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

EXPERT REPORT OF STEPHEN G. KUNIN

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I. INTRODUCTION

1. My name is Stephen G. Kunin. I am employed by the law firm, Oblon, Spivak, McClelland, Maier & Neustadt, L.L.P. ("Oblon"), 1940 Duke Street, Alexandria, VA 22314, and reside in the county of Fairfax, Virginia. I have been asked to testify as an expert witness on behalf of Eli Lilly & Co. ("Lilly"). I confirm that I have no relationship to Eli Lilly and Company or any of its affiliates.

2. I have been asked to provide expert analysis and testimony with respect to United States patent practice and considerations related to the utility requirement both generally and as it relates specifically to the prosecution of Lilly's U.S. Patent Nos. 5,2229,382 covering its product Zyprexa and 5,658,590 covering its product Strattera (the "Zyprexa patent" and the "Strattera patent", respectively). My *curriculum vitae*, including the list of publications that I have authored, is attached hereto as Appendix A. I have testified seven times at trial and once in an arbitration as an expert witness.

II. QUALIFICATIONS

3. I completed my undergraduate studies at Washington University in 1970 with a B.S. degree in Electrical Engineering. I attended the National Law Center of the George Washington University, receiving my Juris Doctor in law with honors in May of 1975. I am a member of the Virginia State Bar and the Bars of the Court of Appeals for the Federal Circuit and Supreme Court of the United States. I am registered to practice as a patent attorney before the USPTO.

4. From 1994 through October 2004, I served as the Deputy Commissioner for Patent Examination Policy in the Office of the Commissioner for Patents in the USPTO. In my ten years as Deputy Commissioner for Patent Examination Policy, I participated in the establishment of patent policy for the various Patent Organizations under the Commissioner for

Patents, including changes in patent practice and patent examiner guidelines as set forth in the Manual of Patent Examining Procedure ("MPEP"), revision of rules of practice and procedures – including, *inter alia*, those rules and practices related to the parts, form, and content of a patent application[1], examination of applications at the USPTO[2], patentability[3], and establishment of examining priorities and classification of technological arts. I also oversaw the operations of the Office of Patent Legal Administration, Patent Cooperation Treaty Legal Administration, and the Office of Petitions.

5. Before my appointment to the position of Deputy Commissioner for Patent Examination Policy, I served as the Deputy Assistant Commissioner for Patents from 1991 to 1994. From 1989 to 1991, I served in that position on an acting basis. In that role, from 1989 to 1994, I had responsibility for supervision of the Patent Examining Group Directors and for managing the Patent Examining Corps (Examining Division). I also had oversight responsibility for the Search and Information Resources Administration that included the Office of Patent Classification and the Office of Patent Program Control that included the Patent Academy. For the majority of 1993, I also was appointed the Acting Assistant Commissioner for Patents.

6. From 1983 to 1989, I managed patent examining groups. On an acting basis in 1982 until being named Group Director in 1983, I directed the Manufacturing Technologies Examining Group 320. In 1984, I formed the Telecommunications, Measuring and Testing Examining Group 260 and became its first Group Director.

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[1] United States Patent and Trademark Office, Manual of Patent Examining Procedure Chapter 600 (March 2014) [hereinafter "2014 MPEP"] (C-70).

[2] 2014 MPEP Chapter 700 (C-71).

[3] 2014 MPEP Chapter 2100 (including section 2107 covering the utility requirement) (C-72).

7. I also served for nine years as an Examiner in the USPTO (1970-1979) and for an additional three years as a Supervisory Primary Examiner ("SPE") (1979-1982). In the latter capacity, I ran the Patent Academy and trained and instructed assistant examiners in the examination of patent applications and served as an Instructor at the Patent Academy of the USPTO. As a patent examiner and/or SPE, I performed or supervised the work required to be performed by the examiner to (1) examine originally filed patent applications, and (2) examine continuing applications, including continuations, continuations-in-part, and divisions.

8. I have considerable direct experience in reviewing the work of patent examiners to determine whether they followed existing patent policies, practices, and procedures and performed examinations of the required quality. This experience came as a result of my serving as Deputy Commissioner for Patent Examination Policy, a Patent Examining Group Director, and a Supervisory Primary Examiner. As a Group Director and a Supervisory Primary Examiner, I was often called upon to review the work of examiners to determine whether those examiners were sufficiently competent to be granted signatory authority. Such reviews included a review of the entire prosecution history of an allowed or pending application to determine whether the invention was understood by the examiner, whether relevant references were properly applied, whether patent policies, practices, and procedures were properly followed and whether the allowed claims were patentable over the art of record. Also, while serving as Deputy Commissioner for Patent Examination Policy, I decided appeals on quality reviewed applications where there was a disagreement between the Office of Patent Quality Review and a Patent Examining Group as to whether prosecution on the merits of a reviewed application should be reopened. I also reviewed and approved requests for reconsideration by a Patent Examining Group Director of an adverse panel decision from the Board of Patent Appeals and

Interferences, and determined whether a Director Ordered Reexamination of an issued patent should be instituted.

9. I have considerable experience in reviewing patent prosecution histories, including specifications and interpreting claim language, as a result of the positions I held at the USPTO for more than 34 years and as a patent attorney in private practice.

III. INSTRUCTIONS

10. I have been asked to testify on the following topics: (a) USPTO practices and procedures for patent examination; (b) an explanation of the USPTO's utility guidelines and how they were developed from 1992 to 2014; and (c) an explanation of the prosecution histories and proceedings before the USPTO for the Strattera and Zyprexa patents.

IV. THE EXAMINATION OF PATENT APPLICATIONS IN THE USPTO

11. In the United States, the USPTO is the duly authorized federal bureau within the U.S. Department of Commerce for administering the laws relating to the granting of patents. The examination of the application consists of a study of the application for compliance with the legal requirements of the patent laws and rules of practice and a search through U.S. and foreign patents, publications of U.S. patent applications, foreign patent documents, and available technical literature, to see if the claimed invention is new, useful, and non-obvious and if the application meets the other requirements of the patent statute and rules of practice. If the examiner's decision on patentability is favorable, a patent is granted.

12. The USPTO has established rules of practice for practitioners to follow in preparing and prosecuting applications. These rules have been codified in the form of Section 1 of Title 37 of the Code of Federal Regulations. Further, as a guide to examiners, patent attorneys and patent agents, the USPTO publishes the MPEP, a compendium of USPTO published polices, practices, and procedures, which comprehensively sets forth the proper course

of action for the various situations which may arise during examination of patent applications in the USPTO.

13. Based on my over 34 years of experience in the USPTO, I have found that patent examiners not only possess technical knowledge in the relevant field of art, but also are trained in USPTO policy, practice, procedure, and patent law. All new and junior examiners are required to participate in a rigorous USPTO training program called the "Patent Training Academy" to learn USPTO policy, practice, procedure, and patent law. In addition, the work of all new and junior examiners must be reviewed by a supervisor.

14. To obtain a valid patent, an inventor must first submit a patent application to the USPTO that contains a description of the inventions that represent the inventor's innovation. It describes what the invention is, what it does, and how to make it.[4] The purpose of this description (or disclosure) requirement is to ensure that the public receives something in return for the exclusionary rights granted to the inventor by the patent.[5] Each patent application must include one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.[6]

15. The USPTO assigns each patent application to one or more examiners with technical knowledge in the relevant field. The examiner then scrutinizes the application to determine whether it meets the statutory requirements for patentability.[7]

16. The Applicants are notified in writing of the Examiner's decision by an "Office Action," which is normally mailed to the attorney or agent of record. The reasons for any

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[4] 2014 MPEP § 608 (C-70).

[5] *Id.*

[6] 35 U.S.C. § 112 (C-73).

[7] 35 U.S.C. §§ 101-103 and 112 (C-73).

adverse action or any objection or requirement are stated in the Office Action and such information or references are given as may be useful in aiding the Applicants to judge the propriety of continuing the prosecution of the application.[8]

17. The Applicants must request reconsideration in writing, and must distinctly and specifically point out the supposed errors in the Examiner's Office Action. The Applicants must reply to every ground of objection and rejection in the prior Office Action. After reply by the Applicants, the application will be reconsidered, and the Applicants will be notified as to the status of the claims, *i.e.*, whether the claims are rejected, or objected to, or whether the claims are allowed, in the same manner as after the first examination. The second Office Action usually will be made final. Amendments may not introduce new matter into the specification or claims.[9]

18. If the Applicant's claims have been twice rejected by the Examiner, the Applicant may appeal from the decision of the Examiner to the Patent Trial and Appeal Board at the USPTO.[10]

19. Once the patent examiner has determined that all statutory patentability requirements and all applicable formalities have been satisfied, he will issue a Notice of Allowability accompanied by a Notice of Allowance and Fee(s) Due. Subsequent to payment of the issue fee the USPTO will proceed to issue the patent.[11] The grant copy of the patent specifies its patent term and the rights conveyed by the patent to exclude others from practicing the subject matter covered by the patent claims.[12] Patents issued by the USPTO are presumed

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[8] 2014 MPEP § 707 (C-71).

[9] *Id.* § 2163.06 (C-72).

[10] 35 U.S.C. § 134 (C-73).

[11] 2014 MPEP §§ 1302-1303, 1306 and 1309 (C-74).

[12] 35 U.S.C. § 154(a)(1) and (2) (C-73).

valid, and the patent is enforceable on the date of its issuance.[13] The burden of establishing the invalidity of a patent or any claim of a patent by clear and convincing evidence is on the party asserting such invalidity.[14]

V. UTILITY GUIDELINES

A. Introduction

20. The USPTO provides guidance to examiners on how to examine patent applications for compliance with the utility requirement through the issuance of patent examination guidelines, which are memorialized in the MPEP. While the Manual does not have the force of law it accurately reflects the USPTO's interpretation of the then current patent law.[15] The Manual is published to provide patent examiners, applicants and their legal representatives with a reference work on patent examination and prosecution practices and procedures. It contains instructions to patent examiners and patent practitioners which are required or authorized to be followed.[16]

21. The USPTO issues new editions or revisions of the MPEP from time to time to reflect practice and procedure changes necessitated by changes in the patent laws by statute, or decisions of the Supreme Court or Court of Appeals for the Federal Circuit, or changes to the rules governing proceedings in the USPTO. The MPEP is also amended where additional clarification for examiners is necessary, such as to explain how to apply the patentability

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[13] 35 U.S.C. § 282(a) (C-73).

[14] *Id.*

[15] The MPEP cites to cases and statutes as a basis for its guidance. I have not provided the specific legal citations when I refer to sections of the MPEP, but full copies of those MPEP chapters with the relevant statutory and decisional law are included as Exhibits C-70 – C-72, C-74 – C-76, C-78, and C-82.

[16] Forward to the 2014 MPEP (March 2014) (C-87).

requirements to new technologies. Finally, the MPEP may be modified for content reorganization and other administrative reasons.

B. The 1992 Utility Guidelines

22. The section dedicated to utility in the Fifth edition of the MPEP, dated November 1992, reflected the criteria for assessing utility under the then current U.S. patent law. It says:

> A rejection on the ground of lack of utility includes the more specific grounds of inoperativeness, involving perpetual motion, frivolous, fraudulent, against public policy. The statutory basis for this rejection is 35 U.S.C. 101. See MPEP § 608.01(p).[17]

23. Further guidance for utility was found in the Disclosure section 608.01(p) of Chapter 600 of the MPEP covering Parts, Form and Content of Applications. This section set forth "Guidelines for Considering Disclosures of Utility in Drug Cases," which were intended to "provide uniform handling of applications disclosing drug or pharmaceutical utility."[18] Two basic principles were established for disclosing utility in drug cases:

> (1) The same basic principles of patent law which apply in the field of chemical arts shall be applicable to drugs, and
>
> (2) The Patent and Trademark Office shall confine its examination of disclosure of utility to the application of patent law principles, recognizing that other agencies of the Government have been assigned the responsibility of assuring conformance to the standards established by statute for the advertisement, use, sale or distribution of drugs.

24. The guidelines state that any proof of a stated utility "may be incorporated in the application as filed, or may be subsequently submitted by affidavit if and when required."[19] .

25. The MPEP explained how to evaluate utility under Section 101 as follows:

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[17] United States Patent and Trademark Office, Manual of Patent Examining Procedure § 706.03(p) (Nov. 1992) [hereinafter "1992 MPEP"] (C-75).

[18] 1992 MPEP § 608.01(p) (C-76).

[19] *Id.*

> Utility must be definite and in currently available form; not merely for further investigation or research but commercial availability is not necessary. Mere assertions such as "therapeutic agents," "for pharmaceutical purpose," "biological activity," "intermediate," and for making further unspecified preparations are regarded as insufficient.
>
> If the asserted utility of a compound is believable on its face to persons skilled in the art in the view of the contemporary knowledge in the art, then the burden is upon the examiner to give adequate support for rejections for lack of utility under this section. On the other hand, incredible statements or statements deemed unlikely to be correct by one skilled in the art in view of the contemporary knowledge in the art will require adequate proof on the part of applicants for patents.[20]

26. Thus a "utility" requires a "real world" use. Utilities that require further research to identify or reasonably confirm a practical beneficial use are not practical utilities in "currently available form." The purpose of requiring practical utility is to limit patent protection to inventions that possess some real world value, as opposed to subject matter that represents simply a starting point for future research. The use must be definite and currently available, i.e., not unknown or indefinite. This does not mean, however, than an invention must be reduced to practice or "currently available" to the public to meet the utility requirement.

27. The MPEP explained that proof of utility "may be established by clinical, *in vitro* or *in vivo* data, or a combination of these that would be convincing to those skilled in the art."[21] Animal tests may be adequate to prove utility in humans where appropriately correlated. Utility may be established by showing that structurally similar compounds exhibit the same predictable pharmacological activity. Additionally, "compositions whose properties are generally

[20] *Id.* (internal citations omitted).

[21] *Id.*

predictable from a knowledge of their components, such as laxatives, antacids and certain topical preparations, require little or no clinical proof."[22]

C. The 1995 Utility Guidelines

28. In September 1995, the MPEP was revised to include new utility guidelines that provided examiners with more up-to-date guidance in the emerging field of biotechnology as well as human therapy.[23] Because utility has always been a straightforward requirement, the previous instructions to examiners on how to apply the utility criteria in the MPEP were minimal. But in 1995 there was a concerted effort to update the utility guidelines to reflect current practice and provide additional guidance to examiners. Revisions were specifically made to explain how to apply the utility standard to therapeutic or pharmacological uses because, as the MPEP noted, "[t]he Federal courts have consistently reversed rejections by the Office asserting a lack of utility for inventions claiming a pharmacological or therapeutic utility where an applicant has provided evidence that reasonably supports such a utility."[24] Accordingly, the MPEP provided additional guidance and instructed examiners to "be particularly careful in their review of evidence provided in support of an asserted therapeutic of pharmacological utility."[25] The changes in the 1995 MPEP also served to consolidate legal guidance on the utility requirement from different parts of the MPEP into Chapter 2100.

29. The North American Free Trade Agreement did not require the U.S. Government to implement any changes affecting the utility requirement in the United States.

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[22] *Id.*

[23] The 1995 Utility Guidelines were initially published in the Federal Register on July 14, 1995 (C-77), and then incorporated into the Sixth edition, Revision 1 of the MPEP in September 1995 (C-78).

[24] United States Patent and Trademark Office, Manual of Patent Examining Procedure § 2107.02 (Sept. 1, 1995) [hereinafter "1995 MPEP"] (C-78).

[25] *Id.*

30. The 1995 MPEP instructs examiners to evaluate each application to ensure compliance with the utility requirement of 35 U.S.C. § 101. The MPEP explains that deficiencies under the utility requirement can arise in one of two forms:

> The first is where it is not apparent why the applicant believes the invention to be "useful." This can occur when an applicant fails to identify any specific utility for the invention or fails to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. The second type of deficiency arises in the rare instance where an assertion of specific utility for the invention made by an applicant is not credible."[26]

Accordingly, examiners must determine whether a claimed invention has a specific utility and whether that utility is credible.

31. Examiners are instructed to ask whether there is an asserted or well-established specific utility for the claimed invention. Where an invention has a well-established utility, an applicant need not provide a specific statement on why the invention is useful.[27]

32. The MPEP provides that specific (or practical) utility must have a "real world value."[28] Specific utility is illustrated as follows:

> Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it *is* considered useful. For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a

[26] 1995 MPEP § 2107.01 (C-78).

[27] *Id.* § 2107.1(b)(ii). A well-established utility is "one that would be immediately apparent to a person of ordinary skill based upon disclosed features or characteristics of the invention, or statements made by the applicant in the written description of the invention." *Id.*

[28] 1995 MPEP § 2107(a) (C-78)

disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. [29]

33. The MPEP further clarified that even where case law requires inventions to provide "an immediate benefit to the public," this does not mean that the claimed invention must be "currently available" to the public. "Rather, any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a 'specific' utility."[30]

34. With respect to credible utility, the MPEP explained that a claimed invention that is wholly inoperative or incapable of achieving a useful result lacks utility.[31] The MPEP notes that instances in which an invention is found to be 'inoperative' and therefore lacking in utility are rare. Where an invention was found to lack a credible utility, it was clear on the factual record "that the invention could not and did not work as the inventor claimed it did."[32] Examples of such cases include a perpetual motion machine (*Newman v. Quigg*, 877 F.3d 1575, 11 USPQ2d 1340 (Fed. Cir. 1989) and a method of controlling the aging process (*In re Elthgroth*, 419 F.3d 918, 164 USPQ 221 (1970)).[33]

35. The 1995 MPEP confirmed that even if an applicant identifies several utilities for an invention, "an applicant need only make one credible assertion of specific utility for the claimed invention" and "additional statements of utility, even if not 'credible,' do not render the

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

[30] *Id.* § 2107.1(a).

[31] 1995 MPEP § 2107.1(b) (C-78)

[32] *Id.*

[33] *Id.* (citing *Newman v. Quigg*, 877 F.3d 1575, 11 USPQ2d 1340 (Fed. Cir. 1989) (C-79) and *In re Elthgroth*, 419 F.3d 918, 164 USPQ 221 (1970) (C-80)).

claimed invention lacking in utility."[34] Moreover, statements made in the description of the invention or incident to the prosecution of the patent cannot on their own be the basis for a lack of utility.[35] "Office personnel should also be especially careful not to read into a claim unclaimed results, limitations, or embodiments of an invention."[36]

36. In evaluating evidence of utility, the 1995 MPEP states: "[T]here is no predetermined amount or character of evidence that must be provided by an applicant to support an asserted utility, therapeutic or otherwise."[37] Evidence of utility will be sufficient "if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true."[38]

37. The 1995 Guidelines also explained that "inventions asserted to have utility in the treatment of human or animal disorders are subject to the same legal requirements as inventions in any other field of technology."[39] "As such, pharmacological or therapeutic inventions that provide *any* 'immediate benefit to the public' satisfy 35 U.S.C. § 101."[40] The MPEP further recognized the "mere *identification* of a pharmacological activity of a compound that is relevant to an asserted pharmacological use" may satisfy the utility requirement.[41] Where an applicant has claimed a process for treating a human or animal disorder "thus asserted utility is usually clear – the invention is asserted to be useful in treating the particular disorder."[42] "If

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[34] 1995 MPEP § 2107.01(a) (C-78).

[35] *Id.*

[36] *Id.*

[37] 1995 MPEP § 2107(f) (C-78).

[38] *Id.*

[39] 1995 MPEP § 2107(c) (C-78).

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

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

[42] *Id.*

the asserted utility is *credible*, there is no basis to challenge such a claim on the basis that it lack utility under 35 U.S.C. 101."[43]

38. Acknowledging that the U.S. courts had consistently reversed rejections by the USPTO asserting a lack of utility for pharmaceutical inventions, Section 2107.02 provides additional guidance to examiners on utility for pharmaceuticals. The MPEP explained: "As a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a *reasonable* correlation between the activity in question and the asserted utility."[44] Sufficient showings for utility may include structural similarity to compounds with established utility, or data from *in vivo* or animal testing to support therapeutic utility where there is a reasonable correlation between the animal model testing and human therapy.[45]

39. The MPEP instructs examiners not to "impose on applicants the unnecessary burden of providing evidence from human clinical trials."[46] Moreover, the fact that an applicant has even initiated human clinical trials creates a presumption that the claimed invention is useful. The MPEP explains:

> Before a drug can *enter* human clinical trials, the sponsor, of then the applicant, must provide a convincing rationale to those especially skilled in the art (e.g., the Food and Drug Administration (FDA)) that the investigation may be successful [i.e. that the drugs could be effective])…. 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.[47]

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

[44] 1995 MPEP § 2107.02(a) (C-78).

[45] *Id.* § 2107.02(b)-(c).

[46] *Id.* § 2107.02(d) (1995).

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

40. It is highly common for patent applicants to file a patent application before conducting clinical trials or any testing on human beings. Usually animal testing will suffice to establish utility in humans if it can be shown that the animal model testing correlated well for a particular disease.

D. The 2001 Utility Guidelines

41. The Eighth edition of the MPEP incorporated the 2001 Utility Guidelines.[48] The 2001 Utility Guidelines were published to provide examiners with updated guidance on the application of the utility standards, especially as applied to examination of claims directed to uncharacterized gene fragments in the field of biotechnology. I was personally involved in drafting these guidelines. At that time, the USPTO had seen a large increase in claims related to uncharacterized gene fragments, and the Office determined that patent examiners needed additional guidance because many questions were being asked on this topic by the public and various parts of the federal government such as the National Institutes of Health.

42. The 2001 Utility Guidelines in the MPEP instructed examiners to review claims to determine whether a claimed invention had "any specific and substantial utility that is credible."[49] Examiners were instructed not to reject applications based on a lack of utility "if the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a 'specific and substantial utility') and the assertion would be considered credible by a person of ordinary skill in the art."[50] The MPEP further explained:

> (i) A claimed invention must have a specific and substantial utility. This requirement excludes "throw-away," "insubstantial," or "nonspecific" utilities,

[48] The 2001 Utility Guidelines were published in the Federal Register on January 5, 2001 (C-81), and then incorporated into the Eighth edition of the MPEP in August 2001 (C-82).

[49] United States Patent and Trademark Office, Manual of Patent Examining Procedure § 2107(II)(B)(2001) (Aug. 2001) [hereinafter "2001 MPEP"] (C-82).

[50] *Id.*

> such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. § 101.[51]

43. The 2001 MPEP provided further clarification of the meaning of "specific utility," similar to that contained within the 1995 MPEP. It also explained that a "specific utility" is "*specific* to the subject matter claimed," which "contrasts with general utility that would be applicable to the broad class of the invention."[52]

44. The 2001 MPEP also provided guidance on the term "substantial utility":

> A substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonable confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use.[53]

The MPEP listed the following examples of situations that would require further research to define a "real world use" and therefore lack "substantial utility": (1) basic research such as studying the properties of the claimed product itself; (2) a method of treating an unspecified disease; (3) a method of assaying a material that itself has no specific or substantial utility; (4) a method of making a material that itself has no utility; and (5) a claim to an intermediate product for use in making a product that has no utility.[54]

45. The MPEP guidance on "credible utility" remained essentially the same as that set forth in the 1995 Guidelines.[55]

46. The evidentiary standards also remained the same. As in the prior versions of the MPEP, the guidance provided to examiners as to consideration of evidence to overcome a lack of

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[51] *Id.* § 2107(II).

[52] 2001 MPEP § 2107.01(I) (emphasis in original) (C-82).

[53] *Id.*

[54] *Id.*

[55] See *id.* § 2107.01(II) (C-82).

utility rejection makes no distinction between pre-filing/pre-priority date evidence of utility and post-filing/post-priority date evidence of utility. Thus post-filing or post-priority date submitted evidence may be submitted to rebut the examiner's *prima facie* showing of lack of utility.[56] The only requirement in the MPEP for new evidence is that it "must be relevant to the issues raised in the rejection."[57]

47. Although the 2001 MPEP revised the terms used to articulate the utility standard under 35 U.S.C. § 101, the new guidance did not change the underlying legal standard as confirmed by the Federal Circuit in *In re Fisher*.[58] A specific or practical utility was the equivalent to the "specific and substantial" utility requirement in the 1995 Guidelines. That is to say, although the language in the 2001 Guidelines was clarified, the utility standard still required that the asserted or well-established credible utility had to be specific or well-defined and have a practical utility that provided a particular real world benefit.

E. Concluding Observations

48. I have reviewed the changes to the utility guidelines set forth in Sections 2107 through 2107.03 of Chapter 2100 of the revisions of the Eighth edition of the MPEP in effect subsequent to August 2001, as well as the Ninth edition of the MPEP published in March of 2014. Based on my review, I have determined that there has been no change in the utility standard or how the utility standard was applied by U.S. patent examiners. In fact the utility guidelines were revised to include the *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005), decision.[59] The *Fisher* decision confirmed that the 2001 Guidelines were consistent with the

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[56] *Eli Lilly v. Actavis Elizabeth, LLC*, No. 2010-1500 (Fed. Cir. 2011) (C-83)

[57] 2001 MPEP § 2107.02(VI) (C-82).

[58] 421 F.3d 1365, 1371 (Fed. Cir. 2005) (C-84).

[59] *Id.*

court's application of the specific, substantial, and credible criteria for determining whether an asserted or well established utility was satisfied for a claimed invention.

49. As to the 2014 Guidelines in effect since March 2014, there have also been no subsequent changes with respect to the utility guidelines issued by the USPTO. The 2014 Guidelines were indicated as being modified in light of the America Invents Act (AIA) law. However, since the AIA made no changes to Section 101 or to the substance of Section 112(a), the utility requirement and applicable substantive aspects of the guidelines remained unchanged.

50. Although the language of the utility guidelines has changed between 1992 and the present time, there has been no substantive or practical change in the standards for judging whether a claimed invention has utility within the meaning of 35 U.S.C. § 101. The utility guidelines always required that the asserted or well established utility be credible. Although early versions of the guidelines referred to a "definite" or "practical" utility rather than "specific" utility, and used "real world value" instead of "substantive" utility, they all referred to the same underlying test for utility. This is evident by the fact that all versions referred to the Supreme Court's *Brenner v. Manson* decision[60] as providing the basis for the utility standard applied in U.S. law.

51. There is a very low threshold for establishing utility. When challenging an assertion of utility the USPTO has the burden to of proving evidence showing that one of ordinary skill in the art would reasonable doubt the asserted as being specific, substantial and credible. As a result of the application of the USPTO utility guidelines, rejections based on lack of utility in the United States are rare.

[60] 383 U.S. 519 (1966) (C-195)

VI. RELEVANT PROSECUTION HISTORIES OF ELI LILLY'S ZYPREXA AND STRATTERA PATENTS IN THE UNITED STATES

A. Lilly's U.S. Patent No. 5,229,382 – The Zyprexa Patent

52. I have reviewed the file wrapper for Zyprexa, U.S. Patent No. 5,229,382 ("the Zyprexa patent").[61] I understand that U.S. Patent No. 5,229,382 is equivalent to the Canadian Patent 2,041,113. The Zyprexa patent was filed on May 22, 1992. The relevant guidelines that the patent examiner would have used were the 1992 Guidelines (see above). During examination of the Zyprexa patent, no questions were raised as to the utility of the claimed invention under 35 U.S.C. § 101. The patent examiner did not provide evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility to shift the burden to applicants to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.

53. As to the other issues raised in the file wrapper, all of the rejections made during examination of the patent, including the rejection based on obviousness, were routine. More specifically, it is not uncommon for examiners to issue *prima facie* rejections for compounds that are selections from a prior art compound on the ground of obviousness, which the applicant may overcome by submitting declaration evidence, as occurred in this case. I did not see anything unusual in the prosecution of the patent application that issued as the '382 patent covering Zyprexa.

B. Lilly's U.S. Patent No. 5,658,590– The Strattera Patent

54. I have reviewed the file wrapper for Strattera, U.S. Patent Application No. 08/371,341 ("the Strattera patent").[62] The patent application, entitled "Treatment of Attention Deficit/Hyperactivity Disorder," was filed on January 11, 1995. The relevant guidelines that the

[61] File history for U.S. Patent No. 5,229,382 (Zyprexa) (C-85).

[62] File history for U.S. Patent No. 5,658,590 (Strattera) (C-86).

patent examiner used were the 1995 Guidelines (see above). During examination of the Strattera patent, no questions were raised with respect to the utility of the claimed invention. The patent examiner did not provide evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility to shift the burden to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility. The patent examiner did not require the submission of data showing treatment of ADHD with tomoxetine. This is consistent with the guidance provided to examiners in the utility guidelines that if an applicant has initiated human clinical trials for a therapeutic product or process, USPTO personnel should presume that the applicant has established that the subject matter of that trial is reasonable predictive of having the asserted therapeutic utility.[63]

55. The rejection of the then pending claims under 35 U.S.C. § 103 for obviousness was routine. Based upon my experience, obviousness is the most common basis for rejection of claims by patent examiners. Such rejections are typically overcome through the submission of (1) attorney arguments pointing out how the examiner's rejections were in error; (2) claim amendments; or (3) affidavits or declarations providing evidence of non-obviousness. In this particular case, the applicants were successful in arguing why the examiner's obviousness rejection was not proper, which resulted in the examiner withdrawing the rejection. The application was then allowed. There was nothing unusual in the prosecution of the patent application leading to issuance of the Strattera patent.

Signed at the City of Alexandria on September 26, 2014

[signed]

STEPHEN G. KUNIN

[63] 1995 MPEP § 2107.03 (C-78).

Appendix A

STEPHEN G. KUNIN

PARTNER[1]

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, L.L.P.
1940 Duke Street
Alexandria, VA 22314

STEPHEN G. KUNIN is the former Deputy Commissioner for Patent Examination Policy with the U.S. Patent and Trademark Office. He has more than 44 years of expertise in intellectual property rights protection and 27 years of organizational management and leadership experience. He was appointed to his former position in March 2000 and has served in a similar capacity since November 1994, under the position's prior title, "Deputy Assistant Commissioner for Patent Policy and Projects." Previously, beginning in July 1989, Mr. Kunin served as Deputy Assistant Commissioner for Patents. He participated in the establishment of patent policy for the various Patent Organizations under the Commissioner for Patents, including changes in patent practice, revision of rules of practice and procedures, establishment of examining priorities and classification of technological arts, and oversaw the operations of the Office of Patent Legal Administration, Patent Cooperation Treaty Legal Administration, and the Office of Petitions. Additionally, in January 1993, Mr. Kunin was designated by the Secretary of Commerce to perform the functions of the Assistant Commissioner for Patents on an acting basis until a new Assistant Commissioner for Patents was appointed in 1994.

Mr. Kunin joined the Patent and Trademark Office (PTO) as a patent examiner in June of 1970. In March of 1977, he became a Senior Examiner in a technology of master's level complexity. He became Director of the Manufacturing Group in May of 1983. When a new Electrical Communications examining group (Group 260) was formed in April of 1984, he became its first Group Director.

Mr. Kunin assumed many leadership roles for the Office, including chairing the Patent Examiner Evaluation Board and the Patent Academy Curriculum Committee. Among his responsibilities, in addition to overseeing the Patent

[1] Mr. Kunin joined the Oblon firm in November 2004.

Examination Policy activities, he served on the USPTO Management Council, the USPTO Committee on Discipline, and the USPTO Executive Committee. He also coordinated several of the Trilateral Projects under the jurisdiction of the Commissioner for Patents. He has been a guest lecturer at a number of prestigious law schools.

Mr. Kunin, as a Partner, serves as a patent consultant who advises clients on patent prosecution and policy matters. He also serves as an expert witness on patent law, policy, practice and procedure. He chairs the firm's Contested Proceedings and General Counsel Committees. His team of Post-Grant Practice Partners maintains the firm's Patents Post Grant Legal Blog www.patentspostgrant.com to share insights and commentary on the complex array of existing and proposed post-grant issues, observe trends, practice tips and news relating to patent reexamination, reissue, and USPTO administrative trials. In February 2011, he was elected by his law partners to the firm's Management Committee. He now serves on the Management Committee as General Counsel of the law firm.

Mr. Kunin also now serves as the Intellectual Property L.L.M. and J.D. Programs Director at the George Mason School of Law where he is an adjunct professor who teaches patent law and intellectual property law classes.[2] He is frequently sought out to lecture to external groups on USPTO administrative trials and USPTO patent prosecution practice.

Education:

Mr. Kunin graduated with honors from Washington University in May of 1970 with a B.S. degree in Electrical Engineering. He attended the National Law Center of the George Washington University, receiving his Juris Doctor degree in law with honors in May of 1975. He is a graduate of the Harvard University Kennedy School of Government SMG Program.

Awards:

Mr. Kunin received numerous awards during his career at the USPTO, including four Gold Medals, four Silver Medals and a Bronze medal from the Department of Commerce, a USPTO Career Achievement Award and the Vice President's Reinventing Government Hammer Award. In 2001 he was named by Intellectual Property Today magazine as one of the most influential people in IP law and was the recipient of the Meritorious Executive Presidential Rank Award. In the February 2002 issue of the Practicing Law Company's magazine "Global Counsel" he was named as one of the most inspiring regulators in the federal government. In December 2004 he received the IPO Leadership Award. In November 2007 he received the 34th Annual Dr. Joseph Rossman Memorial Award from the Journal of the U.S. Patent and Trademark Office Society. In June 2008 he was ranked by Chambers USA as

[2] Mr. Kunin became the IPP Director in January 2005.

one of the top Intellectual Property Lawyers. In August 2009 he was selected by his peers for inclusion in the 2010 edition of The Best Lawyers in America® in the specialty of Intellectual Property Law. In August 2010 he was selected by his peers for inclusion in the 2011 edition of The Best Lawyers in America® in the specialty of Intellectual Property Law. In October 2010 he was named in Washington D.C.'s Best Lawyer's List. In 2011 he was listed as the Top Patent Prosecutor in the Patent Research Review. In March 2011 he was selected by his peers for inclusion in the Best Lawyers in America® for 2011 in the area of Patent Law. He has been recognized in The Legal 500 for 2011 as one of the top patent lawyers. In August 2011 he was selected by his peers for inclusion in the Best Lawyers in America® for 2012 in the area of Patent Law. He has been named as one of the areas top patent attorneys in the 2012 listing of the Legal 500. He is recognized as a key intellectual property attorney in the state of Virginia in the 2012 Chambers USA. He is recommended in the IAM Patent 1000 as an individual practitioner in post-grant procedures. In July 2012 he was nominated by his peers and endorsed by the AIPLA Board of Directors to become a member of the AIPLA Fellows. In August 2012 has was selected by his peers for inclusion in the Best Lawyers in America® for 2013 in the area of Patent Law. In February 2013 Mr. Kunin was awarded the 2012 P.J. Federico Memorial Award by the U.S. Patent and Trademark Office Society. In March 2013 he was selected by his peers for inclusion in the 2013 Edition of The Best Lawyers in America. He is listed as ranked Virginia Intellectual Property attorney in the 2013 edition of Chambers USA. He is listed in the 2013 IAM 1000 national and DC Metro ranking. He is listed as a leading IP lawyer in the United States in the 2013 IP Stars. He has been selected by his peers to be included in the 20th Edition of the 2014 The Best Lawyers in America in the practice area of Patent Law. He has been ranked by IAM 1000 2014 as a top patent attorney. He has been selected to appear in the 2014 Second Edition of IP Stars from Managing IP (MIP) magazine. He is listed as ranked Virginia Intellectual Property attorney in the 2014 edition of Chambers USA. He has been selected by his peers to be included in the 21st Edition of the 2015 The Best Lawyers in America in the practice area of Patent Law.

Memberships:

Mr. Kunin has served on the Editorial Board of the AIPLA Quarterly Law Journal and as an Advisory Committee Member for CASRIP (The Center for the Advanced Studies and Research on Intellectual Property) at the University of Washington's School of Law in Seattle, Washington. He was a Vice-Chair of the IPO U.S. Patent Practice Committee (2005-2008) and was the Vice-Chair of the IPO Patent Law Committee (2011), a former member of the AIPLA's Industry Trilateral Working Group and a member of the Community Patent Review Advisory Board. He was a member of the IP Law 360 Editorial Advisory Board. He is also a member of the LES (Licensing Executives Society), the PTOS (Patent and Trademark Office Society), the AIPLA (American Intellectual Property Law Association), the Federal Circuit

Bar Association, the ABA (American Bar Association) and the Giles S. Rich American Inn of Court. He is also a member of the Virginia State Bar and the bars of the Court of Appeals for the Federal Circuit and Supreme Court of the United States. He is registered to practice as a patent attorney before the U.S. Patent and Trademark Office. He was the Vice Chair of the AIPLA Patent Cooperation Treaty Committee and currently serves as a member of the AIA Strategic Task Force and its Post-Grant Practice Committee. He is a member of the IPO's Post-Grant Practice Committee for the 2014-2015 term and the ABA, IPL Section Patent Law Committee.

Publications:

Mr. Kunin's publications are as follows:

-"Petitions Practice Within the Patent and Trademark Office on Patent Matters," *Journal of the Patent and Trademark Office Society*, August 1991

-"Patentability of Computer Program Related Inventions in the United States," *Journal of Patent and Trademark Office Society,* March 1994, Nov. 1995 and Sept. 1999

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- Jonathan W. Parthum, Philippe J.C. Signore & Stephen G. Kunin, "Keeping Up With Patent Reform in 2011", Aspen Publishers, The Computer & Internet Lawyer, Volume 28, Number 7, July 2011