across all technologies, so a low rejection rate is unsurprising. The more apt analysis would be the rate of rejections based on utility in pharmaceutical and chemical applications. His analysis also omits rejections on the related doctrines of enablement and written description.

¹⁰ Merges Second Report, at para. 12.

¹¹ Merges Second Report, at para. 13.

¹² See e.g., Dan L. Burk and Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 Berkeley Tech. L.J. 1155 (2002) at 1156-1157 (**R-386**); Professor Merges’ analogy to a high jump bar (Merges Second Report,

C. Professor Merges' Interpretation of the Utility Requirement is Inaccurate

1) Professor Merges inaccurately suggests that utility is not about whether the applicant has proven the invention to work

13. Professor Merges is incorrect when he suggests that utility is merely about “speculation about the existence of a use.”¹³ This statement is an inaccurate assessment of the law of utility and is belied by the case law on utility and by the requirement that, for an invention to be ready for patenting, it must be reduced to practice. Reduction to practice requires demonstration that the invention works for its intended purpose.

14. Thus, Professor Merges' assertion that merely identifying a use is sufficient to establish utility is inconsistent with the case law in the United States. For example, in *In re Citron*,¹⁴ the court found the asserted utility lacking notwithstanding a robust disclosure of the claimed compound's uses. In that case, the applicant claimed a compound that could be used to treat cancer along with a variety of other uses that purportedly were supported by experiments. Rejecting the application on the basis of the utility requirement, the court reasoned:

The defect here is that in spite of the somewhat grandiose claims of appellant's specification, purportedly based on actual tests or experiments, not one iota of evidence has been produced tending even to show that tests were actually conducted. We also note that the specification does not contain a single specific experiment, of which the details are supplied, wherein any animal was actually benefited by treatment with the claimed precipitate or serum, or wherein an existing tumor was caused to grow more rapidly.¹⁵

at pp. 5-6) is helpful, though his particular comparison is inapt. He suggests that, to demonstrate how utility has more salience in the pharmaceutical field, one should consider the color of the high jump bar. A “neon orange” bar would be more salient. The color of the bar is not the appropriate comparison. Instead, the analogy is the nature of the high jumper. Even when the bar is at the same height, some high jumpers have more difficulty clearing the bar. For example, on average, taller high jumpers are more successful than shorter high jumpers. Even with the bar at the same height, on average, a shorter jumper will have more difficulty clearing the bar than a taller one. The same applies to patents: some technologies have an easier time clearing the utility requirement, while others (like pharmaceuticals) have a more difficult time on average, even though the bar is the same.

¹³ Merges Second Report, at para. 9.

¹⁴ 325 F.2d 248 (C.C.P.A. 1963) (“*Citron*”) (R-387).

¹⁵ *Citron*, at 253 (R-387).

15. The utility was articulated plainly in the specification; nevertheless, it was insufficient because the applicant had failed to demonstrate he had actually demonstrated the disclosed uses.

16. Professor Merges' statement is also belied by the requirement for an invention to be reduced to practice to demonstrate whether a party has completed the invention. Under the United States prior "first to invent" regime, which was the law until March 2013,¹⁶ priority among competing applicants for an invention was determined by whomever was first to invent and able to establish herself as the inventor.

17. According to United States law, someone is an inventor when she has the complete idea of the invention (called conception) and reduces the invention to practice.¹⁷ The reduction to practice requirement emphasizes the need for an inventor to prove that the invention works for its intended purpose, and thus that it has utility, prior to the filing date. Reduction to practice can be demonstrated in two ways. The first, an actual reduction to practice, happens when the inventor has "constructed an embodiment or performed a process that met all the limitations of the claim, and that he determined that the invention would work for its intended purpose."¹⁸

18. The second way to demonstrate reduction to practice can be "constructive," which means that the applicant satisfies the reduction to practice requirement by filing a patent application. To be a constructive reduction to practice, however, the application must satisfy the enablement, utility, and written description requirements of 35 U.S.C. § 112(a). For mechanical devices, constructive reduction to practice is easier because the

¹⁶ The America Invents Act (AIA) changed the United States to a "first inventor to file" system, effective 18 months after the enactment of the AIA, i.e. March 16, 2013. See Leahy-Smith America Invents Act, Pub. L. 112-29 (Sep. 16, 2011) (**R-451**).

¹⁷ 35 U.S.C. § 102(g): The "first to invent" was the first to conceive of the invention who either was also the first to reduce to practice or was diligent in reducing the invention to practice. Nevertheless, even under the AIA, identifying who is the true inventor may be relevant, particularly as it relates to derivation proceedings. Derivation proceedings award the patent to a party who was the first to invent yet the second to file a patent application if the first filer took the invention from the first inventor. (35 U.S.C. § 135 (2013)) Thus, issues of conception and reduction to practice may return even under the new "first inventor to file" regime.

¹⁸ *Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256 (Fed. Cir. 2002) at 1265 (**R-388**), subsequent mandamus proceeding sub nom. *In re Metal-Lite, Inc.*, 85 F. App'x 731 (Fed. Cir. 2003) (**R-389**).

technology is predictable. For methods of treatment, however, there can be considerable uncertainty as to whether the method will work.

19. Under Professor Merges' view of the law, no such proof that the invention actually worked would ever be required. The requirement for a reduction to practice shows he is wrong. United States patent law is concerned with demonstration that the invention actually works, either prior to, or concurrent with, the application.

20. It would be an odd patent system that allows an applicant to list utterly speculative utilities prior to any proof they are correct, only then to allow the patent on post-filing proof of such utilities. An applicant could file a disclosure that catalogs all sorts of potential utilities for a compound, having never confirmed whether any are in fact correct. Under Professor Merges' viewpoint, that applicant could then subsequently confirm those utilities and still obtain a valid patent. Such gamesmanship is not what the patents system is designed to encourage. Instead, the patent system rewards a party who has actually contributed to the state of the art through a demonstrated use.

2) Professor Merges' Inaccurately Concludes that Convincing Evidence is Not Required to Support a Patent Specification

21. Professor Merges argues that U.S. courts have consistently rejected the idea that patent specification must be supported by convincing evidence.¹⁹ However, the cases he cites do not support his position. His review of these cases, while accurate, is inapposite. Most of these cases addressed claims either to apparatuses²⁰ or to

¹⁹ Merges Second Report, at para. 33.

²⁰ Professor Merges notably relies upon *Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. Gesellschaft m.b.H.*, 945 F.2d 1546 (Fed. Cir. 1991) ("*Tol-O-Matic*") (**C-290**), for the proposition that "[i]t is not required that a particular characteristic set forth in the prosecution history be achieved in order to satisfy § 101." That is true. It is also irrelevant. The claim at issue was an apparatus, a rodless piston-cylinder, and nothing in the claim required a particular utility. Claims to methods of treatment or other uses are easily distinguishable because these types of claims require the particular utility.

Professor Merges' reliance on *Raytheon Co. v. Roper Corp.* (724 F.2d 951 (Fed. Cir. 1983) ("*Raytheon*") (**C-367**)) is also irrelevant to the issues in this arbitration. Indeed, part of the decision that Professor Merges glosses over discusses the importance of the claim in assessing utility. The claims in *Raytheon* were, again, directed to an apparatus, "a 'common cavity' oven capable of conventional thermal cooking, microwave cooking, and pyrolytic self-cleaning." In contrast to *Tol-O-Matic*, however, one of the claims did require a particular utility: the prevention of backflow. The Federal Circuit in *Raytheon* noted at paragraph 956 that:

compounds,²¹ both of which may have multiple utilities. He is correct, therefore, that only one utility is sufficient for claims to apparatuses and compounds. Such analysis is irrelevant, however, when the claim requires a particular utility, which methods of treatment do.

22. Professor Merces cites one method of treatment case, *In re Malachowski*²². The focus in this case, however, was not the particular utility of treating arthritis but instead the subject of the treatment. The claims covered both human and non-human animals.²³ The specification specifically noted the need to treat arthritis in canines and equines.²⁴ Importantly, it was undisputed that there was inadequate support for the treatment of humans.²⁵ The court found sufficient utility, but specifically because the claims were not

While a patent covering a meritorious invention should not be struck down because the patentee has misconceived the scientific principle of his invention, the error cannot be overlooked when the misconception is embodied in the claim.

The court noted Claim 1 required something that “does not and physically cannot happen.” As such, the claim was held invalid for lack of utility. The other claims lacked this requirement, and therefore the court concluded the utility requirement had been satisfied. Contrary to Professor Merces’ assertion, this case emphasizes the importance of looking at whether a particular utility is required by the claim itself and, if so, whether there is adequate support for it. Claims directed to methods of using a compound or methods of treatment invariably require a particular utility – multiple other utilities are irrelevant. As a result, there must be adequate support of that particular utility in the patent specification as of the filing date.

Transco Products, Inc. v. Performance Contracting, Inc., 121 F.3d 728 (1997), 1997 WL 459771, (“*Transco*”) (R-452), a non-precedential opinion, also is unavailing. (Note, the citation listed by Professor Merces is merely a table and does not report the full decision; my discussion therefore will cite to the full opinion found in the Westlaw database). *Transco* deals with an apparatus-- thermal insulation for vessels and piping within nuclear power plants. *Transco*, at *1. The case also supports the importance of looking at the claim in assessing utility. See *id.* at *3 (“In determining utility, we must assess the claimed subject matter.”). Finally, the case involved a factual dispute over the durability of the claimed invention, not whether the apparatus would work at all. *Id.*, at *6 (evidence that “simple nylon would break down *over time*, e.g. about 30 years, due to radiation” insufficient to show lack of operability.”).

²¹ *In re Gottlieb*, 328 F.2d 1016 (C.C.P.A. 1964) (C-258), involved a claim to a compound. The court concluded that because one utility had been demonstrated: use as a plant fungicide, then the claims did not lack utility. The court did not merely rely upon the patent’s disclosure of that utility in the application. Instead, the court relied upon a study that was “sufficient to prove” the usefulness of the compound.

²² 530 F.2d 1402 (C.C.P.A. 1976) (“*In re Malachowski*”) (C-432).

²³ *In re Malachowski*, at 1407 (C-432).

²⁴ *In re Malachowski*, at 1403 (C-432).

²⁵ *In re Malachowski*, at 1404 (C-432) (“There is no dispute that the claimed invention has not been shown to be useful in humans. Appellant has stated in his brief that ‘(p)redictive, but not promising, statements are made relative to human utility. Human utility is contemplated but verification thereof has been left for the future.’”)

specific to humans. In so doing, the court distinguished *In re Buting*²⁶, which dealt with a claim specific to the treatment of humans. The court noted:

In *Buting*, the specification was directed to only the treatment of cancer in humans. The claims read on the ‘administration (of an effective amount of the recited compound) to a patient’ suffering from one of seven types of malignant conditions. Although ‘a patient’ can refer to both humans and animals, when read in light of the *Buting* disclosure, it is clear that only human utility was contemplated.²⁷

23. Because the claim covered animals, the court found adequate support in the Malachowski application. The case, again, turns importantly on the limitations found in the claim. If the claim was specific to treatment of arthritis in humans, the clear implication of the case, following *In re Buting*, is that the claim would have been invalidated for lack of utility.

24. In fact, *In re Buting*, upon which Professor Merges does not rely, is itself even more illuminating. The specification in the patent at issue there detailed considerable information, noting that the compound used in the claimed method had shown “significant activity” against a variety of cancers.²⁸ The specification suggested that such activity had been confirmed by clinical treatment of human subjects.²⁹ The court concluded the claims lacked utility, noting “[w]e are not aware of any reputable authority which would accept appellant’s two clinical cases as establishing utility for treatment of cancer in humans.”³⁰ This case demonstrates that more than a mere statement of utility in the patent is required. Even in the face of clinical data, the court rejected the claims. Specifically distinguishing *In re Krimmel*³¹, upon which Professor Merges relies, the court reasoned “While the court’s consideration of tests demonstrating effectiveness of compounds in treating diseases in animals indicates that such are not to be disregarded, it is clear that such tests must be viewed with respect to the utility

²⁶ 418 F.2d 540 (C.C.P.A. 1969) (“*In re Buting*”) (R-393)

²⁷ *In re Malachowski*, (C-432).

²⁸ *In re Buting*, (R-393).

²⁹ *Ibid.*

³⁰ *In re Buting*, at 542 (R-393).

³¹ 292 F.2d 948 (C.C.P.A. 1961) (“*In re Krimmel*”) (C-439).

asserted.”³² Ultimately the court concluded, “We do not find such evidence, limited to one compound and two types of cancer, to be commensurate with the broad scope of utility asserted and claimed, viz. that of treating seven types of cancer with several compounds.”³³ *Buting* makes clear that satisfying the utility requirement, particularly for treatments directed to humans, requires actual proof of utility and more than the a mere unsupported recitation of an expectant utility.

D. Professor Merges Understates the Similarities of United States’ Written Description and Enablement Requirements with Canadian Policies

25. Professor Merges also fails to consider adequately the importance of including the enablement and written description doctrines in a proper comparative analysis. Both enablement and written description require proof that the applicant did actually invent what is claimed, by requiring a disclosure that demonstrates her possession of the claimed invention and the manner of making and using it. As I explained in my opening report, the three doctrines (utility, enablement and written description) are closely related and often rise or fall together.³⁴ A myopic focus solely on utility doctrine is to miss the forest for the trees.

26. Professor Merges offers an interesting exegesis on what he views as the policies underlying utility, written description, and enablement.³⁵ Conspicuously, he cites no authority for his articulation of the relationships among the three doctrines. The reason is that there is no support in the law for his characterizations. He asserts, without support, that “Utility prevents claiming an invention before its use is established; it prevents inventors from stockpiling structures whose end purpose is as yet unknown. Enablement and written description prevent an inventor from overclaiming the bounds of an invention; they prevent inventors from in effect stockpiling variants and extensions of a given invention.” The law does not cabin enablement and written description so neatly in this fashion. They are also threshold assessments of whether the applicant has

³² *In re Krimmel*, (C-439).

³³ *Ibid.*

³⁴ Holbrook First Report, at para. 9.

³⁵ Merges Second Report, at para. 42.

invented anything *at all*, let alone whether they have claimed more than they invented. The three doctrines thus overlap considerably and in ways that mirror Canadian utility doctrine. The overlap with enablement is particularly clear: if the inventor has not created something that will work, then by definition the specification cannot describe how to make or use the invention.

27. The seminal case for written description law, *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*³⁶, confirms that written description does more than merely police patent scope. In *Ariad*, the inventors “recognized that artificially interfering” with the expression of the gene at issue “could reduce the harmful symptoms of certain diseases.”³⁷ However, as of the filing date, the inventors had not yet discovered any means to artificially interfere with the expression of the gene; instead, “[t]he specification hypothesizes three types of molecules with the potential” to so interfere.³⁸ The court recognized that the claims were broad genus claims, “encompassing the use of all substances that achieve the desired result.”³⁹ Because the inventors had discovered *no such substance* as of the filing date, the case is not merely a scope issue. Had the inventors drafted claims specific to the hypothesized chemicals, the claims would still have failed the written description requirement because the applicant had not disclosed any means of obtaining the desired result. The inventor, rather than simply claiming too broadly, was not yet in possession of *any* embodiments of the invention. As the court reasoned:

Perhaps there is little difference in some fields between describing an invention and enabling one to make and use it, but that is not always true of certain inventions, including chemical and chemical-like inventions. Thus, although written description and enablement often rise and fall together, requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described. For example, a propyl or butyl compound may be made by a process analogous to a disclosed methyl compound, but, in the absence of a statement that the

³⁶ 598 F.3d 1336 (Fed. Cir. 2010) (en banc) (“*Ariad*”)(**R-099**).

³⁷ *Ariad*, at 1340 (**R-099**).

³⁸ *Ariad*, at 1341 (**R-099**).

³⁹ *Ariad*, at 1340 (**R-099**).

inventor invented propyl and butyl compounds, such compounds have not been described and are not entitled to a patent.⁴⁰

28. As such, written description performs two functions. It does police claim scope, but it also ensures that applicants do not file their applications prematurely, before they actually created the invention.

29. As the Federal Circuit further explained in *Ariad*, “the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.”⁴¹ The court also discusses genus claims as a separate form of claim issue.⁴² Non-genus claims, therefore, are also subject to the written description requirement.

30. Confirming that written description applies to claims of narrow scope, and not merely broad genus claims, is the Federal Circuit’s reliance on *In re Ruschig*⁴³ to support its conclusion in *Ariad*.⁴⁴ In *Ruschig*, the court rejected a claim to a *single, specific compound* in light of a broad specification that “encompasses something like half a million possible compounds.”⁴⁵ The court reasoned: “Not having been specifically named or mentioned in any manner, one is left to selection from the myriads of possibilities encompassed by the broad disclosure, with no guide indicating or directing that this particular selection should be made rather than any of the many others which

⁴⁰ *Ariad*, at 1352 (**R-099**).

⁴¹ *Ariad*, at 1351 (**R-099**).

⁴² *Ariad*, at 1351 (**R-099**) (“For generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure...”); see also *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014) at 1299 (**R-103**) (“One particular question regarding the written description requirement has been raised when a genus is claimed but the specification only describes a part of that genus that is insufficient to constitute a description of the genus.”)

⁴³ 379 F.2d 990 (C.C.P.A. 1967) (“*Ruschig*”) (**R-394**).

⁴⁴ To be clear, I do not believe, as the majority suggests in *Ariad*, that *Ruschig* supports a written description requirement as originally adopted in *Regents of the University of California v. Eli Lilly, & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) (“*Lilly*”) (**R-101**). *Ruschig* involves the traditional use of written description to keep new matter from entering subsequent applications. To the extent that the majority in *Ariad* felt those cases inform the written description requirement in its present form, then *Ruschig* demonstrates that written description is not just about claim scope.

⁴⁵ *Ruschig*, at 993 (**R-394**).

could also be made.”⁴⁶ Indeed, Eli Lilly & Co. argued in favor of this view of *Ruschig* in *Ariad*.⁴⁷

31. The case viewed as creating the new written description requirement, *Regents of the University of California v. Eli Lilly & Co.*, is also telling in this regard. In *Lilly*, claim 5 was “specific to a microorganism containing a human insulin cDNA.”⁴⁸ As such, the claim was not an overly broad genus claim, unlike others in the case that “generically recited cDNA” encoding vertebrate or mammalian insulin.⁴⁹ The court rejected claim 5 for lack of written description.⁵⁰ The court concluded the specification was inadequate because it only described “a general method of obtaining the human cDNA...along with the amino acid sequences of human insulin A and B chains.”⁵¹ Moreover, it further concluded that “[w]hile the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA.... Accordingly, the specification does not provide a written description of the invention of claim 5.”⁵²

32. While the most typical application of the written description requirement is to police against overly broad claims, it is not the written description's only function, as these cases demonstrate. It also can invalidate incredibly narrow claims where the disclosure does not demonstrate that the inventor possessed that particular embodiment of the invention. It thus acts both to combat overly broad claim scope *and* to ensure that the inventor actually has created *anything at all* that is patentable.

⁴⁶ *Ruschig*, at 995 (**R-394**).

⁴⁷ *Ariad*, at 1348 (**R-099**) (“According to Lilly, the court properly rejected the claim under a written description requirement separate from enablement because the specification did not disclose the later-claimed compound to one of skill in the art as something the inventors actually invented out of the myriad of other compounds encompassed by the broad disclosure.”)

⁴⁸ *Lilly* at 1567 (**R-101**).

⁴⁹ *Ibid.*

⁵⁰ *Ibid.*

⁵¹ *Ibid.*

⁵² *Ibid.*

33. This role for the written description requirement parallels the Canadian policy interest in ensuring that a party has actually invented what is disclosed at the time of the application if filed. It works to prevent premature applications on inventions that have not been demonstrated to work as of yet.

E. The US Does Not Routinely Permit Post-Filing Evidence to Demonstrate Utility or Enablement

34. Professor Merges' assertion that post-filing evidence to support utility and enablement is routinely used is wrong. Technical evidence generated after the filing date, such as new experiments performed by the applicant or scientific articles, generally cannot be used to demonstrate utility or enablement in the face of an otherwise inadequate disclosure. The reason is straightforward: utility and enablement are assessed as of the filing date. This type of post-filing evidence risks that technological advances subsequent to the filing of the application are used to prepare such evidence and, thus, that the evidence does not properly reflect the state of the art as of the filing date. If this were not the rule, every applicant could file an application with a host of speculative utilities while waiting until later to discover whether that speculation can be confirmed.

35. Of course, evidence generated post-filing that demonstrates a lack of utility or enablement does not suffer from this problem. Such evidence is admissible because it is highly probative as to whether the application had demonstrated utility or an enabling disclosure on the filing date. In this context, timing works against the applicant. Even if the post-filing evidence incorporates subsequent technological advances, if the evidence shows a lack of utility or enablement, then odds are very low the inventor actually demonstrated utility or enablement as of the application's filing date. Many of the cases that Professor Merges relies upon relate to post-filing evidence that confirms a lack of utility or enablement. These cases are inapposite to the issues in this dispute.

36. For example, in footnote 40, Professor Merges relies upon *In re Marzocchi*, stating that “[t]here the court accepted evidence, in the form of a scientific references, that were not prior art to the application at issue – i.e., the references appeared in the

literature after the patent's filing date."⁵³ To be clear, the court concluded that the patent's asserted utility was sufficient: "the circumstances we see do not support the reasonableness of any doubts which the Patent Office might have had concerning the adequacy of appellants' specification disclosure to support these claims."⁵⁴ The case therefore has nothing to do with evidence generated post-filing to demonstrate utility or enablement.

37. More importantly, *Marzocchi* is actually about the evidence that the United States Patent and Trademark Office (USPTO) must bring forward to challenge an applicant's asserted utility or enabling disclosure. The evidence⁵⁵ at issue was used by the United States Patent and Trademark Office (USPTO) to demonstrate that the patent's disclosure was *insufficient*. It was not submitted by an applicant to bolster a claim of an inadequate disclosure, as is the situation in this arbitration.

38. The language that Professor Merges quotes confirms that the court's discussion relates to the USPTO's use of post-filing evidence "to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim."⁵⁶ Specifically, the court noted that "Most often, additional factors, such as the teachings in pertinent references, will be available to *substantiate any doubts* that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof."⁵⁷ The post-filing evidence discussed in footnote 4 of the decision, thus, is evidence substantiating the USPTO's doubts regarding utility or enablement.

⁵³ Merges First Report, at p. 11, n.40; *In re Marzocchi*, 439 F.2d 220 (C.C.P.A. 1971) ("*Marzocchi*") (**R-088**)

⁵⁴ *See Marzocchi*, at 224 (**R-088**).

⁵⁵ The opinion itself is not as clear as Professor Merges suggests regarding the nature of any post-filing evidence. The decision itself does not discuss particular pieces of evidence outside of the patent document, so, aside from a generic reference in a footnote to the use of non-prior art references – which could have been created prior to the filing date – the case does not delineate the nature of any such evidence.

⁵⁶ *See Marzocchi*, at 223 (**R-088**).

⁵⁷ *See Marzocchi*, at 223 – 224 (**R-088**) (footnote omitted and emphasis mine).

39. Subsequent cases confirm that the language in *Marzocchi* is dealing with USPTO's evidence of lack of utility or enablement.⁵⁸ In short, allowing post-filing evidence to show a patent's disclosure is inadequate is uncontroversial. The one-off sentence, indicting the USPTO's evidence as "tend[ing] to strengthen rather than weaken appellants' claim to the breadth of protection they seek," does not somehow transform the nature of the case. USPTO produced arguably post-filing evidence to support its view that the claims were not enabled.

40. In contrast, the courts and the USPTO have, as a general rule, rejected evidence generated post-filing that has been used in an attempt to demonstrate the invention's utility or that the disclosure is enabling. For example, in *In re Glass*,⁵⁹ the applicant submitted four patents to support his argument that his application was enabled. The four patents issued after the applicant's filing date, though they would have qualified as prior art under then-35 U.S.C. § 102(e).⁶⁰ The USPTO held that the patents "could not be accepted as showing the state of the art as of appellant's filing date since they issued thereafter and refused to consider them."⁶¹ The court agreed with the approach of the USPTO holding:

As of its filing date it does not show what is known generally to 'any person skilled in the art,' to quote from § 112. On the other hand, § 112 requires an applicant to so describe his invention as to enable any person skilled in the art

⁵⁸ See *In re Cortright*, 165 F.3d 1353 (Fed. Cir. 1999) at 1357 (**R-068**) (citing *Marzocchi* to support the proposition that "The PTO cannot make this type of rejection, however, unless it has reason to doubt the objective truth of the statements contained in the written description.").

⁵⁹ 492 F.2d 1228 (C.C.P.A. 1974) ("*In re Glass*") (**R-395**). Professor Merges did not discuss *In re Glass*, but it was cited in his block quote on p. 10, paragraph 23, from *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995) ("*In re Brana*") (**C-168**).

⁶⁰ The four patents would have qualified as prior art under 35 U.S.C. § 102(e). At that time, § 102(e) defined as prior art "a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent." In other words, an issued patent in the United States is treated as prior art as of its filing date. Section 102(e) is codification of the Supreme Court's decision in *Alexander Milburn Co. v Davis-Bournonville Co.*, 270 U.S. 390 (1926), 46 S.Ct. 324 (**R-453**). In 1999, § 102(e) was amended once the United States changed its law to allow the publication of patent applications. After the amendment, a patent application would serve as prior art if either the application was published (35 U.S.C. § 102(e)(1)) or when the patent issued (35 U.S.C. § 102(e)(2)). This entire provision was eliminated from the United States patent laws by the America Invents Act, which changed the United States from a first-to-invent to a first-inventor-to-file system. The analog to § 102(e) is found in § 102(a)(2), which is keyed to the date of application and not the date of invention.

⁶¹ *In re Glass*, at 1231 (**R-395**).

to practice it, the purpose being to make the invention understandable to all such persons as soon as the patent issues. Sections 112 and 102(e) rest on different foundations, serve different purposes, and are not comparable. There is nothing ‘unfair’ about the situation. *The board was right in refusing to consider the patents cited by appellant and we, likewise, refuse to consider them.*⁶²

41. This case is a clear example of where the USPTO and court refused to look at post-filing evidence that would have supported the applicant’s position that the patent’s disclosure was sufficient solely because the evidence arose after the filing date.

42. Professor Merges also relies on *In re Krimmel* to suggest that the United States routinely permits post-filing evidence in support of enablement or utility. The case does not support such a rule. The real issue was whether proof of human efficacy was required to demonstrate utility, which the court concluded was not. The affidavits submitted in the case discuss “the evaluation of two of the claimed compounds” for their effectiveness. The case does not explain *when* those tests were performed, however. The affidavit was generated post-filing, but at no point did the USPTO raise an objection based on timing. If the affidavit related to acts occurring prior to the filing date, then such an affidavit is not objectionable. Subsequent cases suggest that the testing was indeed generated pre-filing.⁶³ Further, even if the tests discussed in the affidavit were performed post-filing, they merely replicated what had been done pre-filing.⁶⁴

43. Professor Merges’ reliance on *In re Brana* is also unavailing, as I discussed in my initial report.⁶⁵ Professor Merges ignores these important aspects of *Brana* that limit any broad holding regarding the admissibility of post-filing evidence in support of enablement:

⁶² *In re Glass*, at 1231-1232 (**R-395**) (emphasis added).

⁶³ See *In re Kirk*, 376 F.2d 936 (C.C.P.A. 1967) at 941 n.7 (**R-074**) (“In those cases [including *Krimmel*], the inventors had carried their invention substantially further than appellants here, pharmacological testing having proceeded to an extent that some particular salutary effects on conditions inimical to animals could be ascribed to the compounds in issue there. The general results of those tests were disclosed in the application as filed, in contrast to the situation here.”)

⁶⁴ See *In re Krimmel*, (**C-439**) (“He is conversant with the tests *employed to establish the pharmacodynamics of the said compounds*, these tests being of a standardized type generally carried out under his supervision.” (emphasis added)).

⁶⁵ Holbrook First Report, at paras. 34-36.

- The court held the disclosure was sufficient even without the evidence. As such, the admission of the evidence is of no moment - it was superfluous to the holding of the case.⁶⁶
- The prior art itself supported utility, reducing any improper incorporation of subsequent technical advance.⁶⁷
- The court recognized the very narrow context for this evidence: “[The Kluge declaration] does not render an insufficient disclosure enabling, but instead goes to prove that the disclosure was in fact enabling when filed (i.e., demonstrated utility).”⁶⁸
- The Federal Circuit subsequently has itself limited *Brana*.⁶⁹

44. The law is clear that evidence generated post-filing in support of utility or enablement is not generally admissible. *Brana*, as explained above, is an outlier decision and the use of post-filing evidence in that context was superfluous to the outcome.

F. The United States has Significantly Changed Its Patent Law Since NAFTA

45. Professor Merges suggest that variations in United States patent law are merely minor variances. Such a statement ignores the dramatic impact of *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*⁷⁰ and other subject matter eligibility cases from the United States Supreme Court that dramatically curtailed what subject matter can be patented. It also ignores that the Federal Circuit’s written description doctrine as fully recognized in *Ariad*, which stands alone in the world and has had a dramatic impact in biotechnology and software cases. These are not minor variations but instead significant changes to United States patent law that suggest U.S. courts do not feel constrained by NAFTA in their development of patent law.

46. As I explained in my opening report⁷¹, the Supreme Court’s decision in *Alice* represents a dramatic sea change in the law of patentable subject matter that has

⁶⁶ See *In re Brana*, at 1566 (R-073) (“applicants should not have been required to substantiate their presumptively correct disclosure to avoid a rejection under the first paragraph of § 112.”)

⁶⁷ *In re Brana*, at 1567-1568 (R-073).

⁶⁸ *In re Brana*, at 1567 n.19 (R-073).

⁶⁹ See *In re '318 Patent Infringement Litigation*, 583 F.3d 1317 (Fed. Cir. 2009) at 1325 n.8 (R-054)

⁷⁰ 134 S. Ct. 2347 (2014) (“*Alice*”) (R-108).

⁷¹ Holbrook First Report, at para. 63.

invalidated thousands of patents. Moreover, the United States Supreme Court's decisions in *Association for Molecular Pathology v. Myriad* rejected decades of practice by the USPTO of issuing patents on isolated cDNA,⁷² also invalidating large numbers of extant patents.⁷³ *Mayo v. Prometheus*⁷⁴ has also dramatically reduced the patentability of various diagnostic methods, invalidating even more current patents.

47. *Ariad* itself, as I explained⁷⁵ and which Professor Merges does not deny, represents a dramatic unilateral alteration of United States patent law, creating a doctrine that is unique to the United States. The irony is that this law evolved at the bequest of Lilly, who now wants to cry foul over a doctrine that is consistent with United States patent law, and indeed far more consistent than the U.S. written description doctrine is with patent laws around the world.

48. As I explained, and contrary to Mr. Kunin's assertions, the doctrine of utility has also oscillated over time in the United States.^{76,77}

⁷² See *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012) (Moore, J., concurring-in-part) at 1343 (**R-396**) (“[T]he United States Patent Office has allowed patents on isolated DNA sequences for decades, and, more generally, has allowed patents on purified natural products for centuries.”); *aff'd in part, rev'd in part sub nom. Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (**R-109**).

⁷³ *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012) (Moore, J., concurring-in-part) at 1343 (**R-396**) (“There are now thousands of patents with claims to isolated DNA, and some unknown (but certainly large) number of patents to purified natural products or fragments thereof.”)

⁷⁴ *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, 132 S. Ct. 1289 (2012) (**R-110**).

⁷⁵ Holbrook First Report, at paras. 68-69.

⁷⁶ Professor Merges conspicuously does not address this issue. Indeed, in his writing, Professor Merges appears to agree with my position that the utility doctrine has changed over time. Robert P. Merges, *Justifying Intellectual Property*, (London, 2011) Harvard University Press, p. 182 (**R-450**) (noting “Courts are of course especially well suited to assess these sorts of changes and to adjust rules accordingly” and using as an example “The updating of the utility requirement in patent law to obviate the patenting of gene snippets aimed at capturing the value of later-discovered genes”).

⁷⁷ Holbrook First Report, at paras. 64-66.

49. In summary, the supplemental reports of Professor Merges and Mr. Kunin do not undermine the basic premise of my initial report: a proper comparative analysis requires an analysis not only of United States utility doctrine but also enablement and written description requirements. This trio of doctrines operates to protect against applicants filing prematurely, before they have actually discovered whether the invention truly works. These doctrines are particularly relevant in the pharmaceutical context, notably when addressing a claim to a method of treatment.

Signed at ATLANTA, GA, USA on: 5 Dec 15

[signed]
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JUDICIAL CLERKSHIP

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Danubia, Budapest, Hungary

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Bell, Seltzer, Park & Gibson, Charlotte, NC Summer 94

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Brief of Amici Curiae Mark D. Janis and Timothy R. Holbrook in Support of Neither Party, *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.* (Fed. Cir. October 14, 2009).

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HONORS AND AWARDS

- Chesnut LGBT Person of the Year Award, Emory University, 2015
- 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

Panelist, *Patent Reform Legislation After the AIA and Octane/Highmark*, Patent Litigation in the New Era, Bloomberg/Wiley Rein, Washington, DC, Nov. 12, 2015.

Patent Disclosures and Time, The Disclosure Function of the Patent System, 2015 Vanderbilt Law Review Symposium, Vanderbilt University Law School, Nashville, TN, Nov. 6, 2015.

Panelist, *Practical Tips and Guidance for Post Grant Proceedings at the USPTO*, IP Section of the Georgia Bar Association, Atlanta, GA, Oct. 8, 2015.

Moderator, Panel on Ethics with the Honorable Kimberly A. Moore, U.S. Court of Appeals for the Federal Circuit, 2015 Georgia Intellectual Property Institute, Amelia Island, FL, Sept. 19, 2015.

Moderator, Federal Judicial Panel, 2015 Georgia Intellectual Property Institute, Amelia Island, FL, Sept. 19, 2015.

Method Patent Exceptionalism, Inaugural Tsai Center Symposium on Intellectual Property Law, SMU Dedman School of Law, Dallas, TX, Sept. 18, 2015.

Method Patent Exceptionalism, 15th Annual Intellectual Property Scholars Conference, DePaul College of Law, Chicago, IL, Aug. 6, 2015.

From Outlaws to In-Laws: Obergefell and its Aftermath, Kilpatrick Townsend Lunch Conversation, Atlanta, GA, July 15, 2015.

What's Next After Marriage Equality?, Stonewall Bar Assoc. and Morris, Manning & Martin CLE Event, Atlanta, GA, July 9, 2015.

Commentator, Junior IP Scholars Workshop, Vanderbilt Law School, Nashville, TN, April 23, 2015.

Alumnus Keynote Speaker, Lavender Graduation Ceremony, North Carolina State University, Raleigh, NC, April 21, 2015.

Panelist, *Strategies and Perspectives with regard to New Developments in Patent Law*, Licensing Executives Society (Atlanta Chapter), Atlanta, GA, April 2, 2015.

Patent Year in Review 2014-15, 17th Annual Akron Symposium on Intellectual Property and Policy, University of Akron School of Law, Akron, OH, March 9, 2015.

Innovation Reform in All Three Branches of Government, Keynote Address, Emory Office of Technology Transfer Celebration of Technology and Innovation, March 4, 2015.

Patent Anticipation and Obviousness as Possession, University of Illinois Intellectual Property Colloquium (via Skype due to weather), March 2, 2015.

The Complexity of the Same-Sex Marriage Cases, Emory Law Democrats, Atlanta, GA, Feb. 23, 2015.

Active Active Inducement (Active² Inducement), Patent Law Experts Conference, Naples, FL, Feb. 9, 2015.

Panelist, *Federal Circuit Update*, Association of Corporate Patent Counsel, Winter Meeting, San Antonio, TX, Jan. 26, 2015.

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.

Diversity, Inclusion and Unconscious Bias, GE Power and Water Legal Retreat, Atlanta, GA, Oct. 23, 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 Sughruie 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.