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

REPLY EXPERT REPORT OF STEPHEN G. KUNIN

TABLE OF CONTENTS

Page Nos.

I. INTRODUCTION

1. For this Reply Expert Report, I have been asked to provide my reply to the opinions of the Government of Canada's U.S. patent law expert, Timothy R. Holbrook set forth in his January 26, 2015 Expert Report and the January 27, 2015 Government of Canada Counter Memorial which are in disagreement with the opinions contained in my opening Expert Report.

II. PHARMACEUTICAL INVENTIONS FACE THE SAME LOW BAR UTILITY TEST IN THE U.S. AS OTHER INVENTIONS

2. In paragraph 18 of his Expert Report, Professor Holbrook states that in the U.S. utility "remains a significant barrier to patentability in the pharmaceutical context."[1] He contends that while utility may have a "low bar" for "mechanical or electronic inventions," "utility is not a 'low bar to patentability' in the context of pharmaceutical, chemical, and biotechnology inventions."[2]

3. I disagree. The Manual of Patent Examining Procedure ("MPEP") clearly states that the same utility standard applies to all fields of technology: "Inventions asserted to have utility in the treatment of human or animal disorders are subject to the same legal requirements of utility as inventions in any other field of technology."[3]

4. Professor Holbrook when referring to the credible utility requirement suggests that utility has served as a basis for rejecting of claims by the USPTO for lacking a credible

[1] Report of Timothy Holbrook ("Holbrook Report") at ¶ 1

[2] *Id.*.

[3] MPEP § 2107.01(III) (C-72).

utility.[4] However, as stated in MPEP, it is a "rare instance where an assertion of a specific and substantial utility for the invention made by the applicant is not credible."[5]

5. Professor Holbrook also claims that for "chemical entities and uses of pharmaceuticals for treatment of a medical problem, the requirement for a substantial utility can create a significant burden."[6] I disagree. The substantial utility requirement does not impose a more onerous burden for pharmaceuticals. As stated in the MPEP, "pharmacological or therapeutic inventions that provide *any* 'immediate benefit to the public' satisfy 35 U.S.C. 101[, including the] mere *identification* of a pharmacological activity of a compound that is relevant to an asserted pharmacological use."[7]

6. In my experience, rejections of claims by patent examiners on the basis of lack of utility under 35 U.S.C. § 101 are rare for pharmaceutical inventions as well as for all other inventions.[8]

7. Professor Holbrook also overlooks one important difference between the U.S. utility requirement and Canada's promise utility doctrine. As is the case with respect to other inventions, the utility requirement applied to pharmaceutical inventions is focused on the claims and not on unclaimed asserted utilities that may appear in the written description of the patent application. Note that the title of Section 2107.02(I) of MPEP is "The Claimed Invention is the

---

[4] Holbrook Report at ¶¶ 21-23.

[5] MPEP § 2107.01 (C-72). *See* also MPEP § 2107.02(II)(A) ("Situations where an applicant either fails to indicate why an invention is considered useful, or where the applicant inaccurately describes the utility should rarely arise.") (C-72).

[6] Holbrook Report at ¶ 26.

[7] MPEP § 2107.01(III) (emphases in original) (C-72).

[8] To confirm my conclusion that rejections of claims by USPTO examiners based on lack of utility are rare I conducted an exemplary search of final *ex parte* PTAB decisions on the USPTO's website (http://e-foia.uspto.gov/Foia/PTABReadingRoom.jsp) involving lack of utility rejections for a 10 year period (1998-2008) and determined from this data and the USPTO Annual Reports that fewer than 1% of all final *ex parte* PTAB decisions involved lack of utility rejections.

Focus of the Utility Requirement."[9] The MPEP acknowledges that a patent applicant may include incidental statements in the patent's specification, including "additional statements of utility," but that "[s]tatements made by the applicant in the specification...cannot, standing alone, be the basis for a lack of utility rejection."[10] The MPEP directs patent examiners to "not require an applicant to strike nonessential statements relating to utility from a patent disclosure, regardless of the technical accuracy of the statement or assertion it presents."[11] Unlike Canada's promise utility doctrine, once "one credible assertion of specific utility for the claimed invention" is found, USPTO examiners are instructed not to reject patent application claims for lack of utility based on additional assertions of utility made in the patent specification, even if the statement is inaccurate or not credible.[12] The MPEP further provides that "Office personnel should also be especially careful not to read into a claim unclaimed results, limitations or embodiments of an invention [as d]oing so can inappropriately change the relationship of an asserted utility to the claimed invention and raise issues not relevant to examination of that claim."[13] The focus of the utility requirement in the United States is clearly the *claimed* invention, not incidental statements made in the specification.

---

[9] MPEP § 2107.02(I) (C-72).

[10] MPEP § 2107.02(I) (C-72). *See also id.* ("It is common and sensible for an applicant to identify several specific utilities for an invention" but "additional statements of utility, even if not 'credible,' do not render the claimed invention lacking in utility").

[11] *Id.*

[12] *Id.*

[13] *Id.*

III. POST-FILING EVIDENCE IS ALLOWED TO CONFIRM THAT CLAIMED INVENTION HAD UTILITY WHEN FILED

8. In paragraph 34 of his Expert Report, Professor Holbrook states that "[e]vidence of an invention's utility that is created after the filing date generally should not be considered."[14] However, he agrees that the court in *In re Brana* "allowed the [post-filing data] evidence because it demonstrated the utility of the invention *when the application was filed.*"[15]

9. The USPTO, as set forth in the MPEP, instructs its examiners that applicants are permitted to respond to rejections of claims for lack of utility by providing evidence submitted in an affidavit or declaration under 37 C.F.R. § 1.132 as long as it is relevant to the issues raised in the lack of utility rejection and confirms that the claimed invention had utility at the time the patent application was filed.[16] In my experience, applicants were permitted to supplement their patent applications after their filing dates with additional confirmatory evidence of utility through an affidavit or declaration if the patent examiner questioned the claimed invention's utility in an office action rejecting claims for lack of utility.[17]

IV. THE EVIDENTIARY BURDEN IN THE USPTO FOR SATISFYING THE UTILITY REQUIREMENT IS LOW

10. In its Counter Memorial, Canada states that in the United States, patent applications in the context of pharmaceutical, chemical, and biological inventions are often supported by test results.[18] I interpret Canada's assertion to mean that the specifications of U.S. patent applications often contain human clinical test results.

---

[14] Holbrook Report at ¶ 34.

[15] *Id.* (emphasis in original).

[16] MPEP § 2107.02 (VI) (C-72).

[17] *See id.*

[18] Government of Canada Counter Memorial at ¶ 171.

11. I disagree. In my experience, most U.S. patent applications in the pharmaceutical chemistry arts do not contain human clinical trials evidence. I have seen many U.S. patent applications in this field that contained prophetic examples and examples based on *in vitro* or *in vivo* testing on animal models and the correlation of those results with how the results would be applicable to treatment of humans. While I have seen some instances of human test results or clinical trials in U.S. patent application specifications, I would consider such cases as the exception rather than the norm because many patent applications on pharmaceutical inventions are filed before the results of any human clinical trials have been obtained.

12. Section 2107.03(I) of the MPEP only requires a "reasonable correlation" between pharmacological or biological activity of a compound and the asserted utility: "The applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty, nor does he or she have to provide actual evidence of success in treating humans where such a utility is asserted."[19] In any event, it is important to emphasize, as stated in my First Report, human clinical trials are not required under the MPEP and the mere ***initiation*** of human trials creates a presumption of utility.[20]

[19] MPEP § 2107.03(I) (C-72).

[20] *See* Kunin First Report at ¶ 39; MPEP § 2107.03(IV) ("Office personnel should not impose on applicants the unnecessary burden of providing evidence from human clinical trials. There is no decisional law that requires an applicant to provide data from human clinical trials to establish utility for an invention related to treatment of human disorders.... Thus, as a general rule, if an applicant has initiated human clinical trials for a therapeutic product or process, Office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility.") (emphasis in original) (C-72).

V. THE U.S. LAW ON UTILITY HAS NOT CHANGED

13. In paragraph 65 of his Expert Report, Professor Holbrook suggested that my reference to the 2001 Guidelines as "a more stringent test" was evidence that the law of utility changed in the United States.[21] I disagree.

14. In my article identified in footnote 132 of the Holbrook Report, I used the term "stringent" in the dictionary sense of being more "precise." The new guidelines were issued to give USPTO examiners a structured way to review the evidence of a claim's utility, and were more specific and granular in their treatment of the application of the law of utility in the examination of patent applications. The law on the utility requirement itself, however, did not change. The law of utility in the U.S. remains fundamentally the same as it was enunciated in the Supreme Court's decision in *Brenner v. Manson*, 383 U.S. 519 (1966).

15. Examination guidelines provide a restatement of the applicable law as understood and interpreted by the USPTO. The guidelines provide the framework for how examiners are to conduct patent examination. The framework is an ordered structure or methodology for how the examiners are to systematically analyze the facts of their cases consistent with the requirements of law endeavoring to ensure uniform and consistent patent examination. The guidelines operate like a decision tree by providing a precise (i.e., stringent) sequence of steps that are to be followed by USPTO examiners to ensure proper application of the applicable law in the examination of the claims of patent applications.

[21] Holbrook Report at ¶ 65

16. As I stated in my First Report, the 2001 Utility Guidelines were published to provide guidance to USPTO patent examiners on the application of existing patent law, such as the Supreme Court's decision in *Brenner v. Manson*, to technologies such as uncharacterized gene fragments in the field of biotechnology.[22] Thus, through the 2001 Utility Guidelines, USPTO provided more detailed instructions to patent examiners on the proper application of the existing utility standard to a new technology. The new guidance did not change the underlying legal standard as confirmed by the Federal Circuit in *In re Fisher*.[23] The evidentiary standards also remained the same in the new guidelines for treatment of applicant's rebuttal evidence submitted in response to an examiner's lack of utility rejection.

17. As stated in my First Report, the substance of the utility requirement has not changed in the U.S. since NAFTA.[24] Having reviewed Professor Holbrook's Expert Report, I am still of the view that the utility requirement has been consistent in the U.S. since NAFTA was enacted.

VI. CONCLUSION

18. After consideration of Professor Holbrook's Expert Report and the Government of Canada's Counter Memorial, my opinions that I expressed in my First Report remain the same. Pharmaceutical inventions face the same low bar utility tests as inventions in other fields of technology when applicants are seeking patents from the USPTO. Post-filing evidence is allowed in USPTO patent examination to confirm that the claimed invention had utility at the time the patent application was filed. The evidentiary burden in the U.S. for satisfying the utility

[22] Kunin First Report at ¶¶ 41-47.

[23] 421 F.3d 1365, 1371 (Fed. Cir. 2005) (C-84).

[24] Kunin First Report at ¶¶ 48-50.

requirement during patent examination, including for pharmaceutical inventions, is low. Although the USPTO has updated its Utility Guidelines since 1995, the U.S. law on utility has not changed since NAFTA became effective.

Date: September 9, 2015

[signed]

STEPHEN G. KUNIN