

**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 Professor Robert P. Merges
The University of California, Berkeley, School of Law

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I. Background and Qualifications

1. I am the Wilson Sonsini Goodrich & Rosati Professor of Law and Technology at University of California, Berkeley School of Law, where I have taught since 1995. I am also Co-Director of the Berkeley Center for Law and Technology. I reside in Davis, California. Prior to teaching at Berkeley, I was a Professor of Law at Boston University Law School. I have taught Patent Law virtually every year since 1988, and am the co-author of PATENT LAW AND POLICY (6th Edition 2013), a student casebook that is I believe the most widely-adopted patent law casebook in U.S. law schools. I received a B.S. from Carnegie-Mellon University, a J.D. from Yale Law School, and LL.M. and J.S.D. degrees from Columbia Law School. I am the author of dozens of academic articles on intellectual property law, particularly patent law. The patent casebook is one of seven books I have authored or co-authored in the intellectual property field. A full curriculum vitae is attached.

2. I confirm that I have no relationship to Eli Lilly and Company or any of its affiliates.

II. Summary of Conclusions

3. The utility requirement under U.S. patent law is very easy to meet, except in a few rare cases involving facially incredible inventions (such as perpetual motion machines). As the Federal Circuit said in one case, “[t]he threshold for utility is not high.”¹

4. According to longstanding practice, “[t]he utility requirement of 35 U.S.C. § 101 mandates that any patentable invention be useful and, accordingly, the subject matter of the claim must be operable.”² Once an applicant establishes operability, the claimed invention has been shown to confer “a significant and presently available benefit to the public.”³ A showing of operability is enough to establish that the utility is specific, substantial, and credible.

5. In the United States, an asserted utility is generally presumed to satisfy the utility requirement. Once an inventor presents a specific, credible, and substantial use, the inventor has met his burden. Patent law in the United States does not require the inventor to establish any particular *degree* of usefulness. The invention just has to work – a simple yes/no inquiry. As the Federal Circuit put it, “[t]o violate § 101 the claimed device must be totally incapable of achieving a useful

¹ *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999) (C-165).

² *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed. Cir. 1999) (C-268).

³ *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (C-84).

result”⁴ Post-filing evidence is routinely accepted to establish utility of a claimed invention.

6. The utility requirement “generally presents a low bar to patentability.”⁵ Because of this, patents are very seldom invalidated for failing to meet the standard of utility. In one academic study, only 0.7% of the cases studied involved patents that were invalidated due to lack of utility.⁶ When one considers that only roughly 1-2% of all patents are ever litigated in the United States, it is apparent that utility violations play a trivial role in patent invalidation.

7. The basic standard has been stable for many years. The keystone case in the Federal Circuit is *In re Brana*.⁷ The court in *Brana* found that early stage laboratory testing was adequate to show that the claimed pharmaceutical compound was useful. The Federal Circuit rejected the notion that successful human testing was required to establish utility for a compound ultimately intended as a therapeutic drug.

8. From a comparative U.S. perspective, Canada’s “promise doctrine” represents the adoption of an alternative utility theory that is fundamentally different from that doctrine in the United States. The promise utility doctrine (1) evaluates the degree of utility, whereas U.S. law explicitly rejects this approach in favor of a strictly binary and objective threshold inquiry; (2) represents a radically raised proof of utility that has been consistently resisted for sound policy reasons in U.S. courts; (3) and rejects post-filing evidence of utility, whereas U.S. law recognizes that evidence introduced after a patent is filed – including, for example, proof of commercial use – can definitively establish the presence of utility. This acceptance of post-filing evidence marks the U.S. approach as quite different from the Canadian promise doctrine; in effect evidence of this type in the United States merely helps to back up a plausible assertion of utility made at the time of filing. This is clearly different from a stringent requirement of actual proof as of the filing date, which makes for a much more imposing standard.

9. The basic policy behind U.S. utility doctrine is explained in more detail below. Stated briefly, requiring extensive proof of utility deters investment because it delays the award of an exclusive right until a very significant amount of money has been spent. The right time to award a patent is after some

⁴ *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992) (C-166).

⁵ 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).

⁶ John R. Allison and Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 208 (1998) (C-167).

⁷ *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995) (C-168).

money is spent, and a credible utility can be shown. It is a mistake to require proof of a commercially successful or even simply viable product at the time of filing for a patent –doing so would drive companies away from the research enterprise. This point is especially salient for small companies (such as startups) and university laboratories, both of which may be short on money during the early phases of a research project.⁸

III. Overview of U.S. Patent Law

A. U.S. Patentability Requirements

10. An invention must be useful, novel, and nonobvious to qualify for a U.S. patent (35 U.S.C. §§ 101, 102, and 103). It must also be adequately disclosed (§ 112) and fall within one of the classes of patentable subject matter – *i.e.*, it must be the type of new creation that patent law was meant to cover. Some biotechnology-related inventions are classified as “products of nature,” and hence unpatentable subject matter under U.S. law,⁹ but human-made pharmaceutical products clearly fall into a patentable category.¹⁰

11. All patentability requirements focus on the invention *as claimed*. Indeed, when U.S. patent lawyers speak of “an invention,” this is almost always understood to mean “the invention as claimed.” Thus, requirements for patentability of “an invention” are applied to each claim of a patent application.

12. Utility is usually understood to be the least demanding of the requirements for patentability.¹¹

⁸ A study of young, small companies in the biotechnology industry concluded: “Firms that seek venture-funding appear to be patenting more actively prior to the funding event (and for the purpose of securing funding), and venture-capital investors appear much less willing to fund companies that hold no patents.” Stuart J.H. Graham, Robert P. Merges, Pamela Samuelson, and Ted Sichelman, *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1280 (2009) (C-270).

⁹ See *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (C-271).

¹⁰ Section 101 lists the patentable categories: “machine, manufacture, composition of matter, or . . . improvement thereof . . .” 35 U.S.C. § 101 (C-73). Pharmaceutical compounds, like all human synthesized chemicals, are “manufacture[s]” as well as “composition[s] of matter.”

¹¹ See ROBERT P. MERGES & JOHN F. DUFFY, *PATENT LAW AND POLICY* 209 (6th ed. 2013) (“The vast majority of patent applications are processed without the PTO raising any question as to utility, and the utility doctrine is also rarely litigated as a defense in infringement actions.”) (C-272).

13. Novelty is a demanding test, requiring strict identity between a single piece of prior art and a claimed invention.¹² The essence of novelty is “newness”: an invention is not patentable unless it is new. Three considerations animate the law of novelty and define how the test is applied: (1) the date that defines the relevant prior art – that is, the date before which information must appear in the prior art to count against patentability of an invention; (2) the question of whether a particular piece of information qualifies for the prior art, *e.g.*, whether it was sufficiently public to count as a public use or publication under the statute (35 U.S.C. § 102); and (3) the comparison of the claimed invention with each piece of prior art, to see whether a single piece of prior art contains all the elements of the claimed invention.

14. The third major requirement, nonobviousness (or “inventive step” in other countries) does much of the heavy lifting with respect to quality control in the patent system.¹³ This test asks whether a claimed invention would have been obvious to one skilled in the art at the time it was made. It permits consideration of all relevant prior art, and tests whether the advance represented by the claimed invention is big enough to warrant the grant of a patent. It prevents the patenting of trivial inventions or small, incremental improvements over the prior art.¹⁴ In general, these three cornerstone requirements – utility, novelty, and nonobviousness – have been essentially stable for many years.

15. Section 112(a) ensures adequate disclosure of an invention. It contains two distinct requirements, enablement and written description. (A third, the “best mode” requirement, must technically be met in patent applications but is no longer available as a defense in patent infringement cases.)¹⁵ For an invention to be enabled, an inventor must teach someone in the field how to make and use the full range of things covered by the inventor’s claims.¹⁶ A person having ordinary skill in the art must be able to make and use the claimed invention without undue experimentation based on that person’s general knowledge coupled with what is disclosed in the patent specification.¹⁷ The written description test requires that an inventor show that his or her patent specification explicitly describes the

¹² See, *e.g.*, Robert P. Merges, *Priority and Novelty Under the AIA*, 27 BERKELEY TECH. L.J. 1023 (2012) (C-273).

¹³ See Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 13 (1992) (“Nonobviousness, it has been said, is ‘the ultimate condition of patentability.’” (quoting NONOBVIOUSNESS – THE ULTIMATE CONDITION OF PATENTABILITY (John F. Witherspoon ed., 1980))) (C-274).

¹⁴ See *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (C-275).

¹⁵ See 35 U.S.C. § 282(b)(3)(A) (C-73).

¹⁶ See, *e.g.*, *The Incandescent Lamp Patent (Consol. Elec. Light Co. v. McKeesport Light Co.)*, 159 U.S. 465 (1895) (C-276).

¹⁷ See, *e.g.*, *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988) (C-221).

embodiments of the invention as claimed.¹⁸ The test considers those things taught by the inventor that are actually described in the patent specification.¹⁹

16. There is a well-understood relationship between utility and the disclosure requirements of 35 U.S.C. § 112. Part of the disclosure required by the enablement doctrine is that the applicant must describe “how to use” a claimed invention. Establishing basic operability is necessary but not sufficient to establish “how to use” an invention; as a consequence, establishing a utility for the claimed invention is logically required to meet the “how to use” enablement standard.²⁰ But enablement goes well beyond utility. For example, a patent that claims a range of uses must enable all or virtually all of the claimed uses in order to satisfy the enablement standard, even though operability for a single qualifying use satisfies the utility requirement. This relationship leads to confusion at times, but the law is actually quite clear: utility is a standalone requirement under § 101 although it is relevant to the enablement standard.²¹

17. As with enablement, the written description requirement of Section 112 relates essentially to patent scope: the broader a patent’s claims, the more written description the inventor must provide to the public. Written description calls for explicit teaching of a representative number of embodiments. Because this requirement tracks claim scope, it is fundamentally distinct from utility. Utility is a simple binary test (a claimed invention is useful, or it’s not); written description and enablement are tests of proportionality, requiring that

¹⁸ See generally *Ariad Pharm. v. Eli Lilly & Co., Inc.*, 598 F.3d 1336 (Fed. Cir. 2010) (C-278).

¹⁹ See ROBERT P. MERGES AND JOHN F. DUFFY, *PATENT LAW AND POLICY* 298 (6th ed. 2013) (C-272).

²⁰ See United States Patent and Trademark Office, *Manual of Patent Examining Procedure* (March 2014) § 2107.01 at IV [hereinafter “2014 MPEP”] (C-72):

A deficiency under the utility prong of 35 U.S.C. 101 also creates a deficiency under 35 U.S.C. 112(a) [But] [t]he fact that an applicant has disclosed a specific utility for an invention and provided a credible basis supporting that specific utility does not provide a basis for concluding that the claims comply with all the requirements of 35 U.S.C. 112(a) For example, if an applicant has claimed a process of treating a certain disease condition with a certain compound and provided a credible basis for asserting that the compound is useful in that regard, but to actually practice the invention as claimed a person skilled in the relevant art would have to engage in an undue amount of experimentation, the claim may be defective under 35 U.S.C. 112, but not 35 U.S.C. 101.

²¹ See, e.g., *In re ‘318 Patent Infringement Litigation*, 583 F.3d 1317, 1323-24 (Fed. Cir. 2009) (discussing the relationship between “how to use” and utility) (C-279).

descriptive matter in the specification be commensurate with the scope of a claimed invention.

B. Utility: The Standard of Operability

18. Under U.S. law, an invention is useful if it is operable for a specific and substantial use. “The utility requirement of 35 U.S.C. § 101 mandates that any patentable invention be useful and, accordingly, the subject matter of the claim must be operable.”²² There is a presumption that an asserted utility is credible. Thus, an assertion of utility which is reasonable to one skilled in the art must be taken at face value:

As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented *must* be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter *unless* there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.²³

19. Even where a patent applicant fails to state a utility, a well-understood utility apparent on the face of the application can be enough.²⁴ No exemplification is necessary, and no evidence to demonstrate utility is required. The burden is on the Patent Office to establish that an invention *lacks* utility. Once a *prima facie* case is made questioning utility, the patent applicant has an opportunity to rebut the case, often with post-filing evidence.²⁵

20. Most inventions employ conventional technology in ways consistent with scientific principles. For them, as stated, the Patent Office assumes the truthfulness of utility as asserted by a patent applicant. Only where a claimed invention conflicts on its face with known laws of science – such as perpetual motion machines – does the Patent Office require detailed proof of utility.²⁶ While in

²² *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d at 1358 (C-268).

²³ *In re Langer*, 503 F.2d 1380, 1391 (C.C.P.A. 1974) (emphases in original) (C-280); *see also* 2014 MPEP § 2107.02 at III.A (section title: “An Asserted Utility Creates a Presumption of Utility”) (C-72); *In re Brana*, 51 F.3d at 1565-68 (C-168).

²⁴ *See* 2014 MPEP § 2107.02 at II.B (section title: “No Statement of Utility for the Claimed Invention in the Specification Does Not *Per Se* Negate Utility”) (C-72).

²⁵ *See In re Gaubert*, 524 F.2d 1222, 1224-25 (C.C.P.A. 1975) (“Accordingly, the PTO must do more than merely question operability—it must set forth *factual* reasons which would lead one skilled in the art to question the objective truth of the statement of operability.” (emphasis in original))(C-281).

²⁶ *See, e.g., Newman v. Quigg*, 681 F. Supp. 16, 17-18 (D.D.C. 1988), *aff’d* 877 F.2d 1575 (Fed. Cir. 1989) (perpetual motion machine) (C-79); *In re Swartz*, 232 F.3d 862 (Fed. Cir. 2000) (“cold fusion”) (C-282).

an earlier era, treatments for certain conditions such as baldness and cancer were viewed with suspicion by the Patent Office as being incredible, in more recent years many pharmaceuticals have been developed in these areas. So the Patent Office accepts plausible statements of utility in these fields as in all others.²⁷

21. Operability is closely related to the “specific and substantial” test for utility.²⁸ An invention must work for some specific, real-world-relevant use. The Court of Customs and Patent Appeals (C.C.P.A.) (the predecessor to the Federal Circuit) upheld a rejection in one case, noting “that the nebulous expressions ‘biological activity’ or ‘biological properties’ appearing in the specification convey no more explicit indication of the usefulness of the compounds and how to use them than did the equally obscure expression ‘useful for “technical and pharmaceutical purposes”’ unsuccessfully relied upon by the appellant in *In re Diedrich*, 318 F.2d 946 [C.C.P.A. 1963].”²⁹ So a specific utility means a clearly identifiable real-world use, rather than an expression of general interest.

22. A substantial utility has also been described as “practical utility,” which is how the Supreme Court described the requirement in *Brenner v. Manson*.³⁰ Substantiality means essentially “something more than research interest,” or, in some cases, something beyond a nominal asserted use. A good example of a nominal use is *In re Fisher*,³¹ in which the patentee claimed short snippets of genetic material, where the snippets were known to be included within active genes within a cell, but where the applicant did not know at the time of filing *which* genes the snippets were part of. The Federal Circuit upheld a finding of lack of utility, because the asserted utilities (mostly involving searching and mapping of gene sequences) were research uses rather than substantial uses presently available to the public. It was well understood that the real value of the snippet patents would come later,

²⁷ See, e.g., *In re Brana*, 51 F.3d at 1563, 1565-68 (utility for cancer treatment accepted on basis of *in vitro* testing) (C-168); *In re Cortright*, 165 F.3d 1353, 1357-60 (Fed. Cir. 1999) (noting change in Patent Office practice regarding baldness therapies and accepting evidence of utility for claimed baldness treatment) (C-283); DONALD CHISUM, CHISUM ON PATENTS § 4.04[2] (“More recent decisions eliminate the old double standard for medical inventions on the ground that other government agencies such as the Food and Drug Administration are responsible for regulating the advertising and sale of drugs to the public.”) (C-284). The Federal Circuit noted this line of cases in rejecting a lack of utility argument for one of the patents at issue in this Arbitration. See *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App’x 917, 924-25 (Fed. Cir. 2011) (finding the U.S. patent for Strattera (atomoxetine) did state a valid utility for the compound) (C-83).

²⁸ *In re Fisher*, 421 F.3d at 1371 (C-84).

²⁹ *In re Kirk*, 54 C.C.P.A. 1119, 376 F.2d 936, 941 (1967) (C-285).

³⁰ *Brenner v. Manson*, 383 U.S. 519 (1966) (C-85); see also *In re Fisher*, 421 F.3d at 1371 (explicitly equating “practical” and “substantial” utility) (C-84).

³¹ *In re Fisher*, 421 F.3d at 1371 (C-84).

when researchers identified specific genes useful for actual therapies. Patent claims to snippets falling within these later-discovered genes might have significant economic value, but the identification of snippets does nothing to bring that value to fruition. So the Federal Circuit held that the stated utilities were not “substantial.”³²

23. As noted, an asserted utility is presumed to be correct and accurate, unless it appears to one skilled in the art that it manifestly defies basic principles of chemistry or physics.³³ Of special note, the Patent Office accepts evidence that a drug has been cleared for human clinical trials as *per se* proof of utility. This rule, which was recently restated in *Eli Lilly v. Actavis*,³⁴ is set out in the Manual of Patent Examining Procedure:

Before a drug can enter human clinical trials, the sponsor, often 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. Such a rationale would provide a basis for the sponsor’s expectation that the investigation may be successful. In order to determine a protocol for phase I testing, the first phase of clinical investigation, some credible rationale of how the drug might be effective or could be effective would be necessary. 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.³⁵

24. Regardless of language in the specification discussing prior art, invention efficacy, or comparative results, the standard is the same. It is an objective standard, judged from the point of view of that venerable legal construct in patent law, the person of skill in the art. Some usefulness must be identified, but there is no requirement to prove any particular degree of utility. For example, in *CFMT, Inc. v. YieldUp International Corp.*, the Federal Circuit emphasized that commercial standards for the semiconductor wafer cleaning technology recited in the specification were not the proper basis for determining utility.³⁶ The proper inquiry,

³² *Id.* at 1376; see also Rebecca S. Eisenberg and Robert P. Merges, *Opinion Letter As to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1, 20 (1995) (opining that stated uses failed the utility requirement) (C-286).

³³ See, e.g., *In re Brana*, 51 F.3d at 1566 (“Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention’s asserted utility.”) (C-168).

³⁴ *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App’x at 924 (C-83).

³⁵ 2014 MPEP § 2107.03 at IV (emphases in original) (C-72).

³⁶ *CFMT, Inc. v. YieldUp Int’l Corp.*, 349 F.3d 1333, 1339-40 (Fed. Cir. 2003) (C-288).

according to the court, was to look to the *claims alone*, and ask whether a workable version of the claimed invention had been disclosed:

The inoperability standard for utility applies primarily to claims with impossible limitations Moreover, where a patent discloses several alternative combinations of methods (as most systems claims will), the party asserting inoperability must show that all disclosed alternatives are inoperative or not enabled. *EMI Group [N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342 (Fed. Cir. 2001)] at 1349. The . . . patents [in suit] do not claim an impossible result or an inoperative invention.

Because the preamble term “cleaning” means only “removal of contaminants,” not removal of all contaminants or removal of contaminants according to the [relevant] commercial standard, the inventor shows utility and enables the invention by disclosing “removal of contaminants.” Even if [a particular] embodiment does not achieve complete cleaning, that alone would not render the invention inoperative.³⁷

25. To similar effect is *Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.* (discussing utility in the context of reduction to practice):³⁸

Barmag appears to be equating the utility requirement of 35 U.S.C. § 101 with commercial marketability. . . . [C]ommercial marketability is not a requirement of reduction to practice. So long as Barmag’s machine produced yarn, it had utility in the sense of § 101.

26. And yet another case holds that utility is not to be measured according to the accuracy of statements in the patent’s prosecution history, but instead, and again, by the simple standard of workability:

Accepting that the jury must have found that the device did not work as Proma had argued in distinguishing the prior art, this is not an issue of lack of utility. It is undisputed that the [claimed] Kaiser invention is directed to subject matter expressly included in § 101, and meets the requirements of *In re Nelson*, [280 F.2d 172, 180 (C.C.P.A. 1960)]. It is not required that a particular characteristic set forth in the prosecution history be achieved in order to satisfy § 101. *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835, 105 S. Ct. 127, 83 L. Ed. 2d 69 (1984).³⁹

³⁷ *Id.* at 1339 (C-288).

³⁸ *Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.*, 731 F.2d 831, 839 (Fed. Cir. 1984) (C-289).

³⁹ *Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. Gesellschaft m.b.H.*, 945 F.2d 1546, 1553 (Fed. Cir. 1991), *abrogated on other grounds by Markman v. Westview*

27. This principle has been applied to pharmaceutical inventions as well. In *In re Irons*, for example, the patent examiner had rejected claims to a therapeutic drug, arguing that the evidence offered by the patentee consisted of a comparison between clinical results for the claimed compound and reported results for a prior art compound – a so-called “historical” control.⁴⁰ The examiner said that only a simultaneous, parallel, double-blind study could provide viable evidence of utility. The Court of Customs and Patent Appeals (predecessor to the Federal Circuit) disagreed:

We agree that the proofs of utility should be convincing to one skilled in the art, but we cannot agree with the degree of proof required by the Patent Office. . . . There is apparently little doubt that a double blind control is more reliable than a historical control. But, the evidence clearly indicates that both types of control are accepted. . . . Thus it would appear that tests of the type conducted by appellant are convincing to many skilled in the art. . . . The burden the Patent Office would place on appellant would, in effect, require proof beyond a reasonable doubt that the claimed compound possesses the alleged utility.⁴¹

28. As with the other examples described, the lesson is clear. Basic workability is what is required – and not proof of a high degree of efficacy.

C. Purpose of U.S. Utility Doctrine

29. Utility requires that a claimed invention exhibit basic workability, or operability. It excludes from the patent system inventions that have no practical function. Though in the past utility was invoked to prevent patenting of “immoral” subject matter, this aspect of the doctrine is now severely limited.⁴²

Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) (C-290); *see also In re Anthony*, 414 F.2d 1383, 1398-1400 (C.C.P.A. 1969) (refusing to invalidate patent for anti-depressant drug Monase, despite FDA’s suspension of drug because of acute side-effects) (C-292); *In re Hartop*, 311 F.2d 249, 255-60 (C.C.P.A. 1962) (rejecting argument that patent for thiobarbituric acid was invalid for lack of utility due to potential for dangerous side effects)(C-293); *In re Nelson*, 280 F.2d 172, 178 (C.C.P.A. 1960) (“[I]t has never been a requirement for patentability that there must be any particular degree of utility.”) (C-294).

⁴⁰ *In re Irons*, 340 F.2d 974, 975-77 (C.C.P.A. 1965) (C-295).

⁴¹ *Id.* at 978 (C-295).

⁴² *See, e.g.*, Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 Md. L. Rev. 1051 1063-64 (1988) (describing demise of older case law finding no utility for inventions related to fields such as gambling) (C-296).

Utility in contemporary U.S. patent law now has two dimensions. First, this principle eliminates fanciful or incredible “technologies” from the patent system – such things as perpetual motion machines and cold fusion. Second, and more frequently, utility can be related to the *timing* of patent awards. It ensures that patent applicants receive patents at just the right moment in the life cycle of an invention. The requirements of “specific” and “substantial” utility prevent companies from acquiring patents “too early” on objects of research before any specific, real world use is identified. A “credible” utility is required, but that does not require proof that an invention has a high degree of efficacy, or that a commercially viable version of the invention has been attained. Utility thus grants exclusivity and invites investment while there is as yet a good deal of development required to fulfill an invention’s potential.

30. The policy behind the utility standard in patent law is quite straightforward. Although, as stated, it would be a mistake to permit patents on inoperable things or things not yet identified as having any use, an invention is eligible for patenting as soon as a substantial and credible utility can be shown. This permits an early-stage researcher with a useful result to obtain a patent before investing a large amount of money in extensive testing and development.

31. The case law tends to emphasize this policy: requiring firms to engage in very extensive research and development before they have a patent in hand might discourage them from entering the research contest in the first place. Consider for example *Cross v. Iizuka*.⁴³ There a patent applicant had shown some successful lab results in the testing of the claimed compound. The Board of Patent Appeals and Interferences found this to be sufficient proof of utility, but the opposing party in an interference appealed to the Federal Circuit. The argument on appeal was that the lab results fell short of proof of utility as a human therapeutic. The Federal Circuit disagreed, and in the course of its opinion shed light on the benefits of assigning a patent at a fairly early stage in the research process:

Opinions of our predecessor court have recognized the fact that pharmacological testing of animals is a screening procedure for testing new drugs for practical utility. *See, e.g., In re Jolles*, 628 F.2d 1322, 1327 (C.C.P.A. 1980). This *in vivo* testing is but an intermediate link in a screening chain which may eventually lead to the use of the drug as a therapeutic agent in humans. We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, *in vitro* testing, may establish a practical utility for the compound in question. Successful *in vitro* testing will marshal resources and direct the expenditure of effort to further *in vivo* testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit

⁴³ *Cross v. Iizuka*, 753 F.2d 1040 (Fed. Cir. 1985) (C-297).

provided by the showing of an *in vivo* utility. Cf. *Nelson*, 626 F.2d at 856, 206 U.S.P.Q. at 883.⁴⁴

32. The keystone *Brana* case voiced the same policy concern in rejecting the notion that utility requires extensive human testing:

FDA approval . . . is not a prerequisite for finding a compound useful within the meaning of the patent laws. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.⁴⁵

33. Simple intuition supports the point. Multiple researchers, each of whom understands that other researchers are pursuing the same discovery, invest in early stage research in hopes of obtaining a patent. (If there were no patents no one would invest at all.) Spending on this early-stage research amounts to a gamble: there will only be, at most, a few winners. But the more early-stage research that is required, the more risky the gamble becomes. Obviously, at some price, the expected gain (which is a function of total profit in the market for the end-product, adjusted by the chance of winning given the total number of researchers seeking the patent) drops below the outlay required to seek and enforce the patent. At that point, researchers give up. If too many do that, the pace of research slows and society does not get the benefit of the discovery at issue until much later than it could have.

34. In the pharmaceutical sector, patent protection is a critical factor in a pharmaceutical firm's decision to develop a new product. Without the security of a property right, the risks and costs of drug development would severely limit research effort and significantly reduce the rate of innovation. The development of a new pharmaceutical product is characterized by three distinct challenges: major up-front investment to screen candidates and identify promising molecules; extensive laboratory and clinical testing of promising candidates; and a significant risk that a new product will fail to obtain FDA approval and thus fall short of actual commercialization. Most of the risks and costs are incurred long before making the first sales on the product. Therefore, innovative pharmaceutical companies need to secure patent rights early in the research process. Otherwise, it would be foolish to make future capital investments in further research and clinical

⁴⁴ *Id.* at 1051 (emphasis added) (C-297).

⁴⁵ *In re Brana*, 51 F.3d at 1568 (emphasis added) (C-168).

testing, knowing that without exclusivity a competitor might come along and render all this investment worthless.

IV. Comparing the Canadian “Promise Doctrine” to U.S. Law on Utility

35. Canadian patent law deviates radically from principles in place in U.S. utility doctrine since at least 1965 (the year *Brenner v. Manson* was decided). The basic standard of practical or substantial utility has been replaced in Canada by a wide-ranging inquiry into the degree of utility, coupled with an imposingly high evidentiary standard for proof of utility, which requires that the promised utility (as discovered and construed by the court from the specification) either be “demonstrated” or be based on a “sound prediction” of utility as of the date the patent application was filed.⁴⁶ In addition, Canadian law requires, with regard to “sound prediction,” a heightened disclosure requirement under which evidence establishing a factual basis and a “sound line of reasoning” for the predicted utility must be disclosed in the original patent application. The search for a “promise” concerning the patented invention’s ultimate performance is completely at odds with the simple substantial utility standard in the United States.

A. The Utility of the Strattera and Zyprexa Patents

36. This was the basis, for example, of the Canadian Federal Court decision invalidating Eli Lilly’s Canadian atomoxetine (Strattera) patent (Number 2,209,735). The court stated:

[U]tility is assessed against the inventive promise of the patent An invention is only useful if it does what the inventor claims it will do. In this case the requirement of utility would be met if, at the Canadian filing date of the ‘735 Patent, there was sufficient evidence that atomoxetine was clinically useful in treating some patients with ADHD or, alternatively, that such efficacy could be soundly predicted.⁴⁷

37. A key finding in the opinion was that the new use claimed for the atomoxetine compound, the treatment of Attention Deficit Hyperactivity Disorder (ADHD), required proof of sustained, long-term effectiveness. This promise was *implied*, the court held, because of the widespread knowledge that for most sufferers, ADHD is a chronic disorder.⁴⁸ Because of this, the proffered evidence of

⁴⁶ See, e.g., *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915 (C-160).

⁴⁷ *Id.* at ¶ 93 (C-160).

⁴⁸ *Id.* at ¶ 112 (C-160).

utility – a “pilot study” showing statistically significant short-term results in about half the tested patients – was deemed insufficient to fulfill the promised utility.⁴⁹

38. In *Novopharm Ltd. v. Eli Lilly and Co.*, the Federal Court of Appeal upheld the trial court finding that the ‘735 patent was invalid, because it did not fulfill its “promised utility.”⁵⁰ In the course of explaining the promised utility of the patent, the court of appeals states:

[W]hen the [trial] Judge’s reasons are read as a whole, he was not construing the patent as promising more than its explicit promise that it will treat ADHD in some people. Rather, he was simply interpreting what “treatment” means in this patent in the context of ADHD, a chronic disorder requiring sustained treatment.⁵¹

39. And later in the opinion:

A POSITA [person of skill in the art] would thus understand the promise to mean that atomoxetine will alleviate the symptoms of the disorder in some patients to a clinically meaningful extent. This is not to say that the promise means that clinicians will necessarily prescribe atomoxetine for their patients, because there may be more effective medicines available on the market. The promise does mean, however, that atomoxetine would be regarded by a physician as a realistic option for the treatment of ADHD.⁵²

40. Neither of these statements is consistent with the test of utility under U.S. law. In *Cross v. Iizuka*, the Federal Circuit specifically rejected the argument that the invention in question lacked utility due to the absence of proof of therapeutic (*i.e.*, clinical) effectiveness:

Cross’ position is that the stated purpose or *sole* contemplated utility of the invention of Iizuka is to provide a novel class of compounds which provide ‘practical use’ as ‘therapeutic medicines for diseases caused by thromboxane A₂,’ and therefore the Board erred in its finding as to the stated utility of the Japanese priority application.⁵³

41. The Federal Circuit held:

⁴⁹ *Id.* at ¶ 113 (C-160). The seven-week, placebo-controlled, double-blind, crossover study of Strattera found lacking by the Canadian court bears a striking resemblance to the simultaneous, parallel, double-blind study that a U.S. court held was *unnecessary* to show utility in *In re Irons*. See 340 F.2d at 977-78 (C-295).

⁵⁰ *Novopharm Ltd. v. Eli Lilly and Co.*, 2011 FCA 220 (2011) (C-163).

⁵¹ *Id.* at ¶ 21 (C-163).

⁵² *Id.* at ¶ 23 (C-163).

⁵³ *Cross v. Iizuka*, 753 F.2d at 1045 (emphasis in original) (C-297).

The Board has found that the Japanese priority application of lizuka disclosed a practical utility for the [claimed] compounds . . . in the inhibition of thromboxane synthetase in human or bovine platelet microsomes, *i.e.*, an *in vitro* utility. Clearly, this stated utility as found by the Board has been delimited with sufficient specificity to satisfy the threshold requirements of [earlier cases]. The stated utility of the Japanese priority application is directed to a specific pharmacological activity possessed by the [claimed] imidazole derivatives . . .—the inhibition of thromboxane synthetase *in vitro*.⁵⁴

42. It is manifest that no responsible doctor would extrapolate from a patent’s disclosure of effectiveness in the lab against “platelet microsomes” to a fully safe and effective compound to administer to a suffering human being. Yet that is the standard set up by the promise doctrine in the context of Lilly’s Strattera patent: the claimed compound must be “regarded by a physician as a realistic option for the treatment of ADHD.” This standard is so far beyond operability that it really has little to do with the classical law of utility. It carries the ring of an FDA clinical approval standard. This may be a good standard to apply before drugs are approved for the market but it has little to do with historically established tests for utility in patent law.

43. The entire approach of the Canadian court is inconsistent with basic principles of U.S. utility law. Consider first that the analysis of utility is based on language in the specification, as opposed to an emphasis on the *claims*. Claim 1 of the ‘735 Canadian patent, for example, reads as follows: “1. The use of tomoxetine [*i.e.*, atomoxetine] for treating attention-deficit/hyperactivity disorder in a patient in need thereof.”⁵⁵ The focus in U.S. law is on the basic operability of the invention as claimed. The claim states a treatment, so utility doctrine requires credible evidence that the claimed compound has some degree of effectiveness in treating ADHD. A bald assertion of operability might conceivably meet the standard, if one of skill of the art would believe that compounds of this type, based on the prior art, could be expected to show some action in treating ADHD. But evidence of a successful pilot study would absolutely and unquestionably meet the requisite standard – as the actual decided U.S. case illustrates.⁵⁶ Basic workability is all that needed to be established. Proof of clinical effectiveness was far beyond what the U.S. court demanded. A detailed discussion and critique of the pilot study is out of the question in such a setting. The fact of solid results easily meets the standard. (Indeed, as mentioned, the very fact that the FDA had *approved* a pilot study would be enough, according to the Patent Office.)

⁵⁴ *Id.* at 1048 (C-297).

⁵⁵ Canadian Patent 2,209,735, at claim 1 (C-67).

⁵⁶ *See Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App’x at 924 (C-83).

44. The same is true of the olanzapine (Zyprexa) decision. The Canadian court construed the olanzapine patent (Canadian Patent Number 2,041,113, a “selection invention” derived from a broader genus patent, Canadian Patent Number 1,075,687) as promising substantial benefits above and beyond basic operability against psychosis.⁵⁷ But though the analysis starts with the claims in the ‘113 patent, it is primarily concerned with an extensive analysis of the specification. In paragraphs 94-125, spanning 10 pages of the opinion, the court searches for and identifies the “promised utility” of the ‘113 patent. Ultimately, the trial court (whose opinion on utility was affirmed summarily by the Federal Court of Appeal) identified the following statement in the patent specification as the source of the patent’s “promise”:

Overall, therefore, in clinical situations, the compound of the invention shows marked superiority and a better side effects profile than prior known antipsychotic agents, and has a highly advantageous activity level.⁵⁸

45. It is quite clear in the context of the patent that this statement is directed at the issue of “unexpected success,” common when an improvement patent is filed claiming a particularly effective species drawn from a prior art patent that claims a broad genus. This is known in some countries, including Canada, as a “selection invention” or a “selection patent.” Patent law is no different for a selection invention than for any other invention. As with all patents, a key question for an improvement patent of this type is whether the later-claimed species is obvious in light of the earlier-disclosed genus. The unexpected success, or unusual effectiveness, of the selected species weighs heavily in favor of patentability in such a case.

46. But this issue is completely distinct from utility. The utility analysis under U.S. law would begin with the claimed invention. Two of the relevant claims, for example, are claim 3 (which reads in full: “Olanzapine”); and claim 6 (“The use of olanzapine for the manufacture of a drug for the treatment of schizophrenia.”). The question for claim 3 would be, has the patentee established a substantial use for the compound? But the utility of a species drawn from a prior genus already found to be useful presents an almost per se case of utility. The minimum utility required under U.S. law would seem to be established by virtue of the patentability of the earlier-patented genus. Unless there were unusual circumstances – for example, an allegation that the selected species fell into the small but permissible class of “inoperative species” sometimes found in a broad genus claim – it would seem that the utility of the genus applies *a fortiori* to the later-claimed species. Absent some definitive proof to the contrary, the grant of the prior genus patent demonstrates conclusively the utility of the later-claimed species.

⁵⁷ *Eli Lilly Canada, Inc. v. Novopharm Ltd.*, 2011 FC 1288 (C-146).

⁵⁸ *Id.* at ¶ 45 (quoting Canadian Patent 2,041,113) (C-146).

47. This is implicit in the U.S. olanzapine litigation. The district court mentions cases establishing that utility can be proven via animal testing.⁵⁹ But this is in the context of a discussion of animal tests to support the unexpected success argument, *i.e.*, nonobviousness.⁶⁰ Utility itself was not raised as a defense in the case – presumably because it was so clearly established under the facts. As mentioned earlier, utility is very seldom a winning defense in U.S. patent litigation, precisely because the standard is so easy to meet, and also because inoperative inventions are rarely litigated. An asserted utility is presumed to be correct and accurate, unless it appears to one skilled in the art that it manifestly defies basic principles of chemistry or physics.⁶¹ But if a genus has proven utility, there would normally be no reason to doubt that a species of that genus possesses the same utility.

48. The analysis for claim 6 would be quite similar. That claim says: “The use of olanzapine for the manufacture of a drug for the treatment of schizophrenia.” The question again under U.S. law would be operability, and here the question would be is the drug operable in “the treatment of schizophrenia” – does it show any action in the lab or elsewhere that indicates it is capable of operating against this indication as a drug? Again, the established utility for the genus of which this species is a part serves as a complete answer (barring again any

⁵⁹ See *Eli Lilly & Co. v. Zenith Goldline Pharma., Inc.*, 364 F. Supp. 2d 820, 908 (S.D. Ind. 2005) (citing *In re Krimmel*, 292 F.2d 948, 953 (1961)) (C-148).

⁶⁰ Cf. 2014 MPEP § 2144.08, at II.A.4.d (section title: “Obviousness of Species When Prior Art Teaches Genus”) (citations omitted) (C-72):

Consider the properties and utilities of the structurally similar prior art species or subgenus. It is the properties and utilities that provide real world motivation for a person of ordinary skill to make species structurally similar to those in the prior art. Conversely, lack of any known useful properties weighs against a finding of motivation to make or select a species or subgenus. However, the prior art need not disclose a newly discovered property in order for there to be a *prima facie* case of obviousness. If the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species. For example, based on a finding that a tri-orthoester and a tetra-orthoester behave similarly in certain chemical reactions, it has been held that one of ordinary skill in the relevant art would have been motivated to select either structure. In fact, similar properties may normally be presumed when compounds are very close in structure. Thus, evidence of similar properties or evidence of any useful properties disclosed in the prior art that would be expected to be shared by the claimed invention weighs in favor of a conclusion that the claimed invention would have been obvious.

⁶¹ See, *e.g.*, *In re Brana*, 51 F.3d at 1566 (C-168).

suggestion to one in the field that this particular species might be suspected of being inoperable). Note too that the claim format here – “use for the manufacture” – is dictated by Canadian patent law, which precludes U.S.-style “method of treatment” claims. The U.S. format implicates prescribing doctors as infringers and so is avoided in Canada, whereas the “use for the manufacture” claim covers only the actions of manufacturers. The point is that this claim format in no way implies that the inventor must somehow show that the drug is successfully produced as a commercial product in order to establish utility.

B. The Cost of the Promise Doctrine

49. The theory behind utility, sketched out earlier, is that it encourages investment in the chemical and pharmaceutical fields. It ensures that patents are awarded for a real-world use, and not pure research concepts. Inventors must assert some specific and substantial utility if they want to obtain a patent on their research results, though in many cases no showing (*i.e.*, extrinsic evidence) is required. But at the same time, the threshold level of utility is not high – which permits patentees to obtain exclusivity early enough in their research projects to encourage continuing investment. Securing a patent, or at least knowing that a patent is quite possible if the invention is operable, spurs companies onward in the research enterprise.

50. The promise doctrine fails to advance social interests under this theory for a number of reasons. Foremost is that it requires too much preliminary investment before an inventor can be sure an invention qualifies for a patent. Statements concerning advantageous features, or the ultimate aim or commercial plans for an invention, are likely to be converted into a broad “promise” that must be borne out if a patent is to be awarded. The theory of optimal assignment of property rights tells us that the investment required to back up these statements might well be too great for reasonable researchers to tolerate.

51. The other major problem with the promise doctrine is that it is vague and unpredictable. Take the atomoxetine (Strattera) litigation, for example. Simply because the court believed ADHD to be a “chronic” condition, the patentee was said by the court to have guaranteed the long-term effectiveness of its compound. This “implied” promise, the court said, was not backed by enough proof at the time the patent was filed. Yet the statement was really about ADHD, its nature and ramifications. At filing, the patentee did not explicitly promise effectiveness over any particular time horizon. The point is that the court read this promise into the specification, and then held the patentee to the promise it had found – a promise of long-term effectiveness that had to be demonstrated at the date of filing.

52. Indeed, the lengthy sections in “promise doctrine” cases where courts strive to “locate” the promise speak volumes about how much this doctrine differs from traditional utility. There is usually no doubt what utility is being asserted in a patent application; it is very easy to identify what the inventor believes

the invention can be used for. By constructing an elaborate doctrine concerning location and fulfillment of an invention's promise, the Canadian courts have wandered very far indeed from the straightforward confines of traditional utility doctrine. It is worth pointing out that Strattera did prove over time to be an effective ADHD therapy, even over a long time horizon. But, going forward, the promise doctrine as applied in this case eliminates the incentive to invest the resources needed to establish therapeutic efficacy. By insisting on evidence of long-term effectiveness before a patent is even filed, the promise doctrine might well prevent the development of drugs that *in fact* would turn out to be highly effective over the long run.

V. Conclusion

53. Utility requires that a claimed invention have a specific and substantial utility that is credible. It helps ensure that a real world use is asserted to secure a patent right (preventing speculation), without requiring that too much research is conducted before awarding the patent right (preventing the discouragement of continuing research).

54. The Canadian promise doctrine deviates radically from the utility doctrine as traditionally understood. It requires the investment of extensive resources to back up specification statements regarding advantages and efficacy. According to the theory behind utility doctrine, it requires too much investment prior to the assignment of exclusive rights, and therefore acts as a disincentive to optimal research investment. And finally, it is vague and subjective, which creates litigation risk for inventors. For all these reasons, the promise doctrine, ironically, would appear to itself have very little utility in a well-functioning patent system.

[Signed]

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Attachment A

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Exclusive Remedies and Software Licenses, **4 Computer L. Rep. 478 (January, 1986)** reprinted in **Computer Law 1986** (1987), at 36-42.

Toward a Computerized System for Negotiating Ocean Bills of Lading, **6 J. L. & Commerce 23 (1985)** (with Glenn Reynolds).

Apple v. Franklin: An Essay on Technology and Judicial Competence, **2 Yale L. & Pol'y Rev. 62 (1983).**

HONORS, AWARDS, ETC.

Retrospective Conference in honor of an early paper: "Patent Scope Revisited: Merges & Nelson's 'On the Complex Economics of Patent Scope,' 20 Years After," Indiana University School of Law, October, 2010.

Many papers in Social Science Research Network (SSRN) "Top 10 Downloads" category in Intellectual Property.

Scholarship cited numerous times by the U.S. Supreme Court and lower courts.

Second most-cited scholar in Intellectual Property, in list compiled by Brian Leiter's Law School Reports, <http://leiterlawschool.typepad.com/leiter/2007/09/most-cited-sc-1.html>.

WORKING PAPERS & WORKS IN PROGRESS

Economics of IP Law, chapter in the Oxford Handbook of Law and Economics (forthcoming 2014).

Interdependent Invention: A Limited Defense of Absolute Infringement Liability in Patent Law, June 2014

High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey (with Stuart Graham, Pam Samuelson, and Ted Sichelman), forthcoming Berkeley Technology Law Journal, 2009.

The Trouble with Trolls: Innovation, Rent-Seeking and Patent Reform, forthcoming, Berkeley Technology Law Journal, 2009.

Autonomy and Independence: The Normative Face of Transaction Costs, working paper, September, 2009.

Named Series Editor, Research Handbooks on Intellectual Property Law Series, Edward Elgar Publishers (General Editor of 5 volume series in Intellectual Property Law).

“Back to the Shadows, or Onward and Upward? Current Trends in Patent Law,” posted on “Patently-O” web blog, avail. at www.patently-o.com.

“Medieval Guilds Redux: Contemporary Institutions for Collective Invention,” to be presented at Annual Meeting, Economic History Association, San Jose, CA, Sept. 10, 2004; and Legal Studies Institute, University of Wisconsin, Madison, November, 2004.

“Who Owns the Charles River Bridge? Intellectual Property and Competition in the Software Industry”

OTHER SCHOLARLY ACTIVITIES

Editor-in-Chief, Intellectual Property Abstracts, Social Science Research Network electronic abstracting service with over 2000 subscribers.

VISITING Visiting Professor, Boalt Hall School of Law, University

POSITIONS of California, Berkeley, Spring 1995; Visiting Professor, Harvard Law School, Spring, 1994.

CONGRESSIONAL Hearings on Prior User Rights, House Subcommittee on

TESTIMONY Intellectual Property, September 13, 1994.

Hearings on The Patent Harmonization Act of 1992, Joint Senate/House Hearings, April 30, 1992.

"The Public Interest and Private Patent Bills," Senate Hearings on Patent Extensions (Private Patent Bills), August 1, 1991.

Hearings on State Sovereign Immunity in Patent Infringement Suits, U.S. House of

Representatives, February 8, 1990; testimony cited extensively by majority and dissent in *Florida Prepaid v. College Savings Bank*, U.S. Sup. Ct., case no. 98-531 (June 23, 1999).

Hearings on Patent Misuse, U.S. House of Representatives, May 11, 1988.

Hearings on Animal Patents, U.S. House of Representatives, July 22, 1987.

TALKS AND PRESENTATIONS

Justifying Intellectual Property, Presentation to the Faculty and Students, National Taiwan University Law School, May 2014

Current Developments in US Patent Law, mini-course offered at the National Tsing Hua University Law School, Hsinchu, Taiwan, May 2014

Plenary Talk, Trans-Pacific IP Conference, Suzhou, China (Renmin University Law School campus), November, 2013.

Joint Program for Berkeley-Peking University and Koc University (Turkey): IP and Economic Development, Beijing, November, 2013.

Philosophical Issues in IP Law: Justifying Intellectual Property, University of San Diego Law School, June 2012.

Special Conference on Justifying Intellectual Property, April 2012, Notre Dame Law School: Keynote speaker and discussant.

“Justifying Intellectual Property,” UCLA Entertainment, Media and IP Workshop, Los Angeles, Nov. 6, 2011.

“The America Invents Act: Overview,” Cleveland IP Law Ass’n Quarterly Meeting, Cleveland, OH, October 11, 2011.

“Justifying Intellectual Property,” University of Akron Law School, October 11, 2011.

“Justifying Intellectual Property,” 11th Annual IP Scholar’s Conference, Chicago, Ill., Aug. 11, 2011.

“Justifying Intellectual Property,” Oxford, England, Oxford University Law Faculty, June 15, 2010.

“Recent Trends in IP Rights and Business Models,” International Association of Boalt

Alumni, Annual Conference, London, England, June 17, 2010.

“Secondary Patent Markets,” The Gathering 2.0, Silicon Valley law and business conference, March, 2011.

“Secondary Patent Markets: Theory and Practice,” Los Angeles IP Law Ass’n, Feb. 25, 2011.

“Patent Scope Revisited: Merges & Nelson’s ‘On the Complex Economics of Patent Scope,’ 20 Years After,” Keynote Speaker at conference commemorating 1990 co-authored article, Indiana University School of Law, September 23-24, 2010.

“Property Rights in the Digital Era,” 23rd Annual Horace Manges Lecture, Columbia Law School, April 5, 2010.

“Innovation, Rent-Seeking and Patent Reform,” presentation at University of Arizona Law School, Tucson, AZ, May 1, 2009.

“Demsetzian Property Theory and the Future of Intellectual Property,” presentation at Research Symposium on Property Rights Economics and Innovation,” Northwestern University Law School, November 13, 2008.

“The Concept of Property in the Digital Age,” Baker Botts Distinguished Lecture, University of Houston, April 1, 2008.

IP and New Business Models: Patent Quality and Reliable Assets, presentation at annual Almaden Institute, IBM, San Jose, CA, May 8, 2008.

Kant on Intellectual Property Rights: Concepts and Principles for the Digital Era, presentation at the Cardozo School of Law, New York, September 10, 2007.

Software and Business Method Patents: A Review and Update, presentation at the Intellectual Property Owners Annual Meeting, New York, September 10, 2007.

“IP Under Attack? Worldwide IP Issues in Perspective,” Bay Area Meeting, Association of Intellectual Property Professionals (AIPPI), Spring 2007.

China/US IP Issues: Software Patents and Interoperability: Presentation at SAP, Inc.

The Future of Property, Berkeley Alumni group presentation, Palo Alto, CA, May, 2007.

Patent Law presentation, Federal Judicial Center continuing education for federal judges, Berkeley, June 2007.

“IP and Economic Development,” Day-long presentation, U.C. Berkeley U.S.-China High-level Policymakers’s Conference, September, 2006.

“A Transactional View of Property Rights,” presentation at the Conference on Commercializing Innovation, Washington University School of Law, St. Louis, Nov. 5, 2005.

“Patent Law: Basic Issues, New Developments,” presentation at annual Judicial Conference of the U.S. Court of Appeals for the Fifth Circuit, October 4, 2005.

“A Transactional View of Property Rights,” presentation at the Max Planck Institut for Intellectual Property and Tax Law, Munich, Germany, July 12, 2005.

“Legal and Economic Patent Law Scholarship in the U.S.,” presentation at the University of Mannheim, ZEW Institute, Germany, July, 2005.

“Patent Law Reform: Perspectives and Predictions,” presentation at the National Academies of Science, Patent Reform Conference, June 9, 2005.

Medieval Guilds and the History of Intellectual Property, Conference on the History of Intellectual Property, University of Wisconsin, Madison, Wisconsin, November, 2004.

From Medieval Guilds to Open Source Software: Informal Norms, Appropriability Institutions, and Innovation, Economic History Association Annual Meeting, San Jose, CA, September 10, 2004.

Principle Presenter, Conference on Intellectual Property and Entrepreneurship, Berkeley, CA, June, 2004

Featured Speaker, Heller Ehrman White & McCauliffe Firm Retreat, Aptos, CA, June, 2004

Invited Lecture, Cyberlaw course, Stanford Law School, April, 2004

Tutorial Lecturer and Featured Speaker, Conference on Patent Law Reform, U.C. Berkeley, April, 2004

Panel Speaker, Stanford-Berkeley Innovation Conference, October, 2003.

“Strategic Investments in the Public Domain,” University of Chicago Intellectual Property Conference, June, 2003.

“The Uninvited Guest: Patents on Wall Street,” presentation to Federal Reserve Bank of Georgia, Financial Markets Conference, Sea Island, Georgia, April 5, 2003.

“Intellectual Property: How Much is Too Much?,” Law in the Information Age Lecture, U.C. Davis School of Law, January 31, 2003.

“Is There a ‘Berkeley School’ of Intellectual Property?,” talk before Boalt Hall Alumni Association, Palo Alto, California, April, 2002.

Intellectual Property and Antitrust, Federal Trade Commission Hearings, Berkeley, California, March 5 and 7, 2002.

Intellectual Property Rights and the New Institutional Economics, principal presentation, Taking Stock: Conference on Recent Developments in the Law and Economics of Intellectual Property, Vanderbilt University, April 2-3, 2000.

Current Controversies in Patent Law, Talk at the Intellectual Property Conference, National Academy of Science, Science, Technology and Economic Policy Board, Feb., 2, 2000, Washington, D.C.

Patent Law Update, Ninth Circuit Judicial Conference, U.S. Court of Appeals for the Ninth Circuit, San Diego, California, August, 2000.

Biotechnology Patents in the U.S.: Address to the Conference on the European Biotechnology Directive, Milan, June, 1999.

“Who Owns the Charles River Bridge? Competition and the Software Industry,” paper presented at conference on Innovation and Competition in the Software Industry, Carlsbad, CA, April, 1999 (featured in column by Boston Globe reporter David Warsh, June 20, 1999).

Intellectual Property Rights, Input Markets, and the Value of Intangible Assets, Oliver Williamson’s “Institutions Seminar,” U.C. Berkeley, Dec. 3, 1998.

Intellectual Property Rights, Input Markets, and the Value of Intangible Assets, talk given to Columbia Law School faculty workshop, Nov. 10, 1998.

Property Rights and Employed Inventors, talk given to the combined Economic History and Industrial Organization Workshops, UCLA, Nov. 2, 1998.

Presented paper on “Institutions for Intellectual Property Transactions: The Case of Patent Pools,” NYU Law School Conference on Intellectual Products: Novel Claims to Protection and their Boundaries, June 25-28, 1998.

University Patenting and Licensing and the Biotechnology Industry, introductory address, Berkeley Conference on Biotechnology: New Perspectives on Public Access and Proprietary

Rights, February, 1998.

Commentator, Panel on International Protection for Computer Software and Digital Information, Association of American Law Schools Annual Meeting, January, 1998.

“Property Rights Theory and the Employed Inventor,” Law and Economics Workshop, University of Chicago, November 10, 1997.

“Employee Inventions Law and Employee Exit in High Technology Industries,” paper presented at the Conference on Financing Innovation, Columbia Law School, December 7, 1997.

Panel Presentation on “Intellectual Property: Industry Associations, Standard-Setting & Dell Computer,” 5th Annual Golden State Antitrust & Trade Regulation Institute, San Francisco, October, 1997.

The End of Friction? Property Rights and Contact in the “Newtonian” World of On-Line Commerce, presentation to Stanford Law and Economics colloquium, April, 1997.

“Institutions for Intellectual Property Transactions: The Case of Patent Pools,” NYU School of Law, March, 1997.

Panel Member, Antitrust and Intellectual Property, The Conference Board Annual Conference on Antitrust, New York, N.Y., March, 1997.

“Cantilevered Commerce: Intellectual Property and the Modern Economy,” Inaugural Lecture, Wilson Sonsini Professorship, Berkeley, February 1997.

"Intellectual Property After the GATT Uruguay Round," faculty presentation, Marquette Law School, Milwaukee, Wisconsin, May 8, 1996.

Panel Chair, Intellectual Property Session, American Law and Economics Association Annual Meeting, Chicago, May 9, 1996.

Presented paper on "Antitrust Review of Patent Acquisitions: Property Rights, Firm Boundaries, and Organization," Conference on Antitrust Policy, Canadian Department of Competition Policy, Ottawa, Canada, May 10, 1996.

"Current Issues in International Patent Law," presentation, Salzburg Seminar session on Intellectual Property Rights Internationally, Salzburg, Austria, August, 1995.

"The Economics of Intellectual Property Rights: An Overview and Guide, opening presentation, International Conference on the Economics of Intellectual Property Rights,

International Center for Art Economics, University of Venice, Italy, Oct. 6-8 1994.
"Contracting into Liability Rules (An Extension of the Calabresi and Melamed Framework)," Faculty Presentation, Harvard Law School, May 6, 1994.

"Comments on J. Reichman, *Toward a Third Intellectual Property Paradigm*," Columbia Law School Conference on Intellectual Property, April 22-23, 1994.

"Intellectual Property Policy Issues," presenter and participant, National Institute of Health Workshop on NIH's role in university-industry Sponsored Research Agreements, January, 1994.

"Is Biotechnology Unique? Lessons from Our Industrial Past," paper and talk presented at International Conference on Intellectual Property and the Future of the Biotechnology Industry, University of Washington School of Law, Seattle, Washington, October 21-23, 1993.

"Towards a Transactional View of Intellectual Property: Property Rules, Liability Rules, and Bargaining Breakdowns," paper and talk at Faculty Workshop, University of Michigan Law School, October 15, 1993.

Gave public talk to faculty, students, and patent judges on Patent Scope from an Economic Point of View, George Washington University School of Law, Washington, D.C., September 30, 1992.

Gave talk on "An Economic Rationale for Some Rules of Patent Infringement: The Doctrine of Equivalents and Related Issues," Stanford Law School, Law and Economics Workshop, October 22, 1992.

Gave talk entitled "An Economic Look at Recent Developments in the Law of the Biotechnology Industry," American Economic Association Annual Meeting, January 5, 1993, Anaheim, California.

Invited guest lecturer, Seminar on Technology and the Law, Boalt Hall School of Law, Berkeley, California, March 18, 1993.

Gave paper on "The Impact of Intellectual Property Rights on the Computer Software Industry," Berkeley International Conference on the Economics of the Software Industry, Berkeley, California, March 20, 1993.

Invited participant, Consortium on Competitiveness and Cooperation planning meeting for major new project on The Coevolution of Institutions and Industries, Palo Alto, California, April 16, 1993.

"Uncertainty and the Standard of Patentability," Interdepartmental Colloquium on Technical Change, Carnegie-Mellon University, Pittsburgh, September 16, 1992.

"Thoughts on Patents and Transaction Costs," Conference on the Economics of Intellectual Property, Columbia University, June, 1992.

"Introduction to the Legal Issues," Genome Patent Working Group, Public Forum on Patenting the Human Genome, National Academy of Sciences, May, 1992, Washington, D.C.

Spoke on "Teaching Patent Law," George Washington Law School Conference on Teaching Intellectual Property, May 1992.

"The (Uneasy) Case Against Software Patents," Massachusetts Software Council Annual Meeting, Boston, Jan. 27, 1992.

Presentation to science journalists, Congressional staff members, and scientists: "Patents in Biotechnology and Other Sciences," Banbury Center, Cold Spring Harbor Laboratory, Long Island, Jan. 24-25, 1992.

Gave talk on "The Economics of Property Rights and the Human Genome Initiative," Center for Science and International Affairs, Kennedy School of Government, Harvard University, Nov. 19, 1991.

Keynote Speaker, Boston Patent Law Ass'n Annual Meeting, December 5, 1991.

Panel Member, Franklin Pierce Law Center Biennial Patent Law Symposium, May 2-3, 1991.

Gave presentation on Intellectual Property issues at a Conference on Legal Issues in the Human Genome Project, Arizona State University School of Law, Phoenix, Arizona, March 15-17, 1991.

Presentation on "Economic Impact of Intellectual Property Rules on the Biotechnology Industry," before the Technology and Public Policy group at the Kennedy School of Public Policy, Harvard University.

Gave speech on "The Patent System: Prospects and Problems" at The Cooper Union for the Advancement of Science and Art, New York, January 22, 1991, in conjunction with the Union's retrospective exhibit and public forum on the 200th anniversary of Peter Cooper and the patent system.

Gave short presentation to the Biotechnology Committee of the American Intellectual Property Law Association at their mid-winter meeting in Boca Raton, Florida, January 24, 1991.

Commented on paper and made presentation at John M. Olin Foundation Conference on Intellectual Property, University of Virginia Law School, October 18-20, 1990.

Gave presentation and moderated panel at American Enterprise Institute Conference on Intellectual Property, Washington, D.C., September 27, 1990.

Gave presentation on International Initiatives in Intellectual Property at Boston University International Law Journal Symposium on International Trade, September 25, 1990.

Moderated and gave speech at Tufts Medical School Conference on the Tenth Anniversary of the Chakrabarty Case, Boston, May 25, 1990.

Gave speech on Industrial Policy and the Biotechnology Industry, National Institutes of Health-Pharmaceutical Manufacturers Association Conference on Commercializing Biotechnology, March 1-2, 1990.

Presented Paper on "The Public Research Enterprise in the U.S.: Overview and Prospects," Conference on Legal Aspects of Scientific Research, sponsored by the Universities of Florence and Siena, Italy, June, 1989

Presented paper and gave talk on "Protecting Emerging Technologies, Especially Biotechnology" before the Annual Patent Conference sponsored by the Bureau of National Affairs, Washington, D.C., November 18, 1988.

Presentation on "Economic Approaches to the Problem of Software Patents," MIT Communications Forum, March 23, 1989.

Presentation on "The Intelligent Use of Animals in Research: Legal Issues," Harvard Medical School Genetics Training Research Grant Speakers Series, April 27, 1989.

Presentation on "Patent Misuse and Antitrust Defenses," Symposium on Intellectual Property and the Venture Capital Process, Stanford Law School, May 5, 1989.

Panel Discussion on "Software Copyright," Copyright Society of the United States Meeting, Boston, February 10, 1990.

GRANTS

Kauffman Foundation grant to study Intellectual Property and Entrepreneurship, awarded March, 2007 (co-Principal Investigator, with Pam Samuelson).

Department of Energy competitive grant for conference on Biotechnology: New Perspectives

on Public Access and Proprietary Rights, Feb. 20-21, 1998.

Consortium on Competitiveness and Cooperation, Sloan Foundation, 1994- , to conduct an empirical study of the role of intellectual property rights in facilitating various transactions, from licensing technology to the formation of joint ventures, and the like. I will be conducting the research with Professor Josh Lerner of Harvard Business School.

Alfred P. Sloan Foundation Grant, 1989-1991, to organize and supervise research on Intellectual Property and the Biotechnology Industry. Administered four workshops during 1989-90 academic year.

Office of Technology Assessment Contract Research Award 1993, to study and report on policy issues raised by attempts to patent portions of the human genome.

TEACHING

Designed and co-taught course on IP Decisions, Models, and Strategies at the Haas School of Business, UC Berkeley, Spring 2010.

Taught a course on "Theoretical Foundations of Intellectual Property" at the Max Planck Institut, joint summer program with George Washington University, July, 2005.

First year contracts, one- and two-semester course, since 1988

Seminar in Advanced Topics in Intellectual Property, 1989-1994.

Patent Law, 1989 -

Introduction to Intellectual Property, 1994 - .

Intellectual Property Transactions: Law and Economics, 1994.

Law and Technology Seminar, U.C. Berkeley (Boalt Hall), 1995 - 1997.

Intellectual Property Strategy, 1997.

Intellectual Property in Historical Perspective, 2002 (at UC Davis School of Law).

In addition, I have organized and recruited adjunct faculty for numerous new intellectual property-related courses at Berkeley since 1995.

EDUCATION J.S.D., LL.M., Columbia Law School

J.D., Yale Law School, 1985

B.S., History, Carnegie-Mellon University, 1981. Visiting Foreign Student, Trinity College, Dublin, Department of Modern Irish History, 1980-81.

FELLOWSHIPS & AWARDS From September, 1986 until June, 1988, I was the Julius Silver Fellow in Law, Science and Technology at Columbia Law School; organized and co-taught course on Legal Aspects of the Biotechnology Industry.

Greyhound Fellow and Affiliated Scholar, Center for the Study of Law, Science and Technology, Arizona State University School of Law, Winter 1988.

Coker Fellow (Assistant Instructor), Yale Law School, 1984-85.

Wells Fellow, Jonathan Edwards College, Yale University, 1984-85; coordinator for Wells Technology and Society Lecture Series.

Aley Scholarship, Yale Law School, 1984-85.

PROFESSIONAL ACTIVITIES

Co-founder and Co-Director, Berkeley Center for Law and Technology, a major force in intellectual property and other law and technology issues; rated the #1 IP program by US News and World Report 10 of the past 11 years.

Co-Founder and Managing Director, Ovidian LLC, an IP business and investment consulting firm in Berkeley, CA. One of 5 original co-founders, served as Managing Director for two and one half years, until company was successfully acquired by Pendrell, Inc., of Bellevue, Washington. Now serve as Senior Policy Advisor to Ovidian/Pendrell.

Frequent speaker to federal judges on various intellectual property-related topics, at programs offered by the Federal Judicial Center in conjunction with the Berkeley Center for Law and Technology (e.g., 200 judges, San Francisco, June, 1999; 40 judges, Berkeley, June, 1998).

Organized and led Berkeley Roundtable on Software Protection, May, 1996 (125 attendees)

Organized and participated in the First Digital Content Symposium, November, 1996

Organized and participated in the conference, "Biotechnology and the Law: New

Perspectives on Public Access and Proprietary Rights,” Berkeley Center for Law and Technology, Berkeley California Feb. 20-21, 1998.

Recruited adjunct faculty, and helped organize, innovative new courses (IP Strategy, IP Transactions, Patent Law of Biotechnology and Chemical Industries, Patent Litigation, Entertainment Law, Trade Secrets, etc.)

Solidified student internship program, which includes internships at Netscape Communications, Lucas Digital, LucasFilm, and other leading companies

Conducted extensive fundraising (now roughly \$400,000 annually) and acted as liaison with most prominent Bay Area intellectual property law firms

Special Consultant to the Antitrust Division of the Department of Justice on intellectual property issues, and Member of the Department's Task Force on Intellectual Property, 1994-1999

Consultant to the Director, National Institutes of Health, in the matter of NIH's decision to drop certain human genome-related patent applications

Consultant, U.S. Congress, Office of Technology Assessment, Human Genome Project Intellectual Property Study

Occasional consultant on intellectual property issues and policy for Howard Hughes Medical Institute, Genentech, and other firms; and to the U.S. Patent Office.

Consultant, Office of the United States Trade Representative, on intellectual property issues, 1989-1990

Organizer and Discussion Leader for four symposia on Intellectual Property Rights in the Biotechnology Industry, funded by the Alfred P. Sloan Foundation, 1987-1988

Research Assistant to Professor Richard Nelson, Henry Luce Professor in International Political Economy, 1987. Assembled empirical data on various aspects of industrial research and development for use in papers by Nelson and Merges.

Admitted, California, U.S. District Court for the Northern District of California and U.S. Court of Appeals for the Ninth Circuit, 1986.

Associate, Fenwick, Davis & West, Palo Alto, California, 1985-1986. Corporate associate with emphasis on intellectual property, especially technology licensing, and start-up companies.

Summer Associate, Fenwick, Davis & West, 1984.

Summer Associate, Brown & Bain, Phoenix, Arizona, 1983.

WORK EXPERIENCE Senior Technical Writer, VisiCorp Personal Software, Inc., San Jose, California, 1981-82. I wrote user manuals for various software products, including an advanced version of the VisiCalc spreadsheet program.

Technical Writer, Intel Corporation Advanced Semiconductor Research Facility, Aloha, Oregon, Summer, 1980.

Technical Writing Intern, Intel Corporation, Santa Clara, California, Summer, 1979.

OTHER

Sunday School Teacher, Davis Community Church (Presbyterian USA), 2001- 2007; Adult Education leader, 2007-present. Elder since 2005.