

**In the Arbitration under the Arbitration Rules of the  
United Nations Commission on International Trade Law and  
the North American Free Trade Agreement**  
(Case No. UNCT/14/2)

**ELI LILLY AND COMPANY**  
*Claimant*

v.

**GOVERNMENT OF CANADA**  
*Respondent*

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**Second Expert Report of Professor Robert Merges**  
The University of California, Berkeley, School of Law

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## **I. Summary of Conclusions**

1. This Expert Report makes three basic points.
  - First, in response to the Expert Report of Professor Timothy Holbrook, I note that Professor Holbrook concedes that important features of Canada's Promise Utility Doctrine are inconsistent with U.S. law, and thus with general and traditional principles of utility. For example, Professor Holbrook points out that U.S. utility requires only a showing of simple operativeness, that the inquiry regarding utility in the U.S. is limited to the claimed invention, and that statements of asserted utility are presumed to be true in U.S. patent applications.
  - Second, Professor Holbrook mischaracterizes the utility standard as a "significant barrier" in the pharmaceutical field. This belies the fact that the utility requirement is the same for all inventions. Also, in his numerous published academic works, Professor Holbrook has often correctly stated the overwhelmingly prevailing view that utility in the U.S. is a low standard that is usually met easily by patent applicants. Utility may be more salient in the pharmaceutical field at times (because chemical structures may be assembled before they are shown to be operative), but the standard is no higher than for any other field.
  - Third, while I did not assert in my first Expert Report that NAFTA "froze" the requirements of patent law, the promise utility doctrine is so unprecedented and radical that it defies any common understanding of utility. The promise utility doctrine cannot be regarded as normal variation around a core concept of patentability. This Canadian doctrine has been so transformed as to be unrecognizable as an application of traditional and conventional standards related to the test of utility.

## **II. Holbrook Concedes that Major Features of U.S. Law are Inconsistent with the Promise Utility Doctrine**

2. In his Expert Report, Professor Holbrook makes several assertions that accurately reflect U.S. law and that distinguish the U.S. utility standard from Canada's promise utility doctrine. Those assertions include the following: (1) the operability aspect of utility deals with the basic question of whether the invention works and whether the asserted utility is credible;<sup>1</sup> (2) "the articulated utility is presumed to be true";<sup>2</sup> (3) U.S. law requires that an invention have only one or "a"

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<sup>1</sup> Holbrook Report at ¶ 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 . . .").

<sup>2</sup> *Id.* at ¶ 23.

utility;<sup>3</sup> and (4) that in the United States utility is tested according to the *claimed* invention,<sup>4</sup> and that a wide range of evidence is permissible to establish utility.<sup>5</sup>

3. Because the promise utility doctrine in Canada deviates critically from all of these points of U.S. law, Holbrook implicitly concedes that this doctrine diverges from U.S. utility doctrine.

4. Outside the context of his report, Professor Holbrook has often written in his academic work that utility is generally a low standard. For example, he wrote: “Generally, the utility requirement is easy to satisfy: an invention will be useful ‘if it actually works to achieve at least one of its stated purposes.’”<sup>6</sup> And:

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<sup>3</sup> *Id.* at ¶¶ 20, 27, 29 (references to “a” use or utility).

<sup>4</sup> *Id.* at ¶ 29 (“[A]n asserted use must show that that claimed invention has a significant and presently available benefit to the public.”) (quoting *In re Fisher*, 421 F.3d 1365, 1373 (Fed. Cir. 2005)).

<sup>5</sup> *Id.* at ¶ 33 (“Proof of utility can include test results, human trials, animal tests or *in vitro* experiments . . .”).

<sup>6</sup> Timothy R. Holbrook, “The Expressive Impact of Patents,” 84 WASH. U.L. REV. 573, 600 (2006) (C-434). The full quote:

Generally, the utility requirement is easy to satisfy: an invention will be useful “if it actually works to achieve at least one of its stated purposes.” The inventor must demonstrate that the invention has only one use that benefits society, even if there are numerous other uses that would be detrimental. The courts and the PTO generally use the utility requirement to reject inventions that belie scientific laws, such as a perpetual motion machine. Only in the chemical context is utility really an issue – the mere knowledge of a chemical structure is insufficient for a patent unless a use for the chemical is known. For mechanical devices, utility is rather simple to demonstrate – the mousetrap either snaps closed or it does not. The PTO recently issued guidelines for establishing utility to deal with complications arising from the patenting of human genes and gene fragments. The standard set in the guidelines is that an invention must have a substantial, specific, and credible utility to be eligible for patent protection.

*Id.* at 600-01 (footnotes omitted); *see also* Timothy R. Holbrook, “The Treaty Power and the Patent Clause: Are There Limits on the United States’ Ability to Harmonize?,” 22 CARDOZO ARTS & ENT. L.J. 1, 17 (2004) (footnotes omitted) (C-435):

The Constitution does not detail to what level such progress must be achieved. In reality, measuring progress would be a rather difficult thing to do, as no metric readily exists. In patent law, the standard is clearly low, regardless of the unit of measure. For example, the utility requirement for a patent does not require that an invention be better than the prior art – just different. Even if the invention works less efficiently than the prior art, so long as it is sufficiently different (i.e., novel and nonobvious), then the patent should be granted, and progress would be achieved. Why? Because that different approach

“Utility requires that the invention simply be useful for a specific purpose.”<sup>7</sup> And finally: “The inventor must demonstrate that the invention has only one use that benefits society, even if there are numerous other uses that would be detrimental.”<sup>8</sup>

5. In his academic writings, Holbrook also states that the utility requirement, in the pharmaceutical sector as in other sectors, asks only for identification of a single use: “Only in the chemical context is utility really an issue – the mere knowledge of a chemical structure is insufficient for a patent unless a use for the chemical is known.”<sup>9</sup> As Professor Holbrook has noted, that use must be “substantial, specific, and credible” under U.S. law, but this is not a high bar.<sup>10</sup>

### III. Utility is a Low Standard

6. Professor Holbrook argues that in the United States utility “remains a significant barrier to patentability in the pharmaceutical context.”<sup>11</sup> But by almost any measure, utility is the easiest patentability requirement for applicants and patentees to meet, both in the pharmaceutical field and elsewhere. The “utility threshold is not high.”<sup>12</sup> Only rarely does an invention fail to meet the standard.<sup>13</sup> Among the core patentability criteria of utility, non-obviousness, and novelty, utility is the least likely ground on which a patent is invalidated in litigation.<sup>14</sup>

7. Mischaracterizing the utility test in both Canada and the United States, Professor Holbrook makes this assertion in his Report:

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may actually generate greater progress downstream in a two-steps backward, three-steps forward approach.

<sup>7</sup> Timothy R. Holbrook, “The More Things Change, the More They Stay the Same: Implications of *Pfaff v. Wells Electronics, Inc.* and the Quest for Predictability in the on-Sale Bar,” 15 BERKELEY TECH. L.J. 933, 936 (2000) (footnote omitted) (C-436).

<sup>8</sup> Timothy R. Holbrook, “The Expressive Impact of Patents,” 84 WASH. U.L. REV. 573, 600-601 (2006) (C-434).

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> Holbrook Report at ¶ 13.

<sup>12</sup> *In re Fisher*, 421 F.3d 1365, 1370 (Fed. Cir. 2005) (C-84).

<sup>13</sup> See Michael Risch, “A Surprisingly Useful Requirement,” 19 GEO. MASON L. REV. 57, 58 (2011) (R-61); see also Lee Petherbridge, “Road Map to Revolution? Patent-Based Open Science,” 59 ME. L. REV. 339, 356 n.90 (2007) (“The utility requirement is still properly understood as very low and generally presents a low bar to patentability.”) (C-269).

<sup>14</sup> John R. Allison and Mark A. Lemley, “Empirical Evidence on the Validity of Litigated Patents,” 26 AIPLA Q.J. 185, 208 (1998) (C-167).

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.<sup>15</sup>

This assertion (1) seriously understates the impact of the promise utility doctrine in Canada, and (2) seriously overstates the difficulty of meeting the utility standard in the United States.

8. As to (1), Canada's promise utility doctrine goes far beyond requiring proof that an invention is "known to work as of [its] filing date." There was no question that the compounds claimed in the Canadian Patent No. 2,041,113 (for Zyprexa) and Canadian Patent No. 2,209,735 (for Strattera) *worked* for their basic purpose when they were filed. That is why no other court system in the world except Canada finally determined that the patents failed to satisfy the utility requirement. A thing is "useful," according to the Oxford English Dictionary, if it is "capable of being put to good use."<sup>16</sup> The compounds in these patents had a proven purpose as of their filing date. What they did not have, according to the courts in Canada, was proof convincing enough (to them) to show the presence of all the *qualities and features* they were allegedly stated to have in the specification. The promise utility doctrine is about performance characteristics, qualities, and features, not about having a basic "use."

9. It is true that both the United States and Canada are concerned that inventors be prevented from "merely speculating." But this refers to speculation *about the existence of a use*. As long as a use is identified, there is no risk of speculation. The promise utility doctrine goes very far beyond this traditional concern in U.S. law. In Canada, lack of proof as to performance features and characteristics of an invention is taken as a failure to establish utility – despite convincing proof that the invention at issue is capable of being put to good use. This is a completely different legal test than the utility test in the United States.

10. As to (2), Professor Holbrook states that U.S. law requires the applicant to "demonstrate[] the efficacy of the drug."<sup>17</sup> This is fundamentally in opposition to a basic precept of U.S. patent law. As noted in my initial report, utility

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<sup>15</sup> Holbrook Report at ¶ 17.

<sup>16</sup> "Useful," OED Online, Oxford University Press (September 2014); <http://www.oed.com/view/Entry/220640?redirectedFrom=useful> (CL-70).

<sup>17</sup> Holbrook Report at ¶ 17.

is presumed under U.S. law upon mere *initiation* of a clinical trial.<sup>18</sup> Further, “safety and efficacy” are the classic requirements for drug approval by the FDA, and it is extremely settled law in the United States that patentable utility does *not* equal FDA approval. Even more generally, efficacy suggests effectiveness or a degree of success beyond a mere aim or purpose, which is the core of the utility test in the United States.<sup>19</sup>

**A. Utility in the pharmaceutical field is at times salient, but is no more rigorous than in other fields**

11. Professor Holbrook quotes one of my casebooks as follows:

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.<sup>20</sup>

12. He says this indicates a recognition that utility is not a low bar to patentability in the pharmaceutical field. This is not true. It is merely a statement

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<sup>18</sup> Merges First Report at ¶ 23.

<sup>19</sup> See *In re Krimmel*, 292 F.2d 948, 954 (C.C.P.A. 1961) (holding that as to whether the claimed drug was safe and effective for use in humans, “[i]t is not for us or the Patent Office to legislate and if the Congress desires to give this responsibility to the Patent Office, it should do so by statute”)(C-439); *In re Hartop*, 311 F.2d 249, 260 (C.C.P.A. 1962) (“Although it is true that the advertising and sale or other distribution of appellants’ invention for human therapy in interstate and much of the intrastate commerce will not be legally permissible until experiments with humans have been carried out, we do not think it is within the authority or responsibility of the Patent Office to demand such tests in this particular case . . . .”) (C-293); *In re Anthony*, 414 F.2d 1383, 1395-97 (C.C.P.A. 1969) (“[T]he FDA need not necessarily determine that a drug is commercially useful or usable before it may be ‘useful’ in the patent law sense.”; also refusing to invalidate patent for lack of utility where sale of related drug had been suspended by FDA due to harmful side effects: “That further research may be necessary before the claimed compositions are once again marketed on a commercial scale is not really material to whether those compositions are now useful, nor is it fatal to appellant’s case.”)(C-292); accord *Scott v. Finney*, 34 F.3d 1058, 1063-64 (Fed. Cir. 1994) (for purposes of establishing reduction to practice in an interference: “Testing need not show utility beyond a possibility of failure, but only utility beyond a probability of failure,” citing *Taylor v. Swingle*, 136 F.2d 914, 917 (C.C.P.A. 1943)) (C-440); cf. *In re Watson*, 517 F.2d 465, 474-76 (C.C.P.A. 1975) (explaining that it is not the province of the Patent Office to determine, under § 101, whether drugs are safe)(C-478).

<sup>20</sup> Holbrook Report at ¶ 18 (quoting Robert P. Merges, Peter S. Menell, & Mark A. Lemley, *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* (Wolters Kluwer: 6th ed. 2012)).

that this low bar may have greater relevance in the pharmaceutical field. The fact that molecules are sometimes synthesized without knowing if they have a particular use means that the need to identify a use may arise in the pharmaceutical or chemical sectors more often than in other fields. It means, to use the analogy of a high jump bar in track and field, that the bar is more noticeable. Imagine for example, instead of being black or white, the high jump bar is neon orange. The height of the bar is the same, but it is more prominent – it stands out more. So machines, electronic circuits, software, etc. are almost never constructed without an end purpose or use in mind. The end purpose drives their assembly and construction. Their use, in other words, is apparent on the face of the structure. The chemical fields – including pharmaceuticals – are unusual in that structure sometimes comes first, with no end use in mind. But as soon as a single use is found, the chemical structure in question meets the utility requirement.

13. In that context, the use requirement is more salient. It presents itself more clearly as a bar that must be cleared. But it does not mean the bar is *higher*. Utility presents the same bar for machines, electronic circuits, software inventions, and chemical/pharmaceutical inventions. And it is a low bar: the inventor must show a use, period. The fact that a use is inherent in many inventions (such as machines) does not mean that the use requirement is higher for other inventions (such as pharmaceuticals). In the pharmaceutical field, utility is more apparent as a requirement because it is not met inherently in assembling a chemical structure. But visibility is not the same thing as severity. A more noticeable bar may be no higher than a less noticeable one.<sup>21</sup>

14. To repeat: utility is not a high bar. The same basic test applies for all inventions: does it have a purpose, a use? There is no higher degree of effectiveness or performance required in pharmaceutical inventions. A molecule must have a use, just as a machine or circuit must have a use. But once a basic use or purpose is established, utility is established and that is the end of the matter. Most crucially, there is absolutely no requirement that specific performance characteristics must be established to make an invention “useful” in the patent law sense. What is required is workability, i.e., some basic use.

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<sup>21</sup> See *In re Chilowsky*, 229 F.2d 457, 461-2 (C.C.P.A. 1956) (“There appears to be no basis in the statutes or decisions for requiring any more conclusive evidence of operativeness [i.e., utility] in one type of case than another. The character and amount of evidence needed may vary, depending on whether the alleged operation described in the application appears to accord with or to contravene established scientific principles or to depend upon principles alleged but not generally recognized; but the degree of certainty as to the ultimate fact of operativeness or inoperativeness should be the same in all cases.”) (C-437).

**1. The “operability” standard in U.S. law does not address whether the invention has been proven to work**

15. Professor Holbrook states that “[t]he operability aspect of utility deals with the basic question of whether the invention has been proven to work.”<sup>22</sup> The error in this statement is in the phrase “proven to work.” Under U.S. utility doctrine, credible evidence of operability is required. In many cases the mere assertion of a utility that is plausible will be enough to satisfy this standard. This is obviously a far cry from a requirement that an invention be “proven to work.” Assertions and presumptions are not the same as proof. The same error appears in Professor Holbrook’s statement that an “inventor cannot obtain a patent until she knows the invention will actually work.”<sup>23</sup>

16. Professor Holbrook uses the examples of cold fusion and baldness. These cases do not reflect or establish a general “proof” requirement. They illustrate how the law treats assertions that are inherently *incredible*: it requires further evidence. But these are exceptional cases. Where an asserted utility is inherently plausible to one skilled in the art, that is the end of the matter. Utility is established. Again, this is a far cry from proof. The exceptions of inherently incredible claims of utility do not establish a general requirement of proof.

17. Professor Holbrook quotes from the case of *CreAgri, Inc. v. Pinnacliffe, Inc.*<sup>24</sup> This case involved two patents, one of which claimed a compound derived from waste water at olive processing plants. The water was said to contain olive-related compounds useful, according to claim 1, for treating “coronary inflammation,” “bronchial inflammation,” and “neuro inflammation.”<sup>25</sup> A second claim covered a method for treating an inflammatory condition “selected from the group consisting of: delayed type hypersensitivity reaction, psoriasis, an autoimmune disease, organ transplant, pain, fever, and tissue graft rejection.”<sup>26</sup> The court reviewed the patent specification, plaintiff’s expert witness testimony, and relevant prior art, and concluded that the claims at issue were invalid for lack of utility. Citing the accused infringer’s un rebutted expert opinion, the court stated that one of skill in the art of treating inflammation would not accept the plaintiff/patentee’s asserted utility as true. Furthermore, the court noted that the patentee had not introduced any “data or reasoning” to support the implausible assertion of utility:

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<sup>22</sup> Holbrook Report at ¶ 21.

<sup>23</sup> Holbrook Report at ¶ 22.

<sup>24</sup> Holbrook Report at ¶ 25; *see CreAgri, Inc. v. Pinnacliffe, Inc.*, 2013 WL 6673676 (N.D. Cal. Dec. 18, 2013), *aff’d*, 579 F. App’x 1003 (Fed. Cir. 2014) (C-438).

<sup>25</sup> *CreAgri, Inc. v. Pinnacliffe, Inc.*, 2013 WL 6673676 (N.D. Cal. Dec. 18, 2013), at \*2 (C-438).

<sup>26</sup> *Id.*

Although the operability of a patented therapy need not be demonstrated by testing in order to satisfy the utility and enablement requirements, if the claimed effect would not otherwise be accepted by one of ordinary skill in the art, there must nevertheless be some quantum of data or reasoning that supports the inventor's contention that a therapy operates as claimed.<sup>27</sup>

18. *CreAgri* is in the same category as cases on cures for baldness or cold fusion. An inherently incredible assertion of utility was met by the Patent Office with a request for proof. The proffered evidence was deemed inadequate to establish the utility asserted. So the application for patent was rejected. The case does *not* establish a standard requiring affirmative evidentiary proof of utility in all cases, or even in all cases involving medical or health-related inventions. The utility asserted was inherently questionable to one skilled in the art, based on the prior art and what was generally known in the field.

19. In addition, *CreAgri* repeats the conventional rule that post-filing evidence can be used to mirror or substantiate utility-related statements included in an original specification. Holbrook treats it as a case that works against this rule, but this is a misreading. Holbrook writes: “[T]he district court invalidated the patent for lacking utility, even though the asserted utility was demonstrated subsequent to the patent application.”<sup>28</sup> But *Cre-Agri* does not say this. It is not a case where post-filing evidence was sufficient to establish utility but was disqualified as being too late. The post-filing evidence in *Cre-Agri* would not have established utility even if included in the original specification. No matter when the evidence in *CreAgri* had been introduced, it would not have been enough to defeat a motion for summary judgment that the patent lacked utility and was not enabled.<sup>29</sup>

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<sup>27</sup> *Id.* at \*20 (C-438).

<sup>28</sup> Holbrook Report at ¶ 25.

<sup>29</sup> The court in *CreAgri* says:

[E]ven if it could consider the results [of two studies completed post-filing] at issue, the Court would not conclude that the results create an issue of fact as to whether persons of ordinary skill in the art would accept without question the utility of the claimed treatment as of the filing date of the invention. The first study . . . explicitly disclaims the anti-inflammatory effects of [the claimed compounds]. . . . Thus, *CreAgri*'s own evidence demonstrates that the effectiveness of hydroxytyrosol as an anti-inflammatory was still uncertain to those of ordinary skill in the art even after the date of filing. The second study measured the effect of “olive extract supplement” on male and female volunteers suffering from osteoarthritis or Rheumatoid arthritis. . . . [G]iven that the study only measures the effects of the “olive extract supplement” on Rheumatoid arthritis and osteoarthritis, even a study finding that the supplement was successful in 100% of cases could not

## 2. Substantial and specific utility

20. According to Professor Holbrook, “Substantial utility asks whether the invention’s utility is *sufficient enough* to justify the grant of a patent.”<sup>30</sup> This is true, but the test does not create a high barrier. Substantial utility, as Professor Holbrook recognizes, is defined in distinction to “a possible object of scientific inquiry” – i.e., something that is useful only for research purposes. This is why substantial utility is often equated with “practical” or “real world” utility. The point is that *any* practical, real-world use is enough to satisfy the test of utility. It need not be important, difficult-to-achieve, outstanding, or the like. It is still, as noted earlier, a low bar to patentability. The only point of substantial utility is that this low bar is a real-world bar. An invention whose only use is to prompt further research does not clear it. But any invention with a credible claim to a use in the real world does clear it.

21. This was the point of *Brenner v. Manson*. The U.S. Supreme Court said:

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. . . .<sup>31</sup>

And “substantial utility” was equated specifically with a use or purpose beyond mere research interest:

This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something “useful,” or that we are blind to the prospect that what now seems without ‘use’ may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It

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enable the full scope of the '599 Patent's claims, as the claims recite [other medical conditions] . . . . As discussed above, even if this data was available at the time the patent was filed, the arthritis study cannot enable any of the '599 Patent's claims, as it does not mention hydroxytyrosol or oleuropein. And, even if the data was available pre-filing, and even assuming that the “olive extract supplement” in the study was a supplement with the claimed ratios of hydroxytyrosol to oleuropein, the arthritis study still cannot enable the full scope of the '599 Patent's claims because it only deals with the treatment of arthritis, without mentioning any of the other claimed ailments.

*CreAgri, Inc. v. Pinnacliffe, Inc.*, 2013 WL 6673676, at \*19 (N.D. Cal. Dec. 18, 2013) (C-438).

<sup>30</sup> Holbrook at ¶ 26 (emphasis in original).

<sup>31</sup> 383 U.S. 519, 534 (1966) (C-195).

is not a reward for the search, but compensation for its successful conclusion.<sup>32</sup>

22. The “conclusion” of the search, once again, comes when an inventor identifies a use beyond further research – in the words of the Court, when “specific benefit exists in currently available form.”<sup>33</sup> Again, the simple point is that “substantial” means simply “beyond purely of research interest.”

### 3. Post-filing evidence

23. Professor Holbrook states: “Contrary to Professor Merges’ suggestions post-filing information has been allowed in the United States only in narrow circumstances.”<sup>34</sup> Nothing in my first Expert Report diverges from settled U.S. law. As that report states, “U.S. law recognizes that evidence introduced after a patent is filed – including for example proof of commercial success – *can* definitively establish the presence of utility.”<sup>35</sup> The statement in my initial report is accurate. In *In re Brana*,<sup>36</sup> for example, the Federal Circuit allowed such evidence in the form of an expert’s declaration concerning tests conducted after the patent’s filing date:

The declaration of Michael Kluge was signed and dated June 19, 1991. This declaration listed test results (i.e. antitumor activity) of the claimed compounds, *in vivo*, against L1210 tumor cells and concluded that these compounds would likely be clinically useful as anti-cancer agents. Enablement, or utility, is determined as of the application filing date. *In re Glass*, 492 F.2d 1228, 1232, 181 USPQ 31, 34 (C.C.P.A. 1974). The Kluge declaration, though dated after applicants’ filing date, can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification. *In re Marzocchi*, 439 F.2d at 224 n. 4, 169 USPQ at 370 n. 4. It 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).<sup>37</sup>

This evidence, introduced “to substantiate any doubts as to the asserted utility,” concerned test results that “pertain[] to the accuracy of a statement already in the

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<sup>32</sup> *Id.* at 535-36 (C-195).

<sup>33</sup> *Id.* at 534-535.

<sup>34</sup> Holbrook at ¶ 34 (citing Merges First Report at ¶ 5).

<sup>35</sup> Merges First Report at ¶ 8 (emphasis added).

<sup>36</sup> 51 F.3d 1560 (Fed. Cir. 1995) (C-168).

<sup>37</sup> *Id.* at 1567 & n.19.

specification.”<sup>38</sup> The fact that the test was conducted post-filing did not eliminate it from consideration.

24. In one of Eli Lilly’s own cases, this basic principle was reiterated:

When priority is not at issue, generally the applicant may provide data obtained either before or after the patent application was filed. With reference to demonstration of utility, in *Brana*, 51 F.3d at 1567 n. 19 the court noted that post-filing evidence “can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification.” Here, the utility of tomoxetine is accurately stated in the specification; there is no allegation of falsity in the disclosed utility, and the patent examiner did not require the presentation of additional data.<sup>39</sup>

Quite a number of additional cases might be cited as well. The point is, post-filing evidence of utility is quite routine in U.S. patent law.<sup>40</sup>

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<sup>38</sup> *Id.* (C-168).

<sup>39</sup> *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App’x 917, 925 (Fed. Cir. 2011) (C-83).

<sup>40</sup> *See also In re Krimmel*, 292 F.2d 948 (C.C.P.A. 1961) (C-439). In *Krimmel*, the Court of Customs and Patent Appeals found the inventor had established utility by virtue of an affidavit filed after the examiner’s final rejection of the inventor’s claims (and thus, obviously, post-filing):

[A]ppellant [inventor] *has established by the Drill affidavit* that one of his claimed compounds is indeed useful for a purpose alleged in his application. In our opinion, he needs do no more to satisfy the requirement of 35 U.S.C. § 101 that the claimed invention be useful.

*Id.* at 953 (emphasis added). The *Marzocchi* case cited in *Brana* is to the same effect. There the court accepted evidence, in the form of 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. The references were relevant to the patent applicant’s evidence of enablement. (Because utility under § 101 is a necessary but not sufficient component of the “how to use” aspect of enablement, the case is relevant here.) The court explained:

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. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, [footnote 4: Not necessarily prior art references, it should be noted, since the question would be regarding the accuracy of a statement in the specification, not whether that statement had been made before.] will be

#### 4. Eli Lilly v. Actavis

25. Professor Holbrook states:

As a legal matter, the Federal Circuit's decision [in *Eli Lilly v. Actavis*] 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.<sup>41</sup>

This is, as we say, a big “if.” The Federal Circuit's decision follows established Federal Circuit law, citing and applying the landmark case of *In re Brana*, with which its opinion is perfectly consistent. The usual presumption regarding an unpublished decision is that it is *less controversial* than a published opinion – that it follows and applies settled law in an unremarkable fashion.<sup>42</sup> The unpublished nature of the *Actavis* opinion actually supports the idea, not that it is an aberration, a questionable outlier, but that it states routine rules of law and applies them in an unsurprising and conventional manner. In the U.S. system, an opinion that applies well-known legal principles in a conventional manner is often unpublished, since the decision is not adding anything to established jurisprudence.

26. In any event, Professor Holbrook's extensive treatment of the District Court's opinion in *Actavis*, together with his subtle attempt to undermine the impact of the Federal Circuit opinion in the case, overlooks an elementary fact. In a final, determinative, and fully binding legal decision, the Federal Circuit held that Lilly's patent was valid. It is not this Federal Circuit opinion that is the anomaly here – it is the Canadian courts.

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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.

*In re Marzocchi*, 439 F.2d 220, 223-24 & n.4 (C.C.P.A. 1971) (R-88).

<sup>41</sup> Holbrook Report at ¶ 38.

<sup>42</sup> See Fed. Cir. R. 32.1(b) (“An opinion or order which is designated as non-precedential is one determined by the panel issuing it as not adding significantly to the body of law.”) (C-482); see also *Symbol Techs., Inc. v. Lemelson Med., Edu. & Research Found.*, 277 F.3d 1361, 1368 (Fed. Cir. 2002) (“[n]onprecedential decisions do not give the judiciary free will to reinvent the law; they merely permit a judgment about whether a case contributes significantly to the body of law”)(C-479); see generally Beth Zeitlin Shaw, “Please Ignore This Case: An Empirical Study of Nonprecedential Opinions in the Federal Circuit,” 12 GEO. MASON L. REV. 1013, 1025 (2004) (77% of Federal Circuit opinions issued during the relevant study period were nonprecedential)(C-480).

27. In addition, contrary to Professor Holbrook's supposition,<sup>43</sup> there is no evidence that the crux of the divergence was a classic factual disagreement. Instead, the difference is strictly doctrinal, and owes its origins to Canada's misshapen version of the traditional utility standard.

28. Under Canadian law, the court scoured Lilly's specification for statements implying performance characteristics or expectations in connection with Lilly's invention. When the court concluded that there were in fact such statements, it looked past the credible scientific evidence of utility in the specification, and applied the aberrant promise utility doctrine to reach a divergent legal conclusion, thus invalidating the claims. Though this approach was characterized as a finding of fact, the "factual" question was whether the study was sufficient to demonstrate utility:

The question is whether Lilly had sufficient evidence in 1996 to establish that atomoxetine would deliver on the promise of the patent. The Judge concluded that Teva had established that the answer to this question was, no. I see no reversible error in his determination of this essentially factual question.<sup>44</sup>

29. Manifestly, the "sufficient evidence" to establish utility was there in the specification, under any recognizable version of the traditional utility standard. Claim 1 of the Canadian Patent at issue, Patent No. 2,209,735, claims "The use of tomoxetine [i.e., atomoxetine] for treating attention-deficit/hyperactivity disorder in a patient in need thereof." The scientific study introduced as evidence of utility unequivocally showed that the claimed invention was operative. The study showed quite literally that atomoxetine "treat[ed]" ADHD; 11 of the 21 patients studied showed a 30% or greater reduction in ADHD symptoms over seven weeks.<sup>45</sup> These results were not questioned in the litigation.

30. But the Canadian court went well beyond the claim when it framed the test for utility. It found, in the description of ADHD as a "chronic" condition, a promise that the claimed compound would address ADHD, and that this either implicitly or explicitly meant treatment over a long time span.<sup>46</sup> When the unquestioned and accurate scientific study was placed alongside this measure of utility, it was found inadequate to demonstrate utility, and was not considered at all

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<sup>43</sup> See Holbrook Report at ¶ 39.

<sup>44</sup> *Eli Lilly & Co. v. Teva Canada Ltd.*, 2011 FCA 220, at ¶ 34 (C-163).

<sup>45</sup> *Id.* at ¶¶ 11-12.

<sup>46</sup> *Id.* at ¶ 21. (asserting that when trial court judge said that treatment of chronic ADHD was "implicit in the promise" made, to treat ADHD, he was simply interpreting what 'treatment' means in this patent in the context of ADHD, a chronic disorder requiring sustained treatment").

regarding sound prediction even though Lilly had the study's results prior to the Canadian filing date.

31. The same factual basis easily cleared the “low bar” set by the U.S. utility standard. So this cannot realistically be classified as factual dispute. It is a dispute over what is the proper standard of utility. Under U.S. law, utility begins with the claim. Once the inventor introduces evidence that the compound is in fact useful to “treat[]” ADHD, the matter is at an end. But under Canadian law, the specification is gone over in detail to find promises regarding performance characteristics or qualities of the invention. Then the evidence is laid alongside these promises. The factual evidence is the same, but the test varies, as does the outcome. In addition, valid scientific evidence of the operative nature of the claimed invention was excluded in Canada under the “sound prediction” element of the promise utility doctrine. This again represents a divergent legal standard. No rule compelling disclosure of evidence of utility exists in the United States.

32. The difference, again, was one of legal standards. The facts were the same.

**B. U.S. law specifically rejects an approach equivalent to the promise utility doctrine**

33. A key feature of the promise utility doctrine is that statements regarding performance characteristics of an invention made in or implied from the patent specification must be supported by evidence convincing to the court, or otherwise the patent is invalid.<sup>47</sup> This exact approach has consistently been rejected by U.S. courts. Contrary to Professor Holbrook's statements, the U.S. equivalent of the promise utility doctrine not only does not exist; it has been explicitly rejected.

34. For example, in *Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. Gesellschaft*,<sup>48</sup> the Federal Circuit reviewed a jury verdict finding that a claimed invention was “not useful.” Extensive testing of a working embodiment of the claimed invention had shown that one advantage of the invention touted in the prosecution history of the patent did not actually materialize during testing. The Federal Circuit reversed the jury finding of lack of utility, stating:

Accepting that the jury must have found that the device did not work as [the patentee] had argued in distinguishing the prior art, this is not an issue of lack of utility . . . . It is not required that a particular characteristic set forth in the prosecution history be achieved in order to satisfy § 101.<sup>49</sup>

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<sup>47</sup> See Cl. Mem. at ¶¶ 59-65.

<sup>48</sup> 945 F.2d 1546, 1553 (Fed. Cir. 1991) (C-290).

<sup>49</sup> *Id.*

35. So too in *Transco Products, Inc. v. Performance Contracting, Inc.*<sup>50</sup> There the patentee claimed the use of simple nylon hooks to fasten insulation to piping in a nuclear containment facility. The district court determined that the claims of the '735 patent were directed to nuclear power plant containment areas only, and found as a matter of fact that simple nylon hooks are not suitable because they cannot withstand gamma radiation levels in such a containment area.<sup>51</sup> The district court then concluded that the '735 patent was invalid under 35 U.S.C. § 101 because it was inoperable, since its disclosed structures were “inoperable.”<sup>52</sup>

36. The district court judge invalidated the patent for lack of utility, on the basis of evidence that the claimed nylon hooks would not work well in a high radiation environment.<sup>53</sup> In effect, the district judge held that the inaccuracy of an implied feature of the invention – that it would work well in a high radiation, high-temperature environment – mandated that the patent be invalidated on utility grounds. The Federal Circuit reversed on this point:

A claimed invention is deemed inoperative under section 101 when it requires the impossible or an unattainable result. Therefore, only when a claimed invention has total incapacity to achieve what is claimed is it deemed inoperable. . . . There is no evidence in the record that simple nylon hooks used in a nuclear containment area are totally incapacitated to achieve the result of holding insulation on piping. [Accused infringer] Transco asserts [patentee’s expert] testified that he discovered that simple nylon hooks were not suitable in nuclear containment areas because they could not withstand the radiation. In his affidavit, however, [patentee’s expert] further explained this conclusion. He stated that simple nylon would break down over time, e.g. about 30 years, due to radiation. Therefore, simple nylon hooks are not totally incapacitated in nuclear containment areas. We find the district court's operability determination is clearly erroneous and

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<sup>50</sup> 121 F.3d 728 (Fed. Cir. 1997)(C-431).

<sup>51</sup> *Transco Products Inc. v. Performance Contracting, Inc.*, 1996 WL 153676, at \*2, ¶ 3, and \*4, ¶ 13 (N.D. Ill. Apr. 1, 1996) (C-481).

<sup>52</sup> According to the court:

67. The product disclosed in the Pinsky patent cannot survive in the containment area of the nuclear power plant unless the fastener(s) are Nomex®) material and stainless steel. Because this crucial structure is not shown or discussed in the patent, the patent is inoperable.

68. The Pinsky patent is, therefore, invalid. 35 U.S.C. § 101.

*Id.* at \*11 (C-481).

<sup>53</sup> *Id.* at \*5, ¶ 30.

reverse and hold that the fasteners as claimed in the '735 patent are not inoperable under 35 U.S.C. § 101.<sup>54</sup>

37. A similar case is *Raytheon Co. v. Roper Corp.*<sup>55</sup> There, the patentee had developed a “three way oven” that could be used for conventional cooking and microwave cooking, and was also self-cleaning. One asserted feature of the design was that it prevented two problems in such ovens, “autoignition” and “backflow.” One feature of the oven as described was that it prevented “backflow” during the self-cleaning phase of operation. But at trial it was proven that the oven did not in fact prevent backflow – that the oven largely eliminated autoignition but not due to the prevention of backflow. This led the district court to hold that the invention was “inoperable.” The Federal Circuit disagreed, reversing the invalidity ruling on all claims that did not explicitly call for prevention of backflow.

The district court held the '520 patent invalid in part because Roper's oven, as set forth in [its] claims interpreted . . . failed to accomplish all objectives stated in the patent. . . . *When a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown. . . .* Here, the Torrey invention as set forth in claims 2-7 clearly accomplished at least one, and a major one, of the patent's stated objectives . . . . The incorrectness of Torrey's theory explaining [why backflow was prevented] . . . does not undermine the unchallenged accomplishment of the quoted objective by the ovens set forth in claims 2-7. . . . [A] patentee is not responsible for the correctness of such theories and explanations when their correctness is not related to validity of the claims under consideration.<sup>56</sup>

38. Another set of cases predating the Federal Circuit supports the same point. Under these cases, U.S. courts consistently held that an inventor need not show operability for all utilities asserted in a specification. A showing that the invention achieves any *one* of the asserted utilities is enough to meet the utility standard. In effect, U.S. courts reject the idea that the inventor promises to achieve all the asserted utilities. So in *In re Malachowski*,<sup>57</sup> the Federal Circuit's predecessor court said:

Appellant discloses the use of his invention for canines “because osteoarthritis and osteoarthrosis is very common among elderly canines.” Appellant also alludes to the treatment of equines in that “[h]orses, particularly race horses, commonly suffer with arthritic

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<sup>54</sup> 121 F.3d 728, at \*6 (citations omitted) (C-431).

<sup>55</sup> 724 F.2d 951, 958-59 (Fed. Cir. 1983) (C-367).

<sup>56</sup> *Id.* (emphasis added).

<sup>57</sup> 530 F.2d 1402, 1403 (C.C.P.A. 1976) (C-432).

ailments of a non-infectious etiology consistent with medication by the anthracite coal residue.” Lastly, appellant, having realized that arthritis in its many forms (including rheumatoid arthritis) is also prevalent in humans, “contemplated” administering the claimed composition to humans at a dosage rate of 100 – 1000 mg. per 100 lbs. of body weight.

[But] even if proof of utility of the claimed invention as an anti-arthritic agent for human beings is lacking, there remains the proven utility as an anti-arthritic agent for lower animals. Having found that the claimed composition has utility as contemplated in the specification, § 101 is satisfied and it becomes unnecessary to decide whether it is in fact useful for the other purposes indicated in the specification as possibilities.<sup>58</sup>

39. So too in another case where three potential utilities were asserted, the U.S. court held:

In the instant case, even if the proof of utility in human beings or animals is not adequate, there remains the alleged utility as a plant fungicide. The allegation of utility as a plant fungicide would not normally appear “to be incredible in the light of the knowledge of the art, or factually misleading”. *In re Citron*, 325 F.2d 248, 51 C.C.P.A. Nevertheless, appellants have submitted evidence tending to prove the utility of filipin as a plant fungicide . . . We consider this evidence sufficient to prove that filipin is useful. . . Having found that the antibiotic is useful for some purpose, it becomes unnecessary to decide whether it is in fact useful for the other purposes “indicated” in the specification as possibly useful.<sup>59</sup>

40. To recap, U.S. courts on several occasions entertained arguments that U.S. law ought to be read to incorporate the equivalent of the promise utility doctrine. Those courts rejected this theory every time. So there is no U.S. analogue to the promise utility doctrine, and never has been.

### **C. The relationship between utility, enablement, and written description**

41. Professor Holbrook makes three primary claims regarding the relationship between utility, enablement, and written description: (1) the three doctrines address a common policy concern, with too-early and overbroad claims;

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<sup>58</sup> *Id.* at 1403-05 (C-432).

<sup>59</sup> *In re Gottlieb*, 328 F.2d 1016, 1019 (C.C.P.A. 1964) (quoting *In re Citron*, 325 F.2d 248 (C.C.P.A. 1963)) (C-258).

(2) what Canada does with the promise utility doctrine, the U.S. does with enablement and written description; and (3) therefore as a whole Canadian law and U.S. law are approximately equivalent. I contest each of these claims.

42. First, Professor Holbrook is correct that in some ways the U.S. requirements for utility, enablement, and written description address common policy concerns. But analyzing the U.S. doctrines at this level of generality is not helpful in this case. For example, enablement doctrine can be thought of as preventing claims that reach too far beyond what the inventor has actually achieved in the lab or workshop. One dimension of this is that, like utility, enablement can be seen to center on questions of timing. Both doctrines can serve to prevent an inventor from staking speculative claims – that is, from claiming subject matter that has not been effectively explored at the time of patent filing. In this regard, both utility and enablement can push an inventor to do more, and therefore teach more, prior to gaining the legal right to a broad claim over an invention. But the *way* the doctrines implement this common policy is quite distinct. Utility requires that the claimed invention be useful for some real-world purpose. Enablement and written description require that the inventor teach sufficient information to justify the full scope of the claims sought. Utility prevents claiming a structure before it has a credible use. Enablement and written description prevent claiming beyond what the inventor has actually achieved to date. The two sets of rules are aimed at curbing different types of speculation. 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.

43. So while the U.S. doctrines regarding utility, enablement, and written description serve somewhat similar goals, they do so very differently. Thus the overlap between them is far from complete, and they are not at all interchangeable. Nor do *any* of these U.S. requirements resemble Canada’s promise utility doctrine.

44. Perhaps the best way to see this difference is to look at the Canadian Zyprexa litigation at issue in this arbitration. In both the United States and Canada, the courts found that the claimed invention was enabled, or that the disclosure was adequate. In Canada, this is referred to as the invention having met the sufficiency requirement. The claimed compound was disclosed; its manufacture was explained; proper dosage to achieve therapeutic effect was described.<sup>60</sup> In both the United States and Canada, the information in the specification was deemed adequate to support the full scope of the claims. The claims were deemed commensurate with what was disclosed. They were not overbroad in light of the disclosure. In this sense,

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<sup>60</sup> To quote the opinion: “The ‘113 patent describes the compound of the invention, its advantages, how to make it, and the range within which it can be dosed.” *Eli Lilly Canada, Ltd. v. Novopharm Ltd.*, 2011 FC 1288, *aff’d* 2012 FCA 232, at ¶ 272 (C-146).

the courts addressed any potential concern with speculative claiming, and found that Lilly had satisfied the relevant legal standard.

45. Because the Zyprexa patent was never successfully challenged in the United States on enablement or written description grounds, we can conclude that it satisfied this legal requirement. From that we can infer that the claims in the U.S. Zyprexa patent were found not to be overly speculative.

46. To recap, the Zyprexa patents were not invalidated on enablement, written description, or sufficient disclosure grounds in either the United States or Canada. And the U.S. patent met the traditional utility requirement employed under U.S. law.

47. This means that virtually the *only* ground successfully used to invalidate the Zyprexa patent was the promise utility doctrine in Canada. This patent was filed in 81 countries. Aside from two aberrant outcomes,<sup>61</sup> the patent remained valid everywhere but Canada. Thus it seems clear that Canada's doctrine does not implement a policy concern that is coextensive with accepted enablement/written description/sufficient disclosure rules; nor does it embody the policy behind the traditional utility doctrine as still employed in the United States. Because its doctrine leads to different results, Canada must be implementing a different policy. What that policy is, and what justification it might have, is not my concern here. I simply argue that the policies behind the promise utility doctrine are not coextensive with those behind the other legal rules Professor Holbrook describes.

48. It follows from this that U.S. law does not simply do under a different rubric what Canadian law does with the promise utility doctrine. If that were so, if enablement and written description were simply the "U.S. version" of the promise utility doctrine, cases would come out the same in both jurisdictions. The reasoning would differ but the outcome would be the same. But that is not happening. The United States has no rules that are the "promise utility doctrine" under a different guise. There is no U.S. counterpart to this doctrine.

49. Professor Holbrook states: "In recent years, the Federal Circuit has tightened the enablement requirement, emphasizing the importance of disclosures in the patent document itself."<sup>62</sup> Professor Holbrook may or may not be correct about this, but assuming he is, it means only that the specification in the relevant Lilly patents was examined under the newer, slightly higher, enablement standard described by Professor Holbrook. But this only supports my point. Under U.S. law,

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<sup>61</sup> Lilly's patents for Zyprexa were upheld everywhere other than Slovenia (where a single claim lacked novelty) and Saudi Arabia (where priority dates were the basis of invalidation, but where a Gulf Cooperation Council patent remained valid and enforceable). See Armitage First Report at ¶ 17.

<sup>62</sup> Holbrook Report at ¶ 51.

the invention not only met the utility requirement, it also met what Professor Holbrook characterizes as a slightly higher enablement standard than had been the norm earlier. Once again, we see that Canada's promise utility doctrine is an anomaly. An invention that cleared the classical utility standard *and* a slightly higher enablement standard in the United States was ruled invalid in Canada. This invention met the traditional utility test, and satisfied an enhanced U.S. enablement standard concerned with adequate disclosure, as well as Canada's sufficiency test. The *only* ground on which the patent was invalidated in North America was Canada's promise utility doctrine. Whatever common policy concerns unite the various doctrines in the United States and Canada, this case itself shows significant divergence between the countries – right at the point of focus for this arbitration. With all the concern over too-early filing and inadequate disclosure embodied in U.S. law, the invention here *met* those concerns. The only basis on which it was invalidated in Canada was the promise utility doctrine. Put another way, the invention here passed all the robust tests built into U.S. law. It foundered only at the elevated threshold of the promise utility doctrine. This must mean that whatever the original policy motivation behind Canada's doctrine, it is operating beyond the scope of other doctrines, and therefore producing results that go beyond the implementation of traditional policies.

#### **IV. NAFTA did not Freeze Patent Law in Signatory Nations, but the Promise Utility Doctrine is so Unprecedented and Radical that it Defies Any Common Understanding of Utility**

50. Professor Holbrook says Eli Lilly's position is that NAFTA "froze" patent law in signatory nations the day the treaty was signed.<sup>63</sup> This is not accurate. Eli Lilly argues that the newly created promise utility doctrine in Canada is a radical departure from the traditional patentability criteria enshrined in NAFTA and amounts to an additional utility requirement that is impermissible under Canada's patent-related obligations under NAFTA.

51. Professor Holbrook's examples of subtle changes in U.S. law since NAFTA was ratified therefore have little force. Each of these changes represents normal variation around the core content of traditional patentability requirements. A slight tightening in the nonobviousness test after the U.S. Supreme Court's decision in *KSR* is a good example. This arguably simply restored U.S. law to its traditional contours, which had been modified by the Federal Circuit.<sup>64</sup> Even assuming this is a permanent change in U.S. law, and not a temporary response to a

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<sup>63</sup> Holbrook Report at ¶ 62.

<sup>64</sup> See, e.g., Taryn Elliott, "Post-*KSR* Obviousness: The Effects of the Patent and Trademark Office's Exemplary Rationales on Patent Litigation," 16 *Geo. Mason L. Rev.* 1011, 1094 (2009) ("*KSR* did not create a fundamental change in the obviousness standard; it merely shifted the focus back to the *Graham* [*v. John Deere Co.*, 383 U.S. 1 (1966)] factors and established a standard that is flexible enough to protect the policies underlying the obviousness inquiry.") (C-433).

recent Supreme Court opinion, it does not represent a radical re-writing of what it means for an invention to be nonobvious. It represents instead the normal variation around a core concept of patentability.

52. Now compare this to the changes wrought by Canada's promise utility doctrine. Eli Lilly's data show that the rate of inutility rulings in pharmaceutical cases in Canada increased from 0% to 40% after the advent of the promise utility doctrine. This represents not normal legal variation, but a seismic change in the fabric of the law. Further evidence of the radical nature of the promise utility doctrine comes in the fate of the Lilly patents at issue in this arbitration. They have survived patent office review and litigation in a large number of countries. Each of these national patent systems applies standard tests of patentability. Though naturally some small degree of national variation is assumed, the consistent outcomes on utility point to a common substantive standard. The outcome of a cross-jurisdictional analysis of the validity of the Zyprexa and Strattera patents yields a generally uniform result – the patents are valid and upheld where challenged, particularly with regard to utility.<sup>65</sup> There is one glaring exception: Canada. Through the mechanism of the promise utility doctrine, Canadian law has evolved what amounts to an additional, and very rigorous, test of patentability that invalidates a large portion of pharmaceutical patents. This is not normal legal variation. It is a striking legal innovation. It renders Canadian law highly divergent from the worldwide norm. The fact that Eli Lilly's patents survived utility analysis in every jurisdiction *except* Canada illustrates the extent to which Canadian law has become an extreme outlier.

## V. Conclusion

53. I make three major points:

- (1) Utility is a low standard; Holbrook is wrong to suggest otherwise.
- (2) Utility does not require "proof" of "efficacy."
- (3) The United States does not do "by other means" what Canada does with the promise utility doctrine.

54. Utility in the United States requires credible assertions of operability. This is a low standard – a fact affirmed by every academic who writes on the topic (including Professor Holbrook himself). Assertions can be credible on the face of the invention, and typically are for a machine or electrical circuit, for example. Or they can be credible on the face of statements in a patent specification; if one skilled in the art would find an asserted utility credible, it is so by presumption. This is not the

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<sup>65</sup> See Armitage First Report at ¶¶ 17-18, 26 (noting that for both patents, Canada was the only jurisdiction in which utility was raised as a validity issue).

same as requiring proof. And the assertion in question need only address basic operability. There is no inquiry under U.S. law regarding the need to scour a patent specification for statements or implications concerning performance characteristics of an invention. Utility has nothing to do with such statements. It is only concerned with basic workability. That is why it is a low standard.

55. Utility is no higher in the case of a chemical or pharmaceutical invention. It is simply more relevant to these inventions; it is more salient. That is because chemical structures are often built before there is any indication that they serve a useful purpose or function. Identification of a credible use is required to establish utility. But the test is the same for all types of inventions.

56. Substantial utility means a non-research utility. Workability means something beyond capable of provoking further research interest. It means a practical, non-research use or purpose. As soon as a single non-research use or purpose is established there is patentable utility.

57. Enablement and written description in U.S. law prevent overbroad claiming based on what has been disclosed in a patent specification. They turn on *inadequate disclosure*, as opposed to express or implied statements about product performance or invention characteristics. They are not the same as the promise utility doctrine in Canada. That doctrine has no counterpart in U.S. law, as demonstrated by cases that explicitly reject an analysis along the lines of the promise utility doctrine. There is no equivalent to this doctrine under U.S. law. The disclosure in these patents was found adequate. The only basis for invalidity was the rogue doctrine of promise utility under Canadian patent law.

\* \* \*

Executed at Seoul, South Korea, on September 10, 2015.

[signed]

ROBERT P. MERGES