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To Use or Not to Use: Reforming Patent Infringement, the Public Use Bar, and the Experimental Use Doctrine as Applied to Clinical Testing of Pharmaceutical and Medical Device Inventions

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This article discusses the applicability of the public use bar and the experimental use exception to patent validity and enforceability in the context of clinical testing of pharmaceuticals and medical devices, and as this testing may relate to U.S. Food and Drug Administration (FDA) clinical testing requirements.¹ This article will outline the history and

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1. At the outset, the reader is cautioned to note that there are several "experimental use" theories in patent law, each of which is different. Experimental use arises under the first theory of infringing the patent so that the infringer may obtain necessary clinical data to support FDA related approval applications so that generic products are available when the primary patent expires. See Shashank Upadhye, *Understanding Patent Infringement Under 35 U.S.C. § 271(e): The Collisions Between Patent, Medical Device, and Drug Laws*, 17 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1 (2000); 35 U.S.C. § 271(e)(1) (2000). The second theory occurs when the infringer builds the patented invention merely to satisfy his own curiosity of whether the invention actually works or whether the patent sufficiently teaches how to use the invention. The infringement occurs in the context of "experimenting" to determine operability or sufficiency of teaching. This second theory is also often called the "*de minimis* use" exception. See *Embrex Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1349, 55 U.S.P.Q.2d 1161, 1164 (Fed. Cir. 2000). The third theory occurs when the patentee attempts to either classify his own or others' invalidating public uses as experimental uses. This article concerns the last theory.

application of the public use bar. The article argues that courts are inconsistent in their application, and accordingly, a reform or paradigm shift is necessary. Such reform is necessary because a bright line rule will foster predictability for both patentees and competitors alike. In addition, because other recent significant and economically practical alternatives exist, there is now less need for liberal application of an already nebulous concept.

Identifying public use issues becomes very important in the context of litigation or due diligence. Prior public use is grounds for patent invalidity. Accordingly, those in litigation may make prior public use a priority to invalidate the patent. Those in due diligence may take extra care in conducting the due diligence. For example, if a company is acquiring a patent, the acquirer will investigate the patent's vulnerability. The entire deal may collapse if the public use is sufficient to question the validity. If the patent forms part of an asset pool being purchased or licensed, then the valuation of the pool may be compromised because of the potentially invalid patent. In a sense, the vulnerable patent infects the pool. While the vulnerable patent may not be enough to kill the deal, it may warrant further re-negotiation. If the patent forms part of a bankruptcy corpus, the valuation of the corpus is compromised. A trustee in bankruptcy cannot adequately value the corpus and cannot make informed decisions about whether to license the patent or sell the corpus to generate additional income. For a medical company, the vulnerability of the patent may dictate whether the company is willing to commercialize the product and invest the millions necessary for clinical data and FDA approval. Finally, investigating any patent's vulnerability will dictate whether that patent can be enforced without incurring antitrust liability.

In drug or medical device research and development, a patentee² often conducts clinical trials to evaluate and perfect a newly developed drug or device, or to establish safety and efficacy prior to applying for a patent.³ At one extreme, a

2. As used herein, the term "patentee" is synonymous with the term "patent holder," "inventor," "assignor," or "patent owner" to avoid confusion. Accordingly, the terms should be understood to apply generically to the party who allegedly created the public use, whether it is the inventor or subsequent patent owner.

3. See generally Upadhye, *supra* note 1, at 6; 21 U.S.C. §§ 331, 351, 352, 355(a) (2000).

physician may utilize a medical device of his own design in treating patients in his private medical practice. At the other extreme, a pharmaceutical company may conduct formal, large-scale research and often will associate with doctors at local or out-of-state hospitals to perform clinical trials. Recruitment of patients and other investigators in some cases necessitates publicity of such clinical trials.⁴ As analyzed below, such outside research that occurs prior to the filing date of a patent application may constitute public use and raise the possibility that the court will find the patent invalid.⁵

35 U.S.C. § 102(a) invalidates an issued patent if the invention was known or used by persons other than the inventor⁶ in the United States, before the invention date of the patent.⁷ Similarly, § 102(b) invalidates an issued patent if the invention was in “public use” or “on sale” in the U.S. more than one year prior to the issued patent’s filing date.⁸ Accordingly, under § 102(a), the invalidating use must be by others, whereas under § 102(b), the invalidating public use can be performed by the inventor or by others.⁹ In essence, when a public use of an invention occurs more than one year prior to the filing date, patentability of the invention is lost.¹⁰ The filing date is critical because the filing date freezes the universe of prior art that may be used against the patent. So, under § 102(a), the universe of prior art includes art that has a date anytime before the patent’s earliest effective filing date. For § 102(b), the universe of prior art includes art that is dated more than

4. *But see*, *Teletronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1523 (Fed. Cir. 1992) (finding an exempt use under 35 U.S.C. § 271(e)(1)); *see generally*, Upadhye *supra*, note 1, at 30-43.

5. 35 U.S.C. § 102(b) (2000). For other areas of FDA regulatory interaction with patent law and other FDA-oriented defenses to patent infringement, *see generally*, Upadhye, *supra* note 1.

6. For simplicity, use of the singular “inventor” also means sole or joint inventors.

7. 35 U.S.C. § 102(a) (2000) (“A person shall be entitled to a patent unless . . . (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.”)

8. 35 U.S.C. § 102(b) (“A person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States”).

9. *Id.*

10. *Id.* The filing date is the earliest effective filing date allowable under 35 U.S.C. §§ 119, 120, or 121 (2000).

one year before the patent's earliest effective filing date. As a matter of strategy, it is best to find § 102(b) art to invalidate the patent. Most public use issues in the FDA regulatory process context involve use by the inventor, by others, or by both.

Accordingly, the potential drug or medical device patentee faces a very real dilemma: (1) whether to test the product in large-scale trials to generate the necessary clinical data required by the FDA, but risk creating a public use bar; or (2) file a patent application and incur the associated costs prior to any clinical testing, not knowing if the product will ever be marketed or will even work.

As an aside, also noteworthy is that public use in a foreign country does not constitute a bar to patentability.¹¹ This is likely due to Congress's belief that discovering printed publications or patents in the U.S. or abroad was easier than trying to discover undocumented foreign public uses. This vestige may be less applicable in the modern global context. Nonetheless, § 102 has not been amended to encompass foreign public use or foreign sales as a bar to patentability.

The theme of this article relates to the interaction of the public use bar, the putative experimental use exception,¹² and the use of drugs or devices in medical testing or clinical trials. Part I begins with a basic primer on the public use bar. Part II details some common situations that may arise in clinical trial management. Part III discusses early public use cases and the law's progressive evolution. Part IV discusses the development of the experimental use doctrine. Part V begins a detailed analysis of the public use test and its factors. Part V also describes each factor and cases that give significant weight to each factor. Part VI discusses whether the question of

11. 35 U.S.C. § 102(a).

12. As will be seen in Part IV *et seq.*, public use may be considered distinct from "experimental use." Classifying an activity as experimental use may negate a finding of public use. Essentially, experimental use is use that is for experimental purposes and thus should be "excused" from being classified as an invalidating public use. See *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64, 48 U.S.P.Q.2d 1641, 1645 (1998) ("Nevertheless, an inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention . . . even if such testing occurs in the public eye."). Experimental use is discussed more fully in Parts IV, V, and VI *infra*. "Experimental use negates public use; when proved, it may show that particular acts, even if apparently public in a colloquial sense, do not constitute a public use." *Baxter Int'l, Inc. v. COBE Labs., Inc.*, 88 F.3d 1054, 1059, 39 U.S.P.Q.2d 1437, 1441 (Fed. Cir. 1996).

experimental use is a distinct inquiry from the question of public use. Part VII posits reform in the public use doctrine by discussing whether the public use doctrine ought to be liberally or narrowly construed and establishes a new rule called the “first clear chance” rule. In essence, this new rule puts the onus on the inventor as the person having the first clear chance to protect the invention or file the application. Part VIII concludes that a narrower construction of the public use doctrine is necessary.

I. A PRIMER ON THE PUBLIC USE BAR

The courts define public use as “any use of [the claimed] invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor”.¹³ As mentioned earlier, when public use of an invention occurs more than one year prior to the filing date, patentability of the invention is lost.¹⁴ This seems like a harsh penalty for delay, but as the court noted in *Tone Bros. v. Sysco Corp.*,¹⁵ there are several policy reasons for imposing the public use and on-sale bars.¹⁶ These policies include:

- (A) “One policy underlying the public use bar is to obtain widespread disclosure of new inventions to the public via patents as soon as possible.”¹⁷
- (B) The public use and on-sale bars are meant “to prevent the inventor from commercially exploiting the exclusivity of his [or her] invention substantially beyond the statutorily authorized . . . period.”¹⁸
- (C) Another underlying policy for the public use and on-

13. *Petrolite Corp. v. Baker Hughes, Inc.*, 96 F.3d 1423, 1425, 40 U.S.P.Q.2d 1201, 1203 (Fed. Cir. 1996) (quoting *In re Smith*, 714 F.2d 1127, 1134, 218 U.S.P.Q. 976, 983 (Fed. Cir. 1983) (citing *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881) (the “corset” case)); 35 U.S.C. § 102(b).

14. 35 U.S.C. § 102(b).

15. *Tone Bros. v. Sysco Corp.*, 28 F.3d 1192, 1198, 31 U.S.P.Q.2d 1321, 1324-25 (Fed. Cir. 1994), *cert. denied*, 514 U.S. 1015 (1995).

16. Section 102(b) provides in relevant part that “[a] person shall be entitled to a patent unless . . . the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States” 35 U.S.C. § 102(b) (emphasis added). The Supreme Court established a two-prong test governing the application of the on-sale bar: “First, the product must be the subject of a commercial offer for sale. . . . Second, the invention must be ready for patenting.” *Pfaff*, 525 U.S. at 67.

17. *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1062, 12 U.S.P.Q.2d 1449, 1454 (Fed. Cir. 1989).

18. *Id.*; see MPEP § 2133.03(e)(1).

sale bars is to discourage “the removal of inventions from the public domain which the public justifiably comes to believe are freely available.”¹⁹

Although the public use bar and on-sale bar reside in the same section of the statute, and in some cases the policies underlying the on-sale bar also support the public use bar in theory,²⁰ the bars are directed at different goals. Judge Rich noted that

“[p]ublic use” and “on-sale” bars, while they share the same statutory basis, are grounded on different policy emphases. The primary policy underlying the “public use” case is that of detrimental public reliance, whereas the primary policy underlying an “on-sale” case is that of prohibiting the commercial exploitation of the design beyond the statutorily prescribed time period.²¹

Other Federal Circuit decisions indicate that prevention of improper commercial exploitation is the foremost policy concern.²²

II. APPLYING PUBLIC USE TO CLINICAL TRIALS AND THE COMMON SCENARIOS

If public use can invalidate a patent, how does public use under the statute square with clinical trials? The FDA laws do not impose any restrictions on enrolled patients to maintain confidentiality during such trials. In fact, the only relevant confidentiality laws are those imposed on the doctor to not reveal patient information and the duty of obtaining the patient’s informed consent.²³

In the medical device field, a doctor often implants the

19. *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 550, 16 U.S.P.Q.2d 1587, 1591 (Fed. Cir. 1990) (quoting *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 860, 226 U.S.P.Q. 402, 406 (Fed. Cir. 1985). “[T]he overriding focus of section 102(b) is preventing inventors from reaping the benefits of the patent system beyond the statutory term.” *Ferag AG v. Quipp, Inc.*, 45 F.3d 1562, 1567-68, 33 U.S.P.Q.2d 1512, 1516 (Fed. Cir. 1995); *Allied Colloids Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1574, 35 U.S.P.Q.2d 1840, 1842 (Fed. Cir. 1995).

20. *Baxter Int’l, Inc. v. COBE Labs., Inc.*, 88 F.3d 1054, 1058, 39 U.S.P.Q.2d 1437 (Fed. Cir. 1996); *Tone Bros.*, 28 F.3d at 1198.

21. *Continental Plastic Containers v. Owens Brockway Plastic Prods.*, 141 F.3d 1073, 1079, 46 U.S.P.Q.2d 1277, 1281 (Fed. Cir. 1998).

22. *Ferag AG*, 45 F.3d at 1566 (Fed. Cir. 1995); *Barmag Barmer Maschinenfabrik AG v. Murata Mach. Ltd.*, 731 F.2d 831, 836 (Fed. Cir. 1984); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1375, 48 U.S.P.Q.2d 1225, 1250-51 (Fed. Cir. 1998) (Mayer, J., concurring-in-part, dissenting-in-part).

23. 21 C.F.R. pt. 50 (2002).

device into patients at a hospital or uses the device during routine operations. If such open and unrestricted use is deemed public, the problem becomes evident that future patentability may be foreclosed under § 102(b).

In response, the patentee will argue that this hospital or clinical trial use is an exception to the public use doctrine.²⁴ The patentee often tries to characterize this activity as “experimental use”.²⁵ Thus, a dispute arises about whether a particular activity is a public use or an experimental use.²⁶ Testing drugs and devices *in vivo* and *in vitro* prior to filing the patent application may create significant problems. As shown below in Part V, the normal procedures of associating with physicians to conduct trials introduce a variety of problems that include the sheer number of people involved and the public nature of the testing.

Therefore, an understanding of the historical origin of the public use bar is useful to determine if that historical application applies to the modern FDA clinical trial process. Factors that the early courts considered important may apply to the modern scenarios.

24. The infringer bears the burden of proving invalidity by clear and convincing evidence. Once the infringer establishes a *prima facie* case of public use invalidity by clear and convincing evidence, then the patentee bears the burden of proof by clear and convincing evidence that the alleged uses were experimental. *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1120 n.4, 39 U.S.P.Q.2d 1100, 1104 n.4 (Fed. Cir. 1996) (quoting the trial court’s jury instructions: “[t]he law places the burden on the [patentee] to come forward with convincing evidence showing that these uses were experimental uses”).

25. See *infra* note 59 and accompanying text. An experimental use is defined as “perfecting or completing an invention to the point of determining that it will work for its intended purpose.” *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1061, 12 U.S.P.Q.2d 1449 (Fed. Cir. 1989). In addition, it is the claimed invention that must be in public use or subject to experimentation. The inquiry is not whether unclaimed features are in public use or in experimentation. *In re Brigance*, 792 F.2d 1103, 1109, 229 U.S.P.Q. 988, 991-92 (Fed. Cir. 1986); *W. Marine Elecs., Inc. v. Furuno Elec. Co.*, 764 F.2d 840, 847, 226 U.S.P.Q. 334, 339 (Fed. Cir. 1985); *In re Theis*, 610 F.2d 786, 793, 204 U.S.P.Q. 188, 193-94 (C.C.P.A. 1979).

26. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64, 48 U.S.P.Q.2d 1641 (1998) (“Nevertheless, an inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention . . . even if such testing occurs in the public eye.”). “Experimental use negates public use; when proved, it may show that particular acts, even if apparently public in a colloquial sense, do not constitute a public use.” *Baxter Int’l, Inc. v. COBE Labs., Inc.*, 88 F.3d 1054, 1059, 39 U.S.P.Q.2d 1437, 1441 (Fed. Cir. 1996).

III. EARLY PUBLIC USE CASES – A BROAD DEFINITION OF PUBLIC USE AND NARROWLY TAILORED EXCEPTIONS

One of the earliest public use cases was the 1881 “corset case” of *Egbert v. Lippmann*.²⁷ In 1855, Egbert complained about corset problems to others including her future husband, Barnes.²⁸ Barnes made several inventive corsets from 1855 to 1858, which he presented to Egbert and which she then wore under her clothes in the course of her daily activities, including going out in public. At some time between 1855 and 1863, Barnes and Egbert married. In 1863, Barnes told Sturgis of his new corsets and showed them to Sturgis only once. Barnes applied for the patent in March 1866 and the patent issued in July 1866. The patent statute, at the time, allowed a two-year period following the first public use during which the inventor could apply for a patent.²⁹

The Supreme Court gave three main reasons for invalidating the patent. First, the Court stated that a single use in public can qualify as a public use, and public use does not rise or fall on the number of times the patented article was actually used in public. Multiple uses, however, may give more weight to the public use charge.³⁰

Second, public use does not depend on the number of people to whom its use is known. A public use by a single person can invalidate the patent if the donee, grantee, or vendee of the invention is not under a restriction of secrecy, or other limitation on the public disclosure.³¹

Third, public use does not depend on the publicly visible character of the invention. As the Court hypothesized, many inventions are merely components embedded within the overall machine and are hidden from view. Thus, when the inventor operates the overall machine including the inventive component, without any restrictions of secrecy, that action creates a public use.³² Because Barnes constructed his invention and allowed it to be used by another who was under

27. *Egbert v. Lippmann*, 104 U.S. 333 (1881).

28. *Id.* at 335.

29. Act of July 4, 1836, 5 Stat. 117; as qualified by Act of March 3, 1839, 5 Stat. 353. Congress reduced the grace period time to one year in the 1839 Act.

30. *Egbert*, 104 U.S. at 336.

31. *Id.*

32. *Id.*

no constraints of secrecy for almost eleven years prior to filing the patent application, the public use barred the patent.

Justice Miller's dissent argued that one policy reason behind the public use bar rested in the public's belief that it was free to copy the invention.³³ Focusing on the term "public," Justice Miller argued that because Egbert wore the corset under her clothes and never displayed the corset to others in public, and because the public could not see the corset, the public was not able to copy it because they had no access to it.³⁴ Thus, the public was ignorant of the invention prior to the patent application date.

A. THE SMITH & GRIGGS CASE: REFINING THE DEFINITION OF "PUBLIC USE."

Shortly after the *Egbert* decision, the Supreme Court in *Smith & Griggs Manufacturing Co. v. Sprague* refined its interpretation of the statutory language, stating that a public use that bars access to the patent system is: (i) a use more than two years (now one year) before the patent filing date, and (ii) a use in which a completed invention is used in public, without restriction and in circumstances other than "substantially for the purposes of experiment."³⁵ The *Smith & Griggs* case was one of the first cases to modify the definition of public use to include use of the completed invention. The Court also used the term "experiment" as a possible defense to public use.³⁶

B. THE ELECTRIC STORAGE CASE: DOES THE INVENTOR'S INTENTION MATTER?

The Supreme Court in *Electric Storage Battery Co. v. Shimadzu*,³⁷ clarified certain issues involving public use. First, the Court clarified that invalidity due to public use is an

33. *Id.* at 338-39 (Miller, J. dissenting).

34. *Id.*

35. 123 U.S. 249, 256 (1887). The Patent Act of 1836, 5 Stat. 117, included an "on-sale" bar that precluded patentability for any commercial activity before the application was filed. This was a statutory codification of the absolute novelty bar enunciated in *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 24 (1829). The Patent Act of 1839 created a 2-year grace period for the inventor to file the application. 5 Stat. 353; *see also* *Andrews v. Hovey*, 123 U.S. 267, 274 (1887). The Patent Act of 1939 reduced the grace period from two years to one year. 53 Stat. 1212.

36. *Smith & Griggs*, 123 U.S. at 255-256.

37. 307 U.S. 5 (1939).

affirmative defense that must be proved.³⁸ The Court then clarified the issue of whether the knowledge of the inventor was important. The Court stated that a public use bar attached irrespective of the patentee's consent,³⁹ changing the prior law that public use only occurred when the patentee so consented.⁴⁰ The Court further stated that public use could occur from a single commercial use, if that use was not purposefully hidden.⁴¹ Thus, the ordinary use of the patented machine within the confines of a factory – presumably a confidential or private establishment – in the usual course of producing goods for commercial purposes was a commercial use.⁴² Accordingly, public use no longer required any affirmative conduct by the patentee to make the invention public. Passive public use is still a public use.

As mentioned earlier, labeling conduct as an experimental use may thwart the public use allegation. Experimental use is defined as “perfecting or completing an invention to the point of determining that it will work for its intended purpose.”⁴³ The discussion about public use does not illustrate clearly how experimental use fits in. Thus, a brief discussion of the experimental use doctrine is necessary.

IV. THE DEVELOPMENT OF THE EXPERIMENTAL USE DOCTRINE

City of Elizabeth, NJ v. American Nicholson Pavement Co.,⁴⁴ was one of the earliest cases in which the experimental use doctrine appeared. The inventor of a new wooden road pavement laid down the road on a public Boston street for almost six years prior to applying for the patent.⁴⁵ The Supreme Court held that this was a not a public use within the meaning of the statute.⁴⁶ The Supreme Court noted the following particular circumstances in determining that the use,

38. *Id.* at 17.

39. *Id.* at 19-20.

40. *Id.* at 19.

41. *Id.* at 20.

42. *Id.*

43. *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1061, 12 U.S.P.Q.2d 1449 (Fed. Cir. 1989).

44. 97 U.S. 126 (1877).

45. *Id.* at 129.

46. *Id.* at 135-136.

albeit in the open roads of Boston, was not a public use:⁴⁷ the inventor did not intend to abandon his patent rights;⁴⁸ the purpose of laying down the road in this public environment was to test its qualities;⁴⁹ the inventor was a stockholder in the company that owned the road, even though the public was entitled to use the road;⁵⁰ the road pavement was made and installed by the inventor at his own expense;⁵¹ the inventor visited the site daily to observe the experiment including taking notes of the continuing results;⁵² the site chosen was a desirable site because all levels of traffic would occur over the road thus resulting in diverse test results;⁵³ a long period of time (here six years) may be needed to obtain the useful results of the experiment;⁵⁴ the inventor did not voluntarily allow others to make or use the invention;⁵⁵ and the inventor did not relinquish any control over the invention.⁵⁶

The Court rejected the infringer's argument that because the public was incidentally deriving a benefit from the road, it must be a public use.⁵⁷ Rather, the Court specifically focused on the nature or purpose of the experiment. The inventor's need to place the invention on public roads to test it, heavily favored the characterization as experimental use.⁵⁸ Finally, the Court noted that it was not the public knowledge of the invention, but the public use that precluded patentability.⁵⁹

Soon thereafter, the Court applied these experimental use factors to another public use case. In a remarkably similar fact pattern, the inventor in *Root v. Third Avenue Railroad Co.* used his inventive railway car cable road in San Francisco.⁶⁰ Here the inventor prepared an engineering plan for the proposed

47. *Id.*

48. *Id.* at 133. *But see* Elec. Storage Battery Co. v. Shimadzu, 307 U.S. 5, 19-20 (1939) (stating that intent was irrelevant).

49. *Am. Nicholson Pavement*, 97 U.S. at 133.

50. *Id.* at 133.

51. *Id.*

52. *Id.*

53. *Id.* at 134.

54. *Id.* at 135.

55. *Id.* at 135-36.

56. *Id.*

57. *Id.* at 136.

58. *See id.* at 135-36.

59. *Id.* at 136. Recall that the modern § 102(a) permits "known by others" in the U.S.A. as a potential bar. *See supra* note 7 and accompanying text.

60. *Root v. Third Ave. R.R. Co.*, 146 U.S. 210 (1892).

construction.⁶¹ The inventor participated in its installation and use by the City of San Francisco.⁶² The road was used for several years, with the inventor overseeing its operation.⁶³ In defense to the charge of invalidating public use, the inventor attempted to analogize his facts to the previous *American Nicholson Pavement* case.⁶⁴ In particular, the inventor stated that his use of the road was experimental in that he was observing its durability.⁶⁵ In rejecting his arguments of experimental use, the Supreme Court stated that the inventor sold his invention at a considerable price; that he treated his invention like a commercial product; that he relinquished control over it; and that if he wanted to make changes to it (design alterations), he could not do so; and that the inventor never examined it to determine its fitness for its intended purpose.⁶⁶

V. FACTORS OF THE PUBLIC USE TEST

Therefore, collecting factors from the various cases, one can generate a list of factors to consider in determining whether a use is public or experimental.⁶⁷ These include: (a) the nature of the activity that occurred in public;⁶⁸ (b) the public access to and knowledge of the invention in the public;⁶⁹ (c) whether there was any confidentiality obligation imposed on persons who observed the use;⁷⁰ (d) whether progress records or other indicia of experimental activity were kept;⁷¹ (e) whether persons other than the inventor or those acting for the inventor conducted the experiments;⁷² (f) the number and duration of tests conducted;⁷³ (g) the scale of the tests compared with

61. *Id.* at 215.

62. *Id.* at 214-15.

63. *Id.* at 215.

64. *Id.* at 221.

65. *Id.* at 215-16.

66. *Id.* at 221, 225.

67. There may also be additional factors relevant to a particular case. *Netscape Communications Corp. v. Konrad*, 295 F.3d 1315, 1320, 63 U.S.P.Q.2d 1580 (Fed. Cir. 2002).

68. *Id.*

69. *Id.*

70. *Id.*

71. *Allied Colloids, Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1576, 35 U.S.P.Q.2d 1840 (Fed. Cir. 1995).

72. *Netscape*, 295 F.3d at 1320.

73. *Id.*

commercial conditions;⁷⁴ (h) the length of the test period in comparison with tests of similar products;⁷⁵ and (i) whether payment was made for the product of the tests beyond recovery of the actual costs.⁷⁶

The next section will examine each factor in turn, discussing its importance and which cases, if any, give weight to such factor.⁷⁷ The courts look to the totality of the circumstances when evaluating whether there has been a public use.⁷⁸

A. THE NATURE OF THE ACTIVITY THAT OCCURRED IN PUBLIC

This factor examines the environment and context in which the activity occurred. Although this factor is expansive in nature, it plays only a moderate role in the overall analysis. In the case of *In Re Smith*, the court asked whether the experiment needed to be conducted in a public place or could have been performed at the inventor's premises.⁷⁹ In addition, the court noted that where multiple devices were shown in public, consumer indication of preference of one versus the other negated experimental use.⁸⁰ This is likely because this activity is more akin to gauging commercial acceptability than invention operability.⁸¹ Fundamentally, the *Smith* court asked whether the purpose of the public use was to systematically

74. *Allied Colloids*, 64 F.3d at 1576.

75. *Netscape*, 295 F.3d at 1320.

76. *Id.*

77. Whether an invention was in public use within the meaning of § 102(b) is a question of law, which is based upon underlying issues of fact. *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549, 16 U.S.P.Q.2d 1587, 1591 (Fed. Cir. 1990).

78. *Sinskey v. Pharmacia Ophthalmics, Inc.*, 982 F.2d 494, 498, 25 U.S.P.Q.2d 1290, 1293 (Fed. Cir. 1992) (citing *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 971, 220 U.S.P.Q. 577, 582 (Fed. Cir. 1984)).

79. *In re Smith*, 714 F.2d 1127, 1135, 218 U.S.P.Q. 976, 983 (Fed. Cir. 1983). *Smith* was a five-judge panel decision. *Id.* at 1128. The prior court, the Court of Custom and Patent Appeals (C.C.P.A.) always sat *en banc* in a five-judge panel and accordingly, every decision of the C.C.P.A. was precedential. The Federal Circuit was created on October 1, 1982 as part of the Federal Court Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25. The *Smith* case was decided in August 1983. Accordingly, the case was likely briefed and argued before the creation of the Federal Circuit but decided after its creation. Accordingly, *Smith* ought to be considered a controlling case given that it is a five-judge panel decision.

80. *See Smith*, 714 F.2d at 1135.

81. *Id.*

identify technical problems in the product.⁸² The *Smith* court specifically noted that the inventive carpet freshener did not have to be tested by housewives, but could have been tested in a laboratory.⁸³ This is strong evidence that the court ought to construe any public use to determine if it was necessary to test in public versus in controlled situations.

In *Allied Colloids*, the alleged public use occurred at a customer's location.⁸⁴ The invention involved the degradation of biologic sewage, so it had to be tested *in situ* because biological activity is different amongst sewage and laboratory testing does not guarantee the same results as testing *in situ*.⁸⁵ Therefore, use at a customer's location does not automatically negate experimental use.⁸⁶

In addition, this factor requires consideration of whether it is necessary to test the invention in public. For example, in the medical products analysis, the patentee could argue quite logically that medical devices or drugs that are ultimately bound for human beings require human testing. But it is plain that medical devices and drugs are often tested initially in animal models. Excellent data can be obtained from animal models. While human testing would assist the patentee in obtaining the proper FDA approval, human testing is not itself a predicate for patentability. After all, if the patent claims are broadly drafted not to specify the conditions of intended use, then public use may invalidate any such claims. If, however, some claims are more narrowly drafted to require human use or administration – for example a method of treating pain comprised of administering chemical X to a human patient – then the human clinical trial may be necessary to perfect the invention and prior animal testing public use may not itself invalidate these claims.

Because doctors often use medical devices in the hospital

82. *Id.* at 1136 (citing *Omark Indus. v. Carlton Co.*, 652 F.2d 783, 787, 212 U.S.P.Q. 413, 416-17 (9th Cir. 1980)).

83. *In re Smith*, 714 F.2d at 1135, 218 U.S.P.Q. at 983. In *Smith*, seventy-six housewives were given the carpet freshener to use on their own home carpets. *Id.* at 1137. This was to purportedly evaluate characteristics such as vacuumability, odor control, granular size, effectiveness in different type of carpets (e.g., shag versus pile), etc. *Id.* at 1135-36. The court noted that the tests could have been done in laboratory conditions. *Id.* at 1135.

84. *Allied Colloids, Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1573, 35 U.S.P.Q.2d 1840 (Fed. Cir. 1995).

85. *Id.*

86. *Id.*

environment, it is tempting to argue that use in the hospital, especially in an operating room, is not a public use. After all, operating rooms are not within the general public's access. Accordingly, because the public cannot access the *situs* of the medical device use, it can be argued that the use is not a public use within the meaning of the statute. However, the court in *Minnesota Mining & Manufacturing v. Research Medical Inc.*, ("3M")⁸⁷ addressed this situation differently.

In *3M*, the invention involved a venous return catheter, which is used to drain blood from the heart to prevent excess bleeding.⁸⁸ Plainly, this invention must be used in the clinical environment. In describing the nature of the public use that occurred, the court noted that the public use evidence consisted of use by independent third party doctors.⁸⁹ Each doctor used the same or similar device in the hospital environment.⁹⁰ In fact, one doctor conducted one of his uses in association with the inventor in the operating room itself.⁹¹ This may tend to show that skilled artisans may be present in the operating rooms, and the use may be considered public.

3M argued that these independent uses at the hospital were not public uses. The court, however, disagreed. Specifically, the court noted that the use was not secret, the device was completed, and more importantly, the use occurred in the environment in which it was naturally intended to be used.⁹² To the court, the uses of the catheter in the operating rooms were not secret uses because the invention was intended to be used in these rooms. Moreover, the uses were not under the control of the inventor because the doctors were third parties.⁹³

Therefore, an inventor cannot argue that because the

87. *Minn. Mining & Mfg. Co. v. Research Med., Inc.*, 679 F. Supp. 1037, 6 U.S.P.Q.2d 1401 (D. Utah 1987).

88. *Id.* at 1040.

89. *Id.* at 1045-48.

90. *Id.*

91. *Id.* at 1047 ("Dr. Flege and Hancock discussed with Amrine [the inventor of the patent in suit] the construction and use of the catheter, and permitted him to observe its performance during open heart surgeries by Dr. Flege.").

92. *Id.* at 1049 (citing *Bourne v. Jones*, 114 F. Supp. 413, 419, 98 U.S.P.Q. 206, 210 (S.D. Fla. 1951), *aff'd by adoption*, 207 F.2d 173, 98 U.S.P.Q. 205 (5th Cir. 1953), *cert. denied*, 346 U.S. 897 (1953); *see also* *Marrese v. Richard's Med. Equip.*, 504 F.2d 479, 183 U.S.P.Q. 517 (7th Cir. 1974).

93. *Minn. Mining & Mfg. Co.*, 679 F. Supp. at 1045-48.

invention involved a medical device, that *ipso facto*, the hospital setting testing was a non-public use. Furthermore, because the nature of the intended invention contemplates use in the hospital, and because hospitals are not necessarily limited public access areas, a clever infringer may succeed in discovering the nature and circumstances of the putative public use by the inventor or by others.

B. THE PUBLIC ACCESS TO AND KNOWLEDGE OF THE PUBLIC USE

Generally, the wider the access the public has to the invention, the more likely a public use will be found.⁹⁴ This is because, as the number of exposures increases, the more irrefutable it becomes that members of the exposed public would conclude that the invention was not confidential and was, therefore, free to be used indiscriminately. Although the Supreme Court in *Egbert v. Lippmann* found a public use by the inventor who demonstrated the invention to one non-related person on one single occasion,⁹⁵ the court stated that a finding of public use does not depend on the number of people to whom its use is known. The district court in *System Management Arts v. Avesta Technologies*⁹⁶ found relevant the [large] number of people to whom the invention or product embodying the invention was disclosed.⁹⁷

Patentees often argue that the use was hidden and thus was not public. That is, the public had no access to, or knowledge of, the invention. Hidden uses occur most frequently in the context of patented components as part of a larger assembly, where the assembly will be sold or used *in gross*, and will rarely be disassembled. Hidden uses may also include patented processes used in companies to churn out a

94. See *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 47 U.S.P.Q.2d 1363, 1365 (Fed. Cir. 1998); see also *Carella v. Starlight Archery*, 804 F.2d 135, 231 U.S.P.Q. 644, 1 U.S.P.Q.2d 1209 (Fed. Cir. 1986).

95. *Egbert v. Lippmann*, 104 U.S. 336 (1881).

96. *Sys. Mgmt. Arts v. Avesta Techs. Inc.*, 87 F. Supp. 2d 258, 54 U.S.P.Q.2d 1239 (S.D.N.Y. 2000).

97. *Id.* at 264 (citing *Articulate Sys., Inc. v. Apple Computer, Inc.*, 53 F. Supp.2d 62 (D. Mass. 1999)). The *System Management* court added the factor that it must be the invention itself as claimed (versus unclaimed) that must be in public use. *Id.* As an aside, if the court finds that the claimed invention as a whole was not in public use, but some part of the invention was in public use, then this "public use" part can be combined with other evidence to show that the claimed invention was obvious. This is because the past partial conduct is prior art and can be combined with other evidence in the traditional obviousness analysis. See 35 U.S.C. § 103 (2000).

final unpatented product. Examining or reverse engineering the final unpatented product does not yield the patented process. Arguably, the general public does not have access to the company floor and thus, arguably, it is not in public. Thus, the hidden nature of the use is also a factor because an invisible use plausibly means that the inventor did not perceive as necessary more precautions to protect confidentiality.⁹⁸

For example, in the *Manville Sales* case, Manville was found to have done nothing to lead the public to believe that its invention was in the public domain.⁹⁹ The site of the use was not actually in public – that is, the highway rest area where the light pole assembly was installed was in fact not open to the public – and Manville only communicated with one person regarding the invention.¹⁰⁰ The documents reflecting the testing of the invention were stamped “confidential”.¹⁰¹ In addition, even if the public could access the site, the invention was not easily in public view as it rested atop a 150-foot pole.¹⁰² Also, the fact that Manville tested the product outdoors does not automatically require a public use determination. When

98. *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 550, 16 U.S.P.Q.2d 1587 (Fed. Cir. 1990) (“the invention was mounted atop a 150 foot tall pole in a rest area still closed to the public, making it very unlikely that the public would even see the new design”); *Allied Colloids, Inc. v. Am. Cyanamid Co.*, 64 F.3d. 1570, 1574, 35 U.S.P.Q.2d 1840 (Fed. Cir. 1995) (public access to and knowledge of the public use is one of the factors to consider).

99. *Manville Sales*, 917 F.2d at 550.

100. *Id.* Manville made no attempts to commercialize its invention indicating that it intended to maintain ownership of it. *Id.* The court even noted that Manville could have sold it under the rubric of experimental purposes without losing the protection of the experimental use. *Id.* In some cases, commercially-motivated activity may implicate both the public use and the on-sale bars of § 102. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1266-67 n.3, 229 U.S.P.Q. 805 (Fed. Cir. 1986). Any commercial activity “must be merely incidental to the primary purpose of experimentation to perfect the invention.” *LaBounty Mfg. Inc. v. United States Int’l Trade Comm’n*, 958 F.2d 1066, 1071, 22 U.S.P.Q.2d 1025 (Fed. Cir. 1992) (citing *Pennwalt Corp. v. Akzona Inc.*, 740 F.2d 1573, 1580-81, 222 U.S.P.Q. 833, 838 (Fed. Cir. 1984)). This theory may find support in the 35 U.S.C. § 271(e)(1) jurisprudence because testing and sale of medical devices or drugs for the purposes of gaining FDA approval data is an exemption from patent infringement. *See generally* Upadhye, *supra* note 1. It makes sense that if a medical company can be exempted from infringement for “selling” FDA approval products for the purposes of gaining FDA approval, then surely any commercial activity that is necessary for effectuating the experimental use should be non-barring activity.

101. *Manville Sales*, 917 F.2d at 550.

102. *Id.*

the product is intended for a particular purpose, testing in its ultimate use environment may be necessary to determine operability as intended.¹⁰³ Accordingly, the public had very little access to, or little knowledge of, the invention atop the pole.

Whether the public has access to drugs or devices depends on timing and the nature of the invention. For time-related issues, a device could become public after manufacture or through the distribution chain. That is, the public becomes exposed to the device throughout the logistics chain. It becomes a public use, though, when it is used for its intended purpose. So a public use of a device may occur only during use or implantation. The question, therefore, is whether the public had access to, or knowledge of, the device contemporaneous with the barring use. For drugs, the same questions exist.

Concerning the nature of the invention, plainly some inventions are not used in the open public, but nonetheless may be a public use within the meaning of the law. After all, the general public does not have access to an implanted medical device. Obviously, drugs are not “accessible” to the general public. But for communication by the patient, the public generally has no knowledge of the invention.

C. WHETHER THERE WAS ANY CONFIDENTIALITY OBLIGATION IMPOSED ON PERSONS WHO OBSERVED THE USE

The imposition of a confidentiality obligation on persons who observe the use is an extremely important factor. Recall that one policy underlying the public use bar is that it prohibits the removal from the public domain of inventions the public has been led to believe belong in the public domain.¹⁰⁴ If a person is obligated under a confidentiality agreement to keep the invention secret, this forms a solid basis that no reasonable person under such a confidence could believe he was free to use the invention. If the very nature of experimental or non-public use is the lack of publicity, then “the presence or absence of a secrecy agreement appear[s] to carry the most weight.”¹⁰⁵ If an obligation of confidentiality is important, then how can this

103. *Manville Sales*, 917 F.2d at 551.

104. See *supra* notes 94-97 and accompanying text.

105. *Articulate Sys. Inc. v. Apple Computer, Inc.*, 53 F. Supp.2d 62, 76 (D. Mass. 1999) (citing *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1266, 229 U.S.P.Q. 805 (Fed. Cir. 1986) and *TP Labs. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 972, 220 U.S.P.Q. 577, 593 (Fed. Cir. 1984)).

obligation be proved? Generally, the inventor's subjective intent of experimental use is not given as much weight as objective evidence.¹⁰⁶ In some instances, though, the subjective intent can trump documentary evidence.¹⁰⁷ Subjective intent can be demonstrated by inventor expectations. The district court in *System Management* recently indicated that an expectation of confidentiality (versus an express confidentiality agreement) may be relevant.¹⁰⁸ Cases are opposed on whether confidentiality agreements must be express or implied.¹⁰⁹

For example, in *Netscape*, the court placed great emphasis on the lack of confidentiality.¹¹⁰ In this case, the inventor worked for a laboratory near Berkeley, California.¹¹¹ He submitted an invention disclosure record to his company's patent department.¹¹² Because the nature of the invention involved remotely accessing a computer database, the inventor showed his invention to computing personnel at the University of California (Berkeley).¹¹³ The court noted that the inventor failed to inform the Berkeley personnel of any expectation of confidentiality.¹¹⁴ Moreover, he did not inform them that he submitted an invention disclosure record to his patent department.¹¹⁵ Accordingly, he made no effort to indicate to the users that a general confidentiality expectation existed or that the attendees owed a more specific duty of confidentiality to the

106. *Harrington Mfg. Co. v. Powell Mfg. Co.*, 815 F.2d 1478, 1481 n.3, 2 U.S.P.Q.2d 1364, 1366 n.3 (Fed. Cir. 1986). The court further points to *In re Smith*, 714 F.2d 1127, 1135, 218 U.S.P.Q. 976, 983 (Fed. Cir. 1983) (noting that in determining whether the use is experimental, objective evidence is preferred and the inventor's subjective intent is generally of minimal value). While some courts may state that subjective intent is of minimal value, many courts still state that the intended purpose of the use is a factor to consider, which resurrects a possible subjective intent inquiry.

107. *Moxness Prods. Inc. v. Xomed Inc.*, 891 F.2d 890, 892, 13 U.S.P.Q.2d 1169, 1171 (Fed. Cir. 1989).

108. *Sys. Mgmt. Arts v. Avesta Techs. Inc.*, 87 F. Supp. 2d 258, 268 54 U.S.P.Q.2d 1239 (S.D.N.Y. 2000).

109. *Compare Moleculon Research*, 793 F.2d at 1266 (finding implied confidentiality when disclosure made to colleagues), *with Nordberg Inc. v. Telsmith Inc.*, 881 F. Supp 1252, 1288-89, 36 U.S.P.Q.2d 1577, 1607 (E.D. Wis. 1995) (finding no implied confidentiality).

110. *Netscape Communications Corp. v. Konrad*, 295 F.3d 1315, 1321, 63 U.S.P.Q.2d 1580 (Fed. Cir. 2002).

111. *Id.* at 1318.

112. *Id.* at 1321.

113. *Id.*

114. *Id.*

115. *Id.*

inventor.¹¹⁶

To add further emphasis to the lack of confidentiality, the court specifically noted, "In some circumstances . . . it would be significant that no pledge of confidentiality was obtained from the user.' . . . Lack of a confidentiality agreement is significant [in this case] because [the users] were [Berkeley] computer personnel who could easily demonstrate the invention to others."¹¹⁷

In addition, the court stated categorically that because Konrad was the inventor, any limitations, restrictions, or obligations of secrecy of others using the inventions was owed to Konrad, not to persons or entities funding the activities.¹¹⁸ The onus was on the inventor to protect the confidentiality of the invention.¹¹⁹

Tempering this weight given to confidentiality, in *Allied Colloids*, the district court found the absence of a written confidentiality agreement between Colloids and the City of Detroit particularly important.¹²⁰ The Federal Circuit, however, stated:

Although a written promise of confidentiality is a factor to be considered in appropriate circumstances, such as when persons other than the patentee conduct the experiments . . . the absence of such a promise does not make a use "public" as a matter of law, or outweigh the undisputed fact that no information of a confidential nature was communicated to others.¹²¹

Therefore, the existence of an express or implied confidentiality agreement is merely another factor to be considered.

In yet another case related to patient use, in *MSM Investments Co. v. Carolwood Corp.*,¹²² the court noted that patients were properly informed about the drug they were taking, the inventor did not control the treatments, and no

116. *Id.*

117. *Id.* (quoting *TP Labs. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 220 U.S.P.Q. 577 (Fed. Cir. 1984)) (omission in original quote).

118. *Netscape*, 295 F.3d at 1322-23.

119. *Id.* at 1323.

120. *Allied Colloids, Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1573-74, 35 U.S.P.Q.2d 1840 (Fed. Cir. 1995).

121. *Id.* at 1576; see also *Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529, 1535, 222 U.S.P.Q. 553, 557 (Fed. Cir. 1984); *TP Labs.*, 724 F.2d at 971-72; *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1266, 229 U.S.P.Q. 805 (Fed. Cir. 1986).

122. *MSM Inv. Co. v. Carolwood Corp.*, 70 F.Supp.2d 1044 (N.D. Cal. 1999).

confidentiality existed between the inventor and the patients.¹²³ Accordingly, the court found a public use.¹²⁴ But in *TP Laboratories, Inc. v. Professional Positioners, Inc.*, the Federal Circuit gave no weight to the lack of confidentiality limitations because there was little probability that the dental patient would demonstrate the inventive dental implant to anyone.¹²⁵ Furthermore, the court attached no importance to the lack of a confidentiality pledge.¹²⁶ The *TP Laboratories* court reasoned that, obviously, for an implanted device such as this dental implant, the patient will be exposed to it.¹²⁷ As a matter of law, this exposure alone cannot convert this implantation into a public use.¹²⁸ It is difficult to reconcile *MSM* with *TP Laboratories* because on the one hand, the courts suggest that the inventor must have a confidentiality agreement with not only the doctor, but also the patients.¹²⁹ On the other hand, the lack of confidentiality agreements with patients receiving dental implants played no dispositive role.¹³⁰

In *Moleculon Research v. CBS*, confidentiality was again at issue.¹³¹ In this infringement action, the court noted that the inventor had maintained control over his invention.¹³² Because he shared personal relationships with those to whom he showed the invention, the court noted that this further

123. *See id.* at 1053 (explaining that Carolwood made out a prima facie case of “public use” and that *MSM* did not offer any evidence to negate that showing).

124. *Id.*

125. *TP Labs.*, 724 F.2d at 972, 220 U.S.P.Q. at 593.

126. *Id.*

127. *Id.*

128. *Id.*

129. *MSM*, 70 F.Supp.2d at 1053.

130. *TP Labs.*, 724 F.2d at 972.

131. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1265-66, 229 U.S.P.Q. 805 (Fed. Cir. 1986). In this case, the Rubik’s cube puzzle inventor initially made paper models of the cube puzzle. *Id.* at 1263. His two roommates and a colleague in his class saw the paper model of the cube puzzle while visiting him in his room. *Id.* Later, while working for Moleculon, the company president entered the inventor’s office and saw the inventor’s new wooden prototype. *Id.* The president and the inventor talked about the cube puzzle and the president offered to commercialize it. *Id.* The inventor agreed, assigning all his rights to Moleculon in return for a share of any proceeds. *Id.* Thereafter, Moleculon contacted various toy companies to commercialize it but did not succeed in marketing the cube puzzle. *Id.* The inventor eventually filed a patent application on behalf of Moleculon in 1970, and a patent was issued on April 11, 1972. *Id.*

132. *Id.* at 1266.

demonstrated control over the invention.¹³³ The court characterized the inventor's use as "private and for his own enjoyment."¹³⁴ The court specifically noted that even though no confidentiality agreement existed between the inventor and the president, the presence or absence of any such agreement was not determinative, as it was but one factor to weigh in the multifactor test.¹³⁵

In summary, the nature of public use involves the indiscriminant publicity surrounding the use. Confidentiality agreements (whether express or implied) satisfy three goals: (i) informing the immediate user that he is not free to divulge the invention and he ought not have any belief that the invention is public; (ii) proving, as part of the totality of the circumstances, that the inventor did not intend to relinquish confidentiality in the invention; and that (iii) preferably, a document exists to corroborate any oral testimony that the use was not public.¹³⁶

D. WHETHER PROGRESS RECORDS OR OTHER INDICIA OF EXPERIMENTAL ACTIVITY WERE KEPT.

If the patentee claims an experimental use, it must be corroborated by documentary evidence. The inventor must maintain control over the testing.¹³⁷ The inventor must have controlled the experiments in order for the court to find an experimental use.¹³⁸ This is because experimentation implies that the experimenter cares about, and is searching for, some results. These results could be failures or successes. In searching for these results, the experimenter has most likely determined the means for the search. That is, running experiments would involve choosing the materials, the location

133. *Id.*

134. *Id.*

135. *Id.*

136. *See infra* note 142 and accompanying text (regarding written corroboration of oral testimony).

137. *Lough v. Brunswick Corp.*, 103 F.3d 1517, 1526, 41 U.S.P.Q.2d 1385, 1393 (Fed. Cir. 1997) (declining suggestion for rehearing *en banc*) (Michel, J., dissenting); *Paragon Podiatry Lab., Inc. v. KLM Lab. Inc.*, 984 F.2d 1182, 1187, 25 U.S.P.Q.2d 1561, 1565 (Fed. Cir. 1993); *see also*, William C. Rooklidge & Stephen C. Jensen, *Common Sense, Simplicity and Experimental Use Negation of the Public Use and On Sale Bars to Patentability*, 29 J. MARSHALL L. REV. 1, 30 n.144 (1995) (listing, non-exhaustively, the circumstances relevant to experimental use determination and noting that "the Federal Circuit does not require the lower tribunal to review each factor").

138. *Zacharain v. United States*, 43 Fed. Cl. 185, 192, 51 U.S.P.Q.2d 1493 (1999).

of the tests, the number of tests to run, any control groups required, any recording instruments needed, and may also include a hypothesis about what form the results may take. Accordingly, after all this intellectual energy is spent conceiving the testing conditions, coupled with the physical energy spent performing the tests, it makes no reasonable sense that an experimenter would not monitor the tests or record the results. Rather, it is perfectly logical that the courts would require documentary evidence of putative experimental use. These documents would corroborate the existence of the intellectual and physical energies expended.¹³⁹

Furthermore, if one purpose of experimental use is to determine whether the invention is perfected, then surely documentation is necessary to show why changes to experimental protocols or to the product, if any, were made. The documentation may also corroborate why changes were not made. Improvements or alterations, if any, should be documented so that successes or failures, analyses of results, and reasons therefore can be documented. Requiring documentation answers the ultimate question of whether the invention has been perfected.

But the question remains as to how much documentation is required to support a finding of experimental use. Does the quantity of the documentation depend on the simplicity of the tests or of the invention? If the product needs to be clinically safe, then is more documentation required to corroborate the experimental use? If the FDA approval process requires documentation during the clinical trial, does merely complying with the FDA requirements *ipso facto* mean that the FDA documentation will satisfy this prong of the public use-experimental use test? FDA rules require documentation to prove the safety and efficacy of the drug or device. Once approved, the company may begin interstate marketing. Here, though, the FDA approval can be based on a final product that is already fully tested and commercially, which is in turn based on early prototypical devices, such that approval is necessary to even begin clinical testing, or some intermediate. But again, recall that the invention that is tested in clinical trials may be generations later than what could have been patented (or applied for in an application) in earlier development

139. See e.g., 21 C.F.R. § 814.20 (2002) (requirements of the new device application to include documentation); 21 C.F.R. § 860.7 (2002) (for proving safety and efficacy).

generations. Accordingly, many applicable FDA laws could have little or no impact on the public use of an early stage invention. That is, the public use of an early stage prototype may occur and bar the patent even before any relevant FDA laws regarding record-keeping could be invoked.

Several cases determined experimental use despite a lack of formal record-keeping on the testing.¹⁴⁰ But if written records are not necessary, then what weight is given to the testimony? Can oral testimony alone support a public use change? Generally, oral testimony of prior public use must be corroborated in order to invalidate a patent.¹⁴¹

Written corroboration of oral testimony played an important role in *Juicy Whip, Inc., v. Orange Bang, Inc.*¹⁴² Juicy Whip owned a patent on aesthetically pleasing drink dispensers.¹⁴³ The trial court below invalidated the patent.¹⁴⁴ On appeal, Juicy Whip proffered two different reasons as to why the district court's ruling of invalidity ought to be reversed.¹⁴⁵ First, it argued that the prior art dispensers did not include all the claim limitations. Second, it argued that the oral testimony provided by the *six* witnesses was uncorroborated, and thus did not rise to the clear and convincing evidence necessary to establish a prior public knowledge or use.¹⁴⁶ In response, Orange Bang (the accused infringer) argued that the invalidity verdict was supported by substantial evidence and that its evidence of prior public use need not be completely corroborated by documentation.¹⁴⁷

To prove invalidity, Orange Bang had to prove that each

140. *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 969, 971-72, 220 U.S.P.Q. 577 (Fed. Cir. 1984) (finding experimental use, even though records were scanty at best, and noting that determination of experimental use can only be made on consideration of the whole facts, *including* whether records were kept); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 551, 16 U.S.P.Q.2d 1587 (Fed. Cir. 1990) (finding experimental use with single memorandum of intent to experiment but no records of testing).

141. *See Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1366-68, 51 U.S.P.Q.2d 1001, 1010-11 (Fed. Cir. 1999) ("The law has long looked with disfavor upon invalidating patents on the basis of mere testimonial evidence absent other evidence that corroborates that testimony.").

142. *Juicy Whip, Inc., v. Orange Bang, Inc.*, 292 F.3d 728, 63 U.S.P.Q.2d 1251 (Fed. Cir. 2002).

143. *Id.* at 731-34.

144. *Id.* at 731.

145. *Id.*

146. *Id.*

147. *Id.*

element of the claim was taught in the prior art dispensers.¹⁴⁸ But Orange Bang failed to show an element-by-element comparison between the 1983 and 1988 dispensers and patent claims.¹⁴⁹ The court reviewed the record and concluded that no reasonable juror could have found that Orange Bang established that the 1983 and 1988 prior art dispensers anticipated the claims.¹⁵⁰ In observing the absence of some claimed elements from the prior art, the court noted that most of the testimony consisted of oral testimony. By examining the seminal *Barbed Wire Patent* case, the court also noted the historical reservation toward invalidating a patent based on uncorroborated oral testimony.¹⁵¹

In *The Barbed Wire Patent*,¹⁵² the Supreme Court commented on the dangers of invalidating a patent on oral testimony alone:

In view of the unsatisfactory character of such testimony, arising from the forgetfulness of witnesses, their liability to mistakes, their proneness to recollect things as the party calling them would have them recollect them, aside from the temptation to actual perjury, courts have not only imposed upon defendants the burden of proving such devices, but have required that the proof shall be clear, satisfactory and beyond a reasonable doubt. Witnesses whose memories are prodded by the eagerness of interested parties to elicit testimony favorable to themselves are not usually to be depended upon for accurate information.¹⁵³

The *Barbed Wire Patent* case involved a dispute over the novelty of a patent owned by Glidden for barbed wire.¹⁵⁴ Twenty-four witnesses testified that they saw an anticipating barbed wire fence (the Morley Fence) exhibited at a county fair in 1859.¹⁵⁵ The witnesses included a boy who had been thrown against the fence and cut by the extruding barbs; a deputy marshal who hitched his horse to a fence post near the barbed wire fence and returned to find the horse's nose and breast bloodied by the barbs; and a fair attendee named Potter who saw an exhibit of the fence and was given a sample of the wire by Morley.¹⁵⁶ Potter testified that he kept the sample in a

148. *Id.* at 738.

149. *Id.*

150. *Id.*

151. *Id.* at 740.

152. 143 U.S. 275 (1892).

153. *Id.* at 284.

154. *Id.* at 285.

155. *Id.* at 287.

156. *Id.* at 286-87.

trunk for more than ten years and then produced the sample at trial.¹⁵⁷ Potter's son, however, testified for the patentee and contradicted his father's testimony, saying that no such barbed wire was kept in the trunk.¹⁵⁸ The patentee also presented evidence including two copies of a journal that listed the notice of the fair, but did not mention Morley or his fence. The district court discounted that evidence and the testimony from the patentee's witnesses who attended the fair but had seen "nothing of the Morley fence."¹⁵⁹ The district court determined that it was unlikely that all twenty-four witnesses were lying and accordingly declared the patent invalid.¹⁶⁰ Despite the testimony of twenty-four witnesses and the credibility determinations made by the trial court, the Supreme Court reversed, reasoning that:

The very fact . . . that almost every important patent, from the cotton gin of Whitney to the one under consideration, has been attacked by the testimony of witnesses who imagined they had made similar discoveries long before the patentee had claimed to have invented his device, has tended to throw a certain amount of discredit upon all that class of evidence, and to demand that it be subjected to the closest scrutiny.¹⁶¹

Per the high threshold announced in *Eibel Process*,¹⁶² the Court of Customs and Patent Appeals, in *In re Reuters*, enumerated a list of factors to evaluate the credibility of any oral testimony.¹⁶³ They include:

- (1) delay between event and trial,
- (2) interest of witness,
- (3)

157. *Id.* at 287.

158. *Id.* at 289.

159. Washburn & Moen Mfg. Co. v. Beat 'Em-All Barb-Wire Co., 33 F. 261, 270-71 (C.C.N.D. Iowa 1888).

160. *Id.* at 272 ("Not only is there an entire lack of evidence to show that such a nefarious plan had been undertaken, but no motive can be conceived of, that would induce so large a number of well-known persons to engage in such a conspiracy.").

161. *The Barbed Wire Patent*, 143 U.S. at 284-85. The Supreme Court in *Eibel Process* later clarified that the high standard of proof required when using oral testimony to prove prior public use was not "beyond a reasonable doubt" as stated in *The Barbed Wire Patent*, but was, nevertheless, a *high threshold*. See *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45, 60 (1923) ("The temptation to remember in such cases and the ease with which honest witnesses can convince themselves after many years of having had a conception at the basis of a valuable patent, are well known in this branch of law, and have properly led to a rule that evidence to prove prior discovery must be clear and satisfactory.").

162. See *Eibel Process*, 261 U.S. at 60.

163. See *In re Reuter*, 670 F.2d 1015, 1021 & n.9, 210 U.S.P.Q. 249, 255 & n.9 (C.C.P.A. 1981).

contradiction or impeachment, (4) corroboration, (5) witnesses' familiarity with details of alleged prior structure, (6) improbability of prior use considering state of the art, (7) impact of the invention on the industry, and (8) relationship between witness and alleged prior user.¹⁶⁴

The Federal Circuit analyzes this corroboration requirement using a "rule of reason" analysis.¹⁶⁵

The *Juicy Whip* court then discussed other cases in which the written corroboration of oral testimony regarding prior public use played a role. For example, in *Woodland Trust v. Flowertree Nursery, Inc.*,¹⁶⁶ the Federal Circuit reversed a finding of prior public knowledge and use based solely on uncorroborated oral testimony.¹⁶⁷ There, the patentee owned a method patent for protecting plants from freezing temperatures.¹⁶⁸ The infringer presented the oral testimony of four interested witnesses (as opposed to non-interested witnesses) that the protection method was previously known and used by each of Joseph Burke and William Hawkins at their respective nurseries in Florida.¹⁶⁹ Hawkins' son testified that his father's nursery was destroyed by a tornado in 1978 and not rebuilt until after the patent issued.¹⁷⁰ Burke testified that he used the patented system, but tore it down in 1976.¹⁷¹ In endorsing the testimony and thus finding the patent invalid, the district court stated "to discredit those witnesses in this case the court would be obliged to conclude that all four were deliberate perjurers."¹⁷² But the Federal Circuit reversed and held that that "uncorroborated oral testimony, particularly that of interested persons recalling long-past events, does not, of itself, provide the clear and convincing evidence required to invalidate a patent on this ground."¹⁷³ Specifically, the Federal Circuit stated that on the facts presented, in view of the lack of documents to corroborate and the length of time between the

164. *Id.* (citing *E.I. du Pont de Nemours & Co. v. Berkeley & Co.*, 620 F.2d 1247, 1261 n.20, 205 U.S.P.Q. 1, 11 n.20 (8th Cir. 1980)).

165. *Price v. Symsek*, 988 F.2d 1187, 1195, 26 U.S.P.Q.2d 1031, 1037 (Fed. Cir. 1993).

166. *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 47 U.S.P.Q.2d 1363 (Fed. Cir. 1998).

167. *Id.* at 1373.

168. *Id.* at 1369.

169. *Id.* at 1369-70.

170. *Id.* at 1369.

171. *Id.*

172. *Id.* at 1370.

173. *Id.* at 1369.

invalidating activities and the trial, the oral evidence alone was insufficient to invalidate the patent.¹⁷⁴

The Federal Circuit also paid close attention to the realities of modern times, noting that “the ubiquitous paper trail of virtually all commercial activity” is present.¹⁷⁵ Rarely will there be a lack of some physical records “(e.g., a written document such as notes, letters, invoices, notebooks, or a sketch or drawing or photograph showing the device, a model, or some other contemporaneous record).”¹⁷⁶

The *Juicy Whip* court then analyzed *Finnigan Corp. v. International Trade Commission*,¹⁷⁷ in which the court held that concerns regarding corroboration are not limited to “interested” witnesses.¹⁷⁸ In *Finnigan*, the patent claimed a method for using a “quadruple ion trap” to generate a mass spectrum of a trapped sample.¹⁷⁹ The Federal Circuit held that the claim required the use of a nonresonance ejection.¹⁸⁰ The Commission determined that an uninterested witness named Jefferts had used the claimed invention.¹⁸¹ Jefferts authored an article that taught each element except for the nonresonance ejection.¹⁸² Although this element was absent from his article, he testified he practiced the entire claimed invention including the nonresonance ejection limitation more than one year before Finnigan’s filing date.¹⁸³ In the litigation, Jefferts’s oral testimony was the only evidence of the missing nonresonance ejection limitation.¹⁸⁴ The Federal Circuit reversed the Commission, holding that under the circumstances of the case before it, the oral testimony alone was insufficient to establish prior public use.¹⁸⁵

In the end, what we are left with is Jefferts’ testimony concerning his alleged public use. Such evidence is insufficient as a matter of law to establish invalidity of the patent. This is not a judgment that

174. *Id.* at 1373.

175. *Id.*

176. *Id.*

177. *Finnigan Corp. v. Int’l Trade Comm’n*, 180 F.3d 1354, 51 U.S.P.Q.2d 1001 (Fed. Cir. 1999).

178. *Id.* at 1367-69.

179. *Id.* at 1357.

180. *Id.* at 1364.

181. *Id.* at 1360-61.

182. *Id.*

183. *Id.* at 1364-66.

184. *Id.* at 1365.

185. *Id.* at 1370.

Jefferts' testimony is incredible, but simply that such testimony alone cannot surmount the hurdle that the clear and convincing evidence standard imposes in proving patent invalidity.¹⁸⁶

After reviewing these oral testimony cases, the *Juicy Whip* court determined that Orange Bang's evidence of prior public use did not surmount the clear and convincing evidence hurdle.¹⁸⁷ Applying the *Reuter's* factors,¹⁸⁸ the court determined that: (1) "the testimony about the 1983 and 1988 dispensers came more than eight and twelve years, respectively, after the witnesses saw the dispensers;"¹⁸⁹ (2) "Cretella, the only witness to use the dispensers to serve drinks in public, kept the 1983 dispenser for only one month and the 1988 dispenser for less than three months;"¹⁹⁰ and (3) the six witnesses were interested witnesses: two were defendants in the case, one was an operations manager for the defendant, and one had a relationship with the brother-in-law of one witness.¹⁹¹

Even though one document was proffered to corroborate the oral testimony, this document was not even made until the litigation started and was certainly not made contemporaneously with the public use.¹⁹²

One must remember that the written corroboration of oral testimony rule does not mean that witnesses are not credible *per se*.¹⁹³ Rather, to prove invalidity by public use, it is prudent to have or secure as much documentation as one can.

Finally, a parallel may be drawn between proving inventorship and the requirement that inventorship be corroborated. In certain instances, proving who invented first

186. *Id.* at 1370 (citing *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577, 38 U.S.P.Q.2d 1288, 1291 (Fed. Cir. 1996) (noting that the corroboration rule "provides a bright line for both district courts and the PTO to follow")).

187. *Juicy Whip, Inc., v. Orange Bang, Inc.*, 292 F.3d 728, 743, 63 U.S.P.Q.2d 1251 (Fed. Cir. 2002).

188. *See supra* text accompanying note 164.

189. *Juicy Whip*, 292 F.3d. at 743.

190. *Id.*

191. *Id.* (citing *Oney v. Ratliff*, 182 F.3d 893, 896, 51 U.S.P.Q.2d, 1697, 1700 (Fed. Cir. 1999) ("The uncorroborated oral testimony of [the accused infringer], as the inventor, and his close associates would be insufficient to prove invalidity.")).

192. *Id.* (citing *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1350-51, 60 U.S.P.Q.2d 1091, 1094 (Fed. Cir. 2001). "Documentary or physical evidence that is made contemporaneously with the inventive process provides the most reliable proof that the inventor's testimony has been corroborated." *Id.* (citing *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1373, 47 U.S.P.Q.2d 1363 (Fed. Cir. 1998))).

193. *See id.*

can be dispositive of who is entitled to the patent.¹⁹⁴ Accordingly, competing inventors will each “prove” that he was the first inventor. The Federal Circuit has stated that a party claiming his own prior inventorship must proffer evidence corroborating his testimony.¹⁹⁵ “This rule addresses the concern that a party claiming inventorship might be tempted to describe his actions in an unjustifiably self-serving manner in order to obtain a patent or to maintain an existing patent.”¹⁹⁶ Corroborating documentary or physical evidence that is made contemporaneously with the inventive process provides the most reliable proof that the inventor’s testimony has been corroborated.¹⁹⁷ Because documentary or physical evidence is created at the time of conception or reduction to practice, the risk of litigation-inspired fabrication or exaggeration is mitigated. In contrast to contemporaneous documentary evidence, however, post-invention oral testimony is more suspect, as there is more of a risk that the witness may have a litigation-inspired motive to corroborate the inventor’s testimony, and that the testimony may be inaccurate.¹⁹⁸

By analogy, therefore, if an inventor has to proffer documents to show that he actually invented something, when he invented it, and the circumstances surrounding that invention conception, it stands to reason that an inventor claiming to experimentally use his invention ought to be held to the same standard of documentary proof. The same concerns about fabricating or exaggerating the inventorship process equally apply to concerns about how an inventor may try to fabricate or exaggerate experimental use. It should be noted that the argument for documents is not that documentary evidence is a necessary requirement and that the failure to produce such documents necessarily leads to an irrebutable presumption of public use.¹⁹⁹ Rather, independent

194. 35 U.S.C. § 102(g) (2000).

195. *Price v. Symsek*, 988 F.2d 1187, 1194, 26 U.S.P.Q.2d 1031, 1036 (Fed. Cir. 1993).

196. *Singh v. Brake*, 222 F.3d 1362, 1367, 55 U.S.P.Q.2d 1673, 1676 (Fed. Cir. 2000) (citing *Kridl v. McCormick*, 105 F.3d 1446, 1450, 41 U.S.P.Q.2d 1686, 1689 (Fed. Cir. 1997) (“The tribunal must also bear in mind the purpose of corroboration, which is to prevent fraud, by providing independent confirmation of the inventor’s testimony.”)).

197. *See Woodland Trust*, 148 F.3d at 1371-73.

198. *Id.*

199. *Loral Fairchild Corp. v. Matsushita Elec. Indus. Co.*, 266 F.3d 1358, 1364, 60 U.S.P.Q.2d 1361, 1365-66 (Fed. Cir. 2001).

corroboration of the experimental use is necessary and that documents can provide this independent corroboration.²⁰⁰

Accordingly, in the clinical trial or medical testing contexts, documentation of any testing would be absolutely critical to support any contention of experimentation. Oral testimony of the subjective intent of the inventor, as shown in this section, is fraught with peril. Using *The Barbed Wire* case and others as a guide, it would appear that even many witnesses orally testifying would still not be enough, without some shred of written documentation to corroborate the oral testimony.²⁰¹

E. WHETHER PERSONS OTHER THAN THE INVENTOR OR ACTING FOR THE INVENTOR CONDUCTED THE EXPERIMENTS

Relying on the theories above, maintaining the integrity of the experiments is critical. The experimenters maintain integrity by doing the experiments themselves or maintaining adequate control over third party facilitators. Because the very nature of experimentation implies concern about the tests, it makes sense that the inventor – if he is not conducting the tests himself – will surveil the facilitators. After all, it is the inventor’s contemplation of the invention that counts, not what the facilitators contemplate. The inventor must surveil because once the invention works for its intended purpose, continued use could transform otherwise non-barring experimental use into patent barring public use.²⁰² If the inventor fails to maintain control, the progress from experimental use into public use will occur unbeknownst to the inventor. Accordingly, many cases turn on whether a third party was controlled by the inventor.

For example in *Netscape Communications Corp. v. Konrad*,²⁰³ the invention involved remotely accessing computer databases.²⁰⁴ Thus, the invention actually “resided” at more than one location. In *Netscape*, the inventor lacked any control over the users.²⁰⁵ Although the inventor argued that any users were experimenters, the court noted that all the inventor did

200. *See id.*

201. *See supra* note 152-153 and accompanying text.

202. *See infra* Part V.F.

203. *Netscape Communications Corp. v. Konrad*, 295 F.3d 1315, 63 U.S.P.Q.2d 1580 (Fed. Cir. 2002).

204. *Id.* at 1318.

205. *Id.* at 1322.

was turn on the machine and let users use the machine.²⁰⁶ There was nothing to control who used the machine, what those users did with the machine, and what the users could say or do after using the machine.²⁰⁷ In other words, the inventor invited public use of the machine. Therefore, *Netscape* is an example where the inventor lacked any control over the invention.

In *MSM Investments Co. v. Carolwood Corp.*,²⁰⁸ the court noted that certain activities carried out in a health care clinic constituted a public use.²⁰⁹ In particular, the court noted that a third party doctor had administered the patented drug to patients in the clinic.²¹⁰ The doctor obtained the drug from the inventor but the inventor did not control the drug's subsequent use at the clinic.²¹¹ Thus, the patent was invalidated.²¹² This case is an example of how the lack of inventor control over the actual public user can jeopardize the patent rights. Here it was clear that the drug's inventor did nothing to monitor or control the experiments, hence, the experimental use shroud did not shield the in-clinic use.

In *C.R. Bard, Inc. v. M3 Systems, Inc.*,²¹³ in his concurrence on invalidity, Judge Bryson noted that the putative experiments were conducted at the purchaser's request, not by the inventor.²¹⁴ In fact, the purchaser assumed primary responsibility for the clinical trials and the inventor only maintained passing interest in the trials.²¹⁵ This demonstrated to Judge Bryson that there was no control over the trials and thus no experimentation occurred.²¹⁶

With respect to inventor control over the testing in *Lough v. Brunswick Corp.*,²¹⁷ the inventor selected friends and

206. *Id.*

207. *Id.*

208. *MSM Inv. Co. v. Carolwood Corp.*, 70 F. Supp. 2d 1044 (N.D. Cal. 1999).

209. *Id.* at 1053.

210. *Id.*

211. *Id.*

212. *Id.*

213. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 48 U.S.P.Q.2d 1225 (Fed. Cir. 1998); see also discussion of *C.R. Bard* *infra* note 317 and accompanying text.

214. *C.R. Bard*, 157 F.3d at 1379-80.

215. *Id.* at 1380.

216. *Id.* at 1379-81.

217. *Lough v. Brunswick Corp.*, 86 F.3d 1113, 39 U.S.P.Q.2d 1100 (Fed. Cir. 1996).

professional associates over whom he had control by virtue of their relationship.²¹⁸ Some Federal Circuit rulings allow as a substitute for full control an inventor to exert control through close relationships and notification of experimental purposes.²¹⁹ In *Lough*, the court noted that “Lough was free to test his invention in boats of friends and acquaintances . . . however, Lough was required to maintain some degree of control and feedback over those uses . . . to negate public use.”²²⁰ Therefore, Federal Circuit precedent shows that participation by others in the experiment does not equal a lack of control.²²¹

Although the above are examples of how a public user can trace its use to the inventor, not all public use cases involve the inventor or those in privity with the inventor. Often, the public user may be a third party totally unrelated or unknown to the inventor. The problem is determining how the inventor can protect himself from a third party use. That is, if the inventor and the third party do not even know of each other’s activities, how can the inventor protect himself? In short, he cannot. Third parties may create public uses that will invalidate a later inventor’s patent and there is simply nothing the later inventor can do about it.

For example, in *Baxter International, Inc. v. COBE Laboratories, Inc.*,²²² the issue was whether a third party use at the National Institutes of Health (“NIH”) in Bethesda, Maryland was a public use sufficient to invalidate an unrelated patent.²²³ In *Baxter*, a doctor at the NIH had a problem with a centrifuge device.²²⁴ The doctor contacted another engineer at

218. *Id.* at 1121.

219. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1265-66, 229 U.S.P.Q. 805, 808 (Fed. Cir. 1986); *see also* *LaBounty Mfg., Inc. v. United States Int’l Trade Comm’n*, 958 F.2d 1066, 1072, 22 U.S.P.Q.2d 1025, 1029 (Fed. Cir. 1992) (suggesting that notification of experimental purpose may substitute for control).

220. *Lough*, 86 F.3d at 1122.

221. *See* *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 972, 220 U.S.P.Q. 577, 583 (Fed. Cir. 1984) (“routine checking of [success of the invention] by one of the [inventor’s associates] does not indicate the inventor’s lack of control”); *see also* *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 840 F.2d 902, 906, 5 U.S.P.Q.2d 1788, 1792 (Fed. Cir. 1988) (submitting samples of the invention to food manufacturers for determination of the product’s utility was not inconsistent with experimentation).

222. *Baxter Int’l, Inc. v. COBE Labs. Inc.*, 88 F.3d 1054, 39 U.S.P.Q.2d 1437 (Fed. Cir. 1996).

223. *Id.* at 1056.

224. *Id.*

NIH and asked for help with design changes.²²⁵ The doctor utilized the comments and built a new centrifuge.²²⁶ The centrifuge worked properly for its intended purpose upon its construction.²²⁷ Others came to the doctor's lab at the NIH and saw the centrifuge in action, including co-workers who were not under any confidentiality duty.²²⁸ The doctor also did not make any efforts to keep the centrifuge a secret.²²⁹ The doctor's lab was a public building and the doctor knew that people could come in and out of the lab.²³⁰ No evidence was produced at trial that co-workers were "ethically bound" to keep the device a secret.²³¹ Furthermore, any modifications made by the doctor during the alleged experimental period were merely to fine-tune the centrifuge to his particular purposes, not to test the basic utility.²³² Hence, the NIH use was public.²³³

Meanwhile, Baxter later invented and patented the same invention, without knowledge of the NIH's prior public use.²³⁴ Baxter sued COBE for infringement but COBE defended on the grounds that Baxter's patent was invalid due to prior public use by the NIH doctors.²³⁵ Recognizing that this was a public use beyond Baxter's control, Baxter argued that the NIH doctor's (an admitted third party not related to Baxter in any way) activities were experimental and thus did not constitute a public use.²³⁶ That is, if Baxter could convert the NIH's public use into experimental use, then it would not be a public use sufficient to invalidate Baxter's patent. COBE argued that even though the doctor was a third party unrelated to any party in the litigation, the doctor's use was "by another" and constituted valid public use of the invention sufficient to invalidate the patent.²³⁷

225. *Id.*

226. *Id.*

227. *Id.*

228. *Id.* at 1058.

229. *Id.*

230. *Id.* at 1058-59.

231. *Id.* at 1059.

232. *Id.* at 1060.

233. *Id.* at 1061.

234. *Id.* at 1056.

235. *Id.* at 1056-57.

236. *Id.* at 1059-60.

237. *Id.* at 1059. Recall that 35 U.S.C. § 102(b) (2000) is not limited to public uses created by the inventor only because it contemplates public use "by another" as grounds to invalidate the patent. *See supra* text accompanying

The inventor of the Baxter patent lacked control over the NIH doctor, thus supporting the conclusion that the use was not experimental.²³⁸ Generally, experimental use is a personal (inventor) based defense, and the NIH doctor's use did not inure to the benefit of the Baxter inventor and did not support the underlying policies of public use.²³⁹ The court categorically held that

public testing before the critical date by a third party for his own unique purposes of an invention previously reduced to practice and obtained from someone other than the patentee, when such testing is independent of and not controlled by the patentee, is an invalidating public use, not an experimental use.²⁴⁰

Therefore, third party use of the invention by a totally unrelated party that qualifies as a public use can be used to invalidate the patent.

In *Evans Medical Ltd. v. American Cyanamid Co.*,²⁴¹ another third party use case, the court used the oft-cited totality of the circumstances test to determine if an invalidating public use occurred.²⁴² In *Evans Medical*, Evans, as the patentee, was trying to prove that a use by Takeda (another named defendant) was not public use within the meaning of § 102(b).²⁴³ The court noted that Takeda made no attempts to keep its use secret or experimental.²⁴⁴ The court noted that Takeda sold the drugs to a U.S. company for ¥1.4 million – evidently a commercial sale.²⁴⁵ The court noted the absence of confidentiality agreements between Takeda and the U.S. buyer.²⁴⁶ The claimed invention, a vaccine drug, was described in letters to the patients who were taking the vaccine drug, along with a history of the drug's clinical trials in Japan.²⁴⁷ There was no control over any subsequent U.S. testing and nothing to indicate that Takeda monitored any

note 9.

238. *Baxter*, 88 F.3d at 1060.

239. *Id.* at 1060-61.

240. *Id.*

241. *Evans Med., Ltd. v. Am. Cyanamid Co.*, 11 F. Supp. 2d 338 (S.D.N.Y. 1998), *aff'd*, 215 F.3d 1347, 52 U.S.P.Q.2d 1455 (Fed. Cir. 1999) (unpublished).

242. *Id.* at 366 (citing *Continental Plastic Containers v. Owens Brockway Plastic Prod., Inc.*, 141 F.3d 1073, 1077 (Fed. Cir. 1998)).

243. *Id.*

244. *Id.* at 366-67.

245. *Id.*

246. *Id.* at 367.

247. *Id.*

testing, even though Takeda was to be advised of any results.²⁴⁸ Finally, because Takeda had fully tested the drug in Japan, there was no practical reason to re-test it in the U.S. except to generate FDA approval data, thus indicating that patient trials in Japan did not give any reason to question why U.S. trials would produce different results.²⁴⁹ Thus, it was Takeda's use that caused the public use under § 102(b).

In *Marrese v. Richard's Medical Equipment, Inc.*,²⁵⁰ another health-care related third party public use case, the Seventh Circuit²⁵¹ rejected the patentees arguments that a use in the hospital setting was not a public use sufficient to invalidate the patentee's patent.²⁵² In this case, the public uses of the patented anesthesia masks were used in two separate hospitals over an extended period of time.²⁵³ The hospital uses were completely independent of the patentee's work.²⁵⁴

In yet another third party use case, *Petrolite Corp. v. Baker Hughes, Inc.*,²⁵⁵ Petrolite did not contest that the patented product was publicly used and sold prior to the critical date.²⁵⁶ "Rather, it argue[d] only that these pre-critical date uses and sales were experimental 'because the chemical was not known to work for its intended purpose and . . . the transaction[s] took place as part of a program of experimentation to determine if the chemical would work for that purpose.'"²⁵⁷

The relevant facts of this case follow. The invention

248. *Id.*

249. *Id.* at 367-68; see also Upadhye, *supra*, note 1, at 35-43 (indicating foreign clinical data can be used for U.S. FDA approval).

250. *Marrese v. Richard's Med. Equip., Inc.*, 504 F.2d 479, 183 U.S.P.Q. 517 (7th Cir. 1974) (retired Supreme Court Justice Tom Clark, sitting in designation and writing the opinion).

251. At the time, appeals from the district court involving patent infringement were appealed to the regional circuit court in which the district is located. Per the Federal Courts Improvement Act of 1982, Congress created the Federal Circuit Court of Appeals by merging the Court of Custom and Patent Appeals (C.C.P.A.) and the Court of Claims together. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982). The Federal Circuit is vested with exclusive jurisdiction over patent appeals from any district court or the U.S. Patent Office. *Id.*

252. *Marrese*, 504 F.2d at 482-483.

253. *Id.* at 481-82.

254. *Id.*

255. *Petrolite Corp. v. Baker Hughes, Inc.*, 96 F.3d 1423, 40 U.S.P.Q.2d 1201 (Fed. Cir. 1996).

256. *Id.* at 1426.

257. *Id.*

involved methods of reducing the amount of hydrogen sulphide – a corrosive and toxic gas – in oil and natural gas.²⁵⁸ The chemicals used in the methods “scavenge” the hydrogen sulphide out of the oil or gas.²⁵⁹ Concern arose whether the scavengers could work in cold pipes during cold weather.²⁶⁰ Quaker Petroleum Chemicals Co. was the initial assignee of the patent who then sold the patent rights to Petrolite.²⁶¹ Quaker’s inventors filed the patent application on December 23, 1988 and thus the critical date for analyzing public use was one year before, or December 23, 1987.²⁶² Quaker not only sold specialty chemicals to customers such as Sohio (Standard Oil Company of Ohio), but Quaker would also periodically deliver and install the chemicals directly at the Sohio site.²⁶³ Accordingly, the allegedly invalidating use was based on Quaker providing the chemical scavenger to the various Sohio owned wells and placing that scavenger in those wells. As the gas was being pumped, the scavenger would treat the gas and thus perform the claimed method. Quaker charged Sohio for this scavenger. Thus, Baker argued that it was Quaker’s prior public use that invalidated Petrolite’s patent.

Because a *prima facie* case of public use had been shown, “[t]he burden was on [Petrolite] to present some evidence that would raise a genuine issue of material fact over [the] allegation of experimental use.”²⁶⁴ “To establish that an otherwise public use or sale does not run afoul of § 102(b), it must be shown that the activity was ‘substantially for purposes of experiment.’”²⁶⁵ “Thus, Petrolite had to present admissible evidence raising a genuine issue of material fact that ‘the primary purpose of the work was experimental.’”²⁶⁶

In support of the validity argument, “Petrolite argue[d] that the reaction product had not been shown to work for its

258. *Id.* at 1424-25.

259. *Id.*

260. *Id.*

261. *Id.* at 1425.

262. *Id.*

263. *Id.* at 1427.

264. *Id.* at 1426 (alteration in original) (quoting *Sinskey v. Pharmacia Ophthalmics, Inc.*, 982 F.2d 494, 497, 25 U.S.P.Q.2d 1290, 1292 (Fed. Cir. 1992)).

265. *Id.* (quoting *Sinskey*, 982 F.2d at 498 (quoting *Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1564, 4 U.S.P.Q.2d 1210, 1214 (Fed. Cir. 1987))).

266. *Id.* (quoting *Baker Oil Tools*, 828 F.2d at 1563).

intended purpose prior to the [December 23, 1987] critical date because the inventors were still testing it to make sure that it would not form solids as a by-product.²⁶⁷ But the undisputed evidence was that, at least 20 days prior (December 3, 1987) Quaker made the successful formulation to reduce the amount of hydrogen sulfide to acceptable levels in its intended environment, even in cold weather. Thus, the patent was invalidated because a third party public use of the invention was involved.²⁶⁸

In contrast, *Manville Sales Corp. v. Paramount Systems, Inc.*,²⁶⁹ held that determining whether an invention is “operable for its intended purpose in its intended environment” is not a statutory public use.²⁷⁰ In that case, the district court found that the patent at issue was not invalid because of the on sale or public use bar.²⁷¹ The *Manville* court affirmed, noting that the patentee “did nothing to lead the public to believe that its . . . invention was in ‘the public domain;” that the patentee “did not attempt to extend the patent term by commercially exploiting its invention more than one year before it filed a patent application” and that the patentee’s actions were “entirely consistent with the policy ‘favoring prompt and widespread disclosure of inventions.’”²⁷² On appeal, the Federal Circuit noted that the invention was “specifically designed to withstand year around weather,” and as such, “[p]rior to testing in the winter environment, there really was no basis for confidence by the inventor that the invention would perform as intended, and hence no proven invention to disclose.”²⁷³

In *Petrolite*, though, Quaker had used and tested its invention in its intended environment and determined that it worked.²⁷⁴ There was no evidence in the record that the invention clogged the pipes or lost effectiveness at eliminating hydrogen sulfide in very cold temperatures.²⁷⁵ Rather, there was only subjective evidence that the inventors were not

267. *Id.* at 1427.

268. *Id.*

269. *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 16 U.S.P.Q.2d 1587 (Fed. Cir. 1990).

270. *Id.* at 551.

271. *Id.* at 549.

272. *Id.* at 550.

273. *Id.*; see also *Petrolite*, 96 F.3d at 1427.

274. *Petrolite*, 96 F.3d at 1427.

275. *Id.*

completely satisfied that the invention would be free of any such defects. Thus, the court rejected Petrolite's subjective theories that a reduction to practice of a fully working chemical process was necessary. All that mattered was that the invention could be used in public for substantially its intended purpose.²⁷⁶

To support its subjective intent theories, Petrolite relied on a memorandum dated March 22, 1988 (nine months before the application filing date), to argue that "Quaker envisioned continued testing for weeks or months to determine whether the invention, W-3053, would cause solids to form and clog the system. But another Quaker memorandum indicated that it believed that it had a marketable product as of December 3, 1987" (one year and twenty days before the application filing date).²⁷⁷ Moreover, "the evidence showed that, even if the inventors felt that additional field tests were necessary to verify the invention's reliability, Quaker was sufficiently satisfied with it to promote and sell it to a number of customers."²⁷⁸ Petrolite's arguments to the contrary could not create a genuine issue of material fact. "The subjective belief of inventors . . . must be weighed against objective evidence which indicates otherwise."²⁷⁹ "Petrolite also argued, *inter alia*, that the district court erred in concluding that Quaker did not maintain exclusive control over the testing of W-3053."²⁸⁰ The Federal Circuit disagreed. The district court recognized that, "[w]hile control is not determinative, it is an important factor."²⁸¹

276. *Id.*

277. *Id.*

278. *Id.*

279. *Id.* (quoting *U.S. Env'tl. Prods., Inc. v. Westall*, 911 F.2d 713, 717, 15 U.S.P.Q.2d 1898, 1902 (Fed. Cir. 1990) (reasoning that "[I]f a mere allegation of experimental intent were sufficient, there would rarely if ever be room for summary judgment based on a true 'on sale' defense under 35 U.S.C. § 102(b)" citing *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1150, 219 U.S.P.Q. 13, 17 (Fed. Cir. 1983)); see also *Sinskey v. Pharmacia Ophthalmics, Inc.*, 982 F.2d 494, 499, 25 U.S.P.Q.2d 1290, 1294 (Fed. Cir. 1992) ("[A]fter-the-fact testimony of an inventor's subjective 'experimental intent' is entitled to minimal weight.").

280. *Petrolite*, 96 F.3d at 1427.

281. *Id.* (quoting *U.S. Env'tl. Prods., Inc.*, 911 F.2d at 717); see also *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1120, 39 U.S.P.Q.2d 1100, 1105 (Fed. Cir. 1996) ("The last factor of control is critically important, because, if the inventor has no control over the alleged experiments, he is not experimenting.").

In addition, the

evidence indicated that the security measures taken at the site were standard measures taken by Sohio [and were] not requirements imposed by Quaker. While these security measures may have been important to Quaker in deciding with whom it would do business, there was no evidence that Quaker required such measures. Moreover, there was no evidence that Quaker had entered into any secrecy agreement with Sohio, and Sohio officials testified that they were free to analyze the reaction product if they wished to do so. The district court also found that, although there was 'strong evidence' that Quaker regarded the product as experimental, there was no evidence that Quaker informed purchasers that the invention was experimental. The purchasers testified that the sales were ordinary commercial transactions. The experimental use doctrine operates in the inventor's favor to allow the inventor to refine his invention or to assess its value relative to the time and expense of prosecuting a patent application. If it is not the inventor or someone under his control or 'surveillance' who does these things, there appears to us no reason²⁸² why he should be entitled to rely upon them to avoid the statute.

"For example, Petrolite assert[ed] that 'it is noteworthy that Quaker substantially discounted the price charged for the chemical to compensate Sohio for the risk it was bearing on a '100% experimental' product.'" ²⁸³ That is, if the invention were experimental, why would one pay "full price" for it, not knowing if it would actually work? The Federal Circuit noted, however, "[a] patent owner may have created an on-sale bar despite losing money on a sale."²⁸⁴

With respect to inventor control as a safe harbor, experimental use requires a benefit to the inventor and any refinements must be made for the inventor's benefit. If a third party who is not under the inventor's control or surveillance creates the refinements, there is no reason to apply the experimental use defense because that party's refinements have nothing to do with the inventor.²⁸⁵

282. *Petrolite*, 96 F.3d at 1427-28. (In this case, Sohio's standard security measures would be protecting the site hardware and installation area, or fencing off the area. Sohio took no other security measures to ensure that the scavenger and claimed method were hidden from the public.) (quoting *In re Hamilton*, 882 F.2d 1576, 1581, 11 U.S.P.Q.2d 1890, 1894 (Fed. Cir. 1989)); see also *Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529, 1535, 222 U.S.P.Q. 553, 557 (Fed. Cir. 1984); *In re Smith*, 714 F.2d 1127, 1136, 218 U.S.P.Q. 976, 983 (Fed. Cir. 1983).

283. *Petrolite*, 96 F.3d at 1428.

284. *U.S. Envtl. Prods.*, 911 F.2d at 717.

285. *Baxter Int'l, Inc. v. COBE Labs. Inc.*, 88 F.3d 1054, 1060, 39

In summary, third party use – that is, non-inventor use – may create a public bar. The problem with this rule is that it becomes very difficult to protect the patent from the invalidity challenge because the patentee generally has no control over that third party's activities. In the medical field prior public use sufficient to invalidate the patent may exist without the inventor in question knowing about it. As identified above, control over others is extremely important and inventors must police others to ensure that such control exists. A medical company can get into serious public use bar trouble if the inventions are randomly distributed to others without supervision, if the others do experiments without reporting results to the inventor, or if the others design and run the clinical trials without consulting with the inventor.

F. HOW MANY TESTS WERE CONDUCTED

It stands to reason that as the number of tests conducted increases, the danger the invention may be perceived to exist in the public domain increases. It also follows that the greater the number of tests conducted could mean that more tests than necessary were performed. Those extra tests could be considered unsheltered uses. In *Kinzenbaw v. Deere & Co.*,²⁸⁶ Deere used a prototype planter for 1400 hours in plantings in its own fields. Later, "Deere sought to test the warrantability, durability, and acceptability of the planter."²⁸⁷ Deere used its independent dealers to make the prototype available to farmers for further use. The farmers used the prototypes for 1,500 hours in 16 states, totaling 40,000 acres of use.²⁸⁸ The number of hours and total usage could be akin to running a large

U.S.P.Q.2d 1437 (Fed. Cir. 1996). The court observed that:

One of the policies underlying experimental use as a negation of public use is allowing *an inventor* sufficient time to test an invention before applying for a patent. "The experimental use doctrine operates in the inventor's favor to allow *the inventor* to refine his invention or to assess its value relative to the time and expense of prosecuting a patent application. If it is not the inventor or someone under his control or 'surveillance' who does these things, there appears to us no reason why he should be entitled to rely upon them to avoid the statute."

Id. (citing *In re Hamilton*, 882 F.2d at 1581) (emphasis in original) (internal citation omitted).

286. *Kinzenbaw v. Deere & Co.*, 741 F.2d 383, 222 U.S.P.Q. 929 (Fed. Cir. 1984).

287. *Id.* at 390.

288. *Id.*

number of tests. The Federal Circuit noted that Deere's only argument to defend against the public use charge was that the farmers' use was secret. The Federal Circuit noted that even if the use was secret, the commercial character made it public. The court specifically noted that although secrecy is one factor to determine if the use was experimental or public, secrecy alone does not negate public use.²⁸⁹ *Kinzenbaw* also could have argued the invention was adequately tested after 1400 hours and the later 1500 hours were unnecessary. While this case is not strictly about the number of tests conducted, this case does illustrate that an invention can be "secretly" used and still be considered a public use. By analogy, clinical trials often require hundreds, if not thousands, of tests.

Because certain inventions must last for extended periods of time, durability testing in the intended environment is also important. Testing durability is an appropriate consideration in experimentation where durability is an implicit feature of the invention. This is true even when that durability is not specifically claimed.²⁹⁰ To this end, most medical devices are claimed via structural claims and it is difficult to structurally claim a durability feature. For example, stents placed in neck arteries must withstand the constant rotational forces associated with normal neck movement. Of course, the stent must last for years. The structural component responsible for the improved stent may be a specific configuration of struts connecting adjacent stent wires. A claim to the stent would expressly claim the structural features of the stent struts, but only implicitly call out the durability feature of lasting for years. Accordingly, large scale testing, with repeat testing, may be necessary depending on the underlying invention.

G. THE SCALE OF THE TESTS COMPARED WITH COMMERCIAL CONDITIONS

Commercialization could be the death-knell of experimental use. Accordingly, an infringer would seek to characterize tests as commercial sales. Merely because experimentation occurs does not mean that the tests must be free to the test subject. Often in a clinical testing, the tested

289. *Id.*

290. *EZ Dock, Inc. v. Schafer Sys., Inc.*, 276 F.3d 1347, 1353, 61 U.S.P.Q.2d 1289, 1293 (Fed. Cir. 2002); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 550, 16 U.S.P.Q.2d 1587, 1592 (Fed. Cir. 1990).

product is sold to the investigator.²⁹¹ The question in this circumstance is whether the price charged was reasonable. Things to consider are whether the price charged was simply cost-recovery, whether a profit was realized, whether more products were sold than were reasonably necessary to conduct the tests, whether the sales were to testers or non-testers, and so forth. Thus, if the scale of the test was large and some of the above factors were met, the court may find the tests were more commercial than experimental.

In *Lough*, the court halfheartedly acknowledged the inventor's steadfast refusal to commercially exploit his invention before filing.²⁹² Previous Federal Circuit cases have attached great, perhaps dispositive weight to this factor.²⁹³ Accordingly, the scale of the *Lough* inventor's commercialization was small. Simply because a prototype used in the experiment was ultimately sold, as in *Lough*,²⁹⁴ does not necessarily create an invalidating public use.²⁹⁵

Experimental use does not apply to market testing situations designed to gauge customer demand.²⁹⁶ It should be noted that merely because the experimental use comes in contact with a customer does not *per se* disqualify the experimental use and convert it into a commercial, and therefore public, use.²⁹⁷

In *Allied Colloids*,²⁹⁸ the trial judge invalidated the patent

291. See Upadhye, *supra* note 1, at 39-42.

292. *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1121, 39 U.S.P.Q.2d 1100 (Fed. Cir. 1996).

293. *Ferag AG v. Quipp, Inc.*, 45 F.3d 1562, 1566, 33 U.S.P.Q.2d 1512, 1515 (Fed. Cir. 1995) ("Foremost among these is the policy of preventing inventors from exploiting the commercial value of their inventions while deferring the beginning of the statutory term."); see also *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1266-67, 229 U.S.P.Q. 805 (Fed. Cir. 1986).

294. *Lough*, 86 F.3d at 1121

295. *Watson v. Allen*, 254 F.2d 342, 347, 117 U.S.P.Q. 68, 71 (D.C. Cir. 1958) ("We believe the protective umbrella of the experimental use doctrine should include reasonable disposal of models and prototypes of the invention once their usefulness to the inventor has ended – reasonable in view of the nature of the device and the probability of discovery and appropriation of the invention by strangers."); see also *Goodwin v. Borg-Warner Corp.*, 157 F.2d 267, 273, 70 U.S.P.Q. 387, 393 (6th Cir. 1946) (finding experimentation even though the automobile containing the seal was later sold).

296. *In re Smith*, 714 F.2d 1127, 1135, 218 U.S.P.Q. 976, 983 (Fed. Cir. 1983).

297. *Allied Colloids, Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1575, 35 U.S.P.Q.2d 1840, 1843 (Fed. Cir. 1995).

298. *Id.*

based on public use, as the patentee tested the product at the site of a potential customer. The Federal Circuit reversed, stating that a jury could have found that the alleged public use was not in public or was experimental. Specifically, the testimony showed that successful preliminary results indicated more expansive tests were required.²⁹⁹ None of the intended customer's personnel saw the device in action, even though it was at the customer's facility. None knew of the tests performed or the test results. Moreover, tests were performed in a remote location at the customer's facility.³⁰⁰ Although the customer's personnel entered the general testing area, they entered for other purposes and did not observe the tests. The patentee's personnel kept research logs of the experiments done *in situ*³⁰¹ and ensured strict control over test samples, the testing period was very short, very small quantities of the invention were used, and testing was free of charge (there was no commercial gain). That the patentee ultimately hoped to gain the customer's business did not dictate that tests the patentee performed at the customer's site were commercial and triggered a public use bar.³⁰² While not explicitly stated, that the invention was free of charge likely weighed heavily in finding no public use. Combining the expansive nature of the tests required with the lack of profit indicates that a direct proportionality exists: a high number of tests, or large scale testing, combined with a profit component would result in a finding of public use.

The court reasoned that the law recognizes an inventor's need (1) to test the invention, (2) to ascertain whether it will work for its intended purpose, and (3) to ascertain whether the work is complete or what further changes are necessary.³⁰³ Such testing and development may even require disclosure to the public without being an invalidating public use. That the public testing ultimately may lead to commercial gain does not convert the testing into invalidating public use.³⁰⁴

299. *Id.*

300. *Id.*

301. *See* TP Labs., Inc. v. Prof'l Positioners, Inc., 724 F.2d 965, 972, 220 U.S.P.Q. 577, 583 (Fed. Cir. 1984) (test logs are relevant to whether activity is experimental).

302. *Allied Colloids*, 64 F.3d at 1576.

303. *Id.*

304. *Id.* at 1576-77; *Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1563, 4 U.S.P.Q.2d 1210, 1213 (Fed. Cir. 1987); *see also* *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 840 F.2d 902, 906, 5 U.S.P.Q.2d 1788, 1792

In *Caterpillar Tractor Co. v. Berco S.P.A.*,³⁰⁵ the court stated that the determination of experimental use will depend on the nature of the invention and the manner in which it is utilized. A patent will not be invalidated where “those who will eventually be using the product under conditions that are likely to be difficult to duplicate in the lab” conduct tests for durability and performance.³⁰⁶ In this case, Caterpillar used the invention at its own testing grounds. On occasion, the invention was placed on tractors owned by third parties in separate states. Caterpillar’s intent in field-testing was to ascertain the operation of the invention in different soil conditions in various climates. Durability, life, and reliability needed to be determined. The invention had changed structure and configuration as a result of the tests.³⁰⁷

H. THE LENGTH OF THE TEST PERIOD IN COMPARISON WITH TESTS OF SIMILAR PRODUCTS

Under this factor, testing should be conducted in context with the desired end use of the product. For example, pioneer drugs or devices will have no counterpart against which to measure safety or efficacy. That is, there is not likely to be a similar product with which to compare such inventions. Therefore, for pioneer devices or drugs, full-scale testing may be necessary to determine if the device or drug will work for its intended purpose. Accordingly, testing ought to be carefully tailored to the invention.³⁰⁸ Once an experimental purpose is identified, the court ought to examine the scope and length of the inventor’s activities to determine if they were reasonable in terms of the invention’s purpose.³⁰⁹ This is important in those instances where durability is required and a prolonged testing

(Fed. Cir. 1988).

305. *Caterpillar Tractor Co. v. Berco S.P.A.*, No. C80-0384-B, 1982 WL 52145, 215 U.S.P.Q. 948, (D. Wyo. Sept. 30, 1982), *aff’d on other grounds*, 714 F.2d 1110, 219 U.S.P.Q. 185 (Fed. Cir. 1983).

306. *Caterpillar*, 215 U.S.P.Q. at 958.

307. *Id.* at 953.

308. *City of Elizabeth, N.J. v. Am. Nicholson Pavement Co.*, 97 U.S. 126 (1877); *Allied Colloids, Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1577, 35 U.S.P.Q.2d 1840 (Fed. Cir. 1995); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 550-51, 16 U.S.P.Q.2d 1587 (Fed. Cir. 1990); *Caterpillar*, 215 U.S.P.Q. at 958.

309. *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 98 F.3d 1318, 1322, 40 U.S.P.Q.2d 1450 (Fed. Cir. 1996).

period is justified.³¹⁰

It should also be remembered that if the invention involves a “me-too” type drug or device, often times large scale testing is not necessary for the FDA approval process. FDA laws permit “me-too” drugs or devices to piggyback off the clinical trial data of the predicate drug or device.³¹¹ Accordingly, it makes less sense to permit large scale or long testing periods if a similar product having a similar safety and efficacy profile already exists. Therefore, “me-too” devices or drugs should be entitled to narrower protection.

I. WHETHER PAYMENT WAS MADE FOR THE PRODUCT OF THE TESTS

Commercialization is antithetical to experimental use. Accordingly, it would appear that this factor could be dispositive of the public use inquiry. But mere payment for the alleged experimental device cannot *ipso facto* convert experimental use into public use.³¹² If this were the case, then payment would convert a multi-factor test into a single factor test – something the courts would be loath to do.

One can also draw an analogy to 35 U.S.C. § 271(e) to demonstrate why payments may be allowed. Under § 271(e), payments do not convert non-infringing use into infringing use because devices and drugs are expensive to produce and payments to recover costs are acceptable. Accordingly, in the experimental use context, any payments made ought to be for cost recovery. Thus, an inquiry into the profit motive may be necessary.

Clever attorneys can argue over what constitutes a “cost” for the purposes of calculating a profit. Patentees will lump as many expenses as possible into “cost” so the maximum possible amount can be recovered within the shelter of experimental use. The ideal situation would occur when the payment price equals the underlying costs the patentee incurred. An infringer will attempt to exclude most expenses included in the payment amounts from “costs.” The rationale is that if certain amounts are included in the payment price, but are not considered costs,

310. *Id.* (citing *Manville Sales*, 917 F.2d at 551.).

311. See Upadhye, *supra* note 1, at 26-28 & 48-60, (describing the PMA-510(k) process for “me-too” devices, and the NDA-ANDA process for “me-too” drugs).

312. For there to be a commercial public use, that use must provide a profit or commercial advantage *to the inventor*.

they are more properly characterized as profit. Because clever attorneys can argue “costs” as an integral factor of the experimental-public use inquiry, it would be proper to itemize via a bright line rule which costs and profits are properly characterizable as implicating the public use bar. In looking at the test of whether activity implicates the public use bar, it is useful to review cases illustrating acceptable payment methods.

In *Grain Processing Corp. v. American Maize-Products Corp.*,³¹³ the Federal Circuit noted the testing period length, quantity of invention shipped, and payments made for the invention. The Federal Circuit affirmed the district court’s finding that the use was experimental.³¹⁴ The court noted that it was industry custom for the inventor of a proposed ingredient to submit samples to food manufacturers for their determination of the product’s utility.³¹⁵ Such testing was necessary because the invention could interact with other food ingredients. Here, the testing period was very short, and very small quantities of the samples were shipped free of charge.³¹⁶

In *C.R. Bard Inc., v. M3 Systems, Inc.*,³¹⁷ Bard sued M3 for infringement of a spring loaded needle biopsy gun. M3 asserted a variety of defenses including that Bard had sold some guns to its clinical trial administrator prior to the critical date.³¹⁸ While the *C.R. Bard* court discussed the sale of guns during clinical trials, it also drew parallels to the public use issue.³¹⁹

Judge Mayer, in his partial concurrence and dissent, rejected Bard’s arguments that it had not yet obtained FDA approval, had not conducted clinical testing, was not ready to

313. 840 F.2d 902, 906, 5 U.S.P.Q.2d 1788, 1792 (Fed. Cir. 1988).

314. *Id.* at 904.

315. *Id.* at 906.

316. *Id.*

317. *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 48 U.S.P.Q.2d 1225 (Fed. Cir. 1998).

318. *See generally id.* at 1356-57. Bard quoted a certain price to its potential marketing distributor. *Id.* at 1356. Interestingly, the same marketing distributor also arranged for the clinical trials. *Id.* The distributor purchased the 10 guns and 250 needles, and paid Bard (who had submitted as standard sales invoice to the distributor). *Id.* It was undisputed, though, that the guns were sold at cost and thus Bard derived no profit for them. *Id.*

319. *See id.* at 1356, (citing *In re Mahurkar*, 71 F.3d 1573, 1577, 37 U.S.P.Q.2d 1138, 1142 (Fed. Cir. 1995), for the proposition that “actual sale of two prototype catheters did not place the invention in the public domain or lead the public to believe that the device was freely available” (internal quotations omitted)).

distribute the products, and had not finalized the commercial product.³²⁰ Judge Mayer noted that clinical testing is not required before use or sale can bar patent rights.³²¹ Later clinical trials cannot save a prior use or sale, because clinical trials “are merely one possible policy reason why [the sale or use] might be excused from the bar.”³²² Because the inventor only contemplated the distribution of the guns to be sales and not clinical trials, the later clinical testing was irrelevant.³²³ Moreover, Judge Mayer specifically stated that the FDA approval process does not insulate sales because even illegal sales could trigger the on-sale bar.³²⁴

In dissent,³²⁵ Judge Newman asserted that M3 argued unsuccessfully that the “on sale” bar arose simply because Bard used its standard sales invoice in connection with the clinical trials.³²⁶ Judge Newman noted “cost defrayal arrangements between collaborators are not deemed to be invalidating sales, nor are payments for use substantially for test purposes.”³²⁷ The limited number of clinical trial investigators involved – in this case only four hospitals – further supported the lack of an invalidating sale.³²⁸ Notably, Judge Newman concluded that the limited sale of guns to its clinical trial administrator did not contravene the policies of § 102(b).³²⁹

A final interesting aspect of the *C.R. Bard* case involves the subsequent device improvements made because of the clinical trial investigation. Bard argued that many

320. See generally *id.* at 1374-78.

321. *Id.* at 1376.

322. *Id.*

323. *Id.*

324. *Id.*

325. The reader is advised to read the *C.R. Bard* decision carefully in order to track the sections that comprise the majority opinion and the dissent. Although Judge Newman was the primary author of the opinion, she dissented on the “on-sale” issue by stating that she would have found the patents valid on this issue. See *id.* at 1354 n.4. But Judges Mayer and Bryson teamed to hold the patents invalid on the “on-sale” issue. Accordingly, Judge Newman’s dissent is placed within the main opinion, rather than at the end of the opinion – and a failure to heed the instruction in footnote 4 (157 F.3d at 1354 n.4) may lead the reader to the erroneous conclusion that the majority held the patents valid under the “on-sale” issue. See also *id.* at 1369 n.9. (another admonishment for careful reading regarding antitrust issues in this case).

326. *Id.* at 1356.

327. *Id.*

328. *Id.*

329. *Id.*

improvements were made as a result of the clinical trials; thus any prior commercialization was meaningless.³³⁰ Judge Mayer dismissed this argument, stating that improvements must be both “inventive redesigns” and that these inventive redesigns must be claimed.³³¹ This reinforces the principle that for a claim to be invalid, the subject matter of the claims must be in public use before the critical date.³³² Moreover, experimental use does not apply to unclaimed features of the invention.³³³ Thus, demonstration of improvements that do not constitute public use must be for patentability and experimentation, not to make the invention more attractive to buyers.³³⁴

In summary, the above factors demonstrate that courts can and will focus on one or more particular factors to determine if an invalidating public use exists. Courts can and will focus on just a few factors without analyzing or balancing the others. More disturbingly, courts can and will focus on the “control” and the “written records” factors as the two most important and potentially dispositive factors in the test. Accordingly, one ought to examine any investigational or experimental protocols to solidify the degree of control and the quantity/quality of

330. *See id.* at 1377-78.

331. *Id.* at 1378.

332. *See* *Scaltech Inc. v. Retec/Tetra, L.L.C.*, 178 F.3d 1378, 1383, 51 U.S.P.Q.2d 1055, 1058 (Fed. Cir. 1999). “A claimed invention is considered to be on sale within the meaning of § 102(b) if, more than one year before [the critical date] . . . the invention [is] ready for patenting.” *Id.* Proving that the invention has been reduced to practice is one way of showing that the invention is ready for patenting. *Id.* “The ‘invention’ which has been offered for sale must, of course, be something within the scope of the claim.” *Id.* As a result, the party with the burden of proof must show that “*the subject of the barring activity met each of the limitations of the claim*, and thus was an embodiment of the claimed invention.” *Id.* (emphasis added).

333. *In re Smith*, 714 F.2d 1127, 1135-36, 218 U.S.P.Q. 976, 983-84 (Fed. Cir. 1983).

334. *See* *Netscape Communications Corp. v. Konrad*, 295 F.3d 1315, 1321, 63 U.S.P.Q.2d 1580, 1585 (Fed. Cir. 2002) (“To establish that an otherwise public use does not run afoul of section 102(b), it must be shown that the activity was substantially for purposes of experiment.”) (internal quotes omitted). An invention may exist under a § 102(b) bar even though it is later improved or refined. *See* *Baxter Int’l Inc. v. COBE Labs, Inc.*, 88 F.3d 1054, 1059, 39 U.S.P.Q.2d 1437, 1442 (Fed. Cir. 1996) (citing *City of Elizabeth, N.J. v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 134 (1877) for the proposition that “[t]he use of an invention by the inventor . . . by way of experiment, and in order to bring the invention to perfection, has never been regarded as [a public] use”). Accordingly, once the inventor realizes that the invention works for its intended purpose, any later experimentation could be invalidating public use. *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1061, 12 U.S.P.Q.2d 1449, 1453 (Fed. Cir. 1989).

written records. Once these two factors are solidified, a patentee stands a better chance of saving the patent from invalidity. That said, evidence of experimentation may exist in other forms, and may play a role in determining whether public use and experimental use are separate inquiries. As shown in the next section, these inquiries ought to be collapsed into one inquiry.

VI. IS THE QUESTION OF EXPERIMENTAL USE DIVORCED FROM THE QUESTION OF PUBLIC USE?

Whether public and experimental use are separate inquiries is important as it affects the burden of proof and burden-shifting. This is demonstrated by example. In a traditional patent suit, the infringer must prove invalidity by clear and convincing evidence.³³⁵ The burden of proving invalidity is on the infringer. When the invalidity case is made, the burden shifts to the patentee to rebut the invalidity case. The infringer will then win the invalidity issue unless the patentee can rebut it.

In the case of public use/experimental use, if the issue of public use is separate from experimental use, then the infringer need only establish a *prima facie* case of public use. This will shift the burden to the patentee to either refute the showing of public use or establish that the use was experimental. That is, the patentee bears the burden of proving experimental use. Unless the patentee proves this, the *prima facie* case of invalidity will hold and the patent will be held invalid.

On the other hand, if experimental use is part of the public use inquiry, the burden is on the infringer to establish, *prima facie*, that the case was a statutory public use and not an experimental use. This favors the patentee because the infringer shoulders the entire burden. Therefore, the question of whether the alleged conduct is a public use versus an experimental use remains. If the use is experimental, the use is not a public use.³³⁶ Therefore, under this rule, an experimental use ought to be classified as a non-public use,

335. *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1365, 51 U.S.P.Q.2d 1001, 1008 (Fed. Cir. 1999); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360, 220 U.S.P.Q. 763, 770 (Fed. Cir. 1984).

336. *Allied Colloids Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1574, 35 U.S.P.Q.2d 1840, 1842 (citing *City of Elizabeth, N.J.*, 97 U.S. at 134-35).

rather than being classified as an “exception” to public use. This would be akin to treatment of hearsay in evidence law, in which certain statements can be classified as hearsay (not admissible), non-hearsay (admissible because it is not hearsay in the first place), or hearsay but falling under an exception (admissible even though it is hearsay because it falls under an exception).

In *Tone Bros. v. Sysco Corp.*,³³⁷ the court clarified the procedural postures of a public use defense as applied to design patents.³³⁸ Because the public use bar was an affirmative defense and invalidated the patent, the infringer bore the burden of proving invalidity by clear and convincing evidence.³³⁹ The court stated that in determining public use, evidence of experimentation is part of the totality of the circumstances inquiry.³⁴⁰ The Federal Circuit took pains to state that the public use inquiry is not distinct from the experimental exception.³⁴¹ Thus, the test was not “(1) was there a public use, and if so, (2) was the public use for a bona fide experimental purpose and thus excused.”³⁴² The court reasoned that the public use and experimental use exceptions did not require distinct inquiries since both were grounded in the same underlying policies.³⁴³

337. *Tone Bros. v. Sysco Corp.*, 28 F.3d 1192, 31 U.S.P.Q.2d 1321 (Fed. Cir. 1994).

338. *Id.* at 1197 n.4. Under 35 U.S.C. § 171 (2000), one may obtain a design patent for “any new, original, and ornamental design for an article of manufacture.” The design must also be non-obvious. § 171 (“The provisions for this title relating to patents for inventions shall apply to patents for designs, except as otherwise provided.”); *In re Borden*, 90 F.3d 1570, 1574, 39 U.S.P.Q.2d 1524, 1526 (Fed. Cir. 1996). Infringement of a design patent requires that the designs have the same general visual appearance, such that it is likely that the purchaser would be deceived into confusing the design of the accused article with the patented design. *See Gorham Mfg. Co. v. White*, 81 U.S. (14 Wall.) 511, 528 (1872). The accused design must also contain substantially the same points of novelty that distinguished the patented design from the prior art. *L.A. Gear, Inc. v. Thom McAn Shoe Co.*, 988 F.2d 1117, 1125, 25 U.S.P.Q.2d 1913, 1918 (Fed Cir. 1993); *Lee v. Dayton-Hudson Corp.*, 838 F.2d 1186, 1187, 5 U.S.P.Q.2d 1625, 1625 (Fed. Cir. 1988); *Litton Sys., Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 1444, 221 U.S.P.Q. 97, 109 (Fed. Cir. 1984).

339. *Tone Bros.*, 28 F.3d at 1197 n.4; *Manville Sales Corp. v. Paramount Sys. Inc.*, 917 F.2d 544, 549, 16 U.S.P.Q.2d 1587 (Fed. Cir. 1990).

340. *Tone Bros.*, 28 F.3d at 1198.

341. *Id.* at 1198-99 (“Evidence of experimentation is part of the totality of the circumstances considered in a public use inquiry.”).

342. *Id.*

343. *See id.* at 1199-1200.

In *TP Laboratories*, the court stated,

[I]t is incorrect to impose on the patent owner, as the trial court in this case did, the burden of proving that a “public use” was “experimental.” These are not two separable issues. It is incorrect to ask: “Was it a public use?” and then, “Was it experimental?” Rather the court is faced with a single issue: Was it a public use under § 102(b)?³⁴⁴

An analogy may be drawn to the on-sale bar. If experimental use is separate from the on-sale bar, then logically it should be separate from the public use bar. This is because both bars are grounded substantially in the same policies. The dissent in *Continental Plastic Containers, Inc. v. Owens Brockway Plastic Products, Inc.*, linked the same considerations to the on-sale bar stating that the on-sale bar considered the totality of the circumstances and that experimental use as an exception to the on-sale bar was part of that totality inquiry.³⁴⁵

As mentioned above, one school of thought maintains that the question of experimental use is part and parcel with the public use question, in that experimental use is part of the totality of the circumstances test.³⁴⁶ But in *Lough*, the court asserted that the inquiry of public use and experimentation is a two-step process in which the first inquiry is whether the use is a public use and the second is whether the use falls under the experimental use exception.³⁴⁷ *TP Laboratories*, the clearest exposition of the unitary approach to public use, was decided in 1984 and *Tone Bros.* was decided in 1994. *Lough*, however, was decided in 1996. To the extent that *Lough* is contrary to *Tone Bros.* or *TP Laboratories*, the prior cases represent controlling law. This is because earlier panel decisions are *stare decisis* to later panel decisions unless later overruled by an *en banc* court.³⁴⁸

344. *TP Labs., Inc. v. Profl Positioners, Inc.*, 724 F.2d 965, 971, 220 U.S.P.Q. 577, 582 (Fed. Cir. 1984) (“[I]f a *prima facie* case is made of public use, the patent owner must be able to point to or must come forward with convincing evidence to counter that showing.”); see also *EZ Dock, Inc. v. Schafer Sys., Inc.*, 276 F.3d 1347, 1351-2, 61 U.S.P.Q.2d 1289 (Fed. Cir. 2002) (clearly affirming that the inquiry is unitary and not distinct).

345. 141 F.3d 1073, 1082 (Fed Cir. 1998).

346. See, e.g., *TP Labs.*, 724 F.2d at 971.

347. See *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1120, 39 U.S.P.Q.2d 1100 (Fed. Cir. 1996) (explaining that “both parties agree that the issue presented on appeal is whether the [public use], . . . prior to the critical date, constituted experimental use so as to negate the conclusion of public use”).

348. *Newell Co. v. Kenney Mfg., Inc.*, 864 F.2d 757, 765, 9 U.S.P.Q.2d 1417,

Thus, if public use is divorced from experimental use the factors for each test may be separated and independently stated. Although the following list of factors may be slightly repetitive with respect to the public use test, the evidentiary factors (discussed in *City of Elizabeth, N.J. v. American Nicholson Pavement Co.* and its progeny) to determine if a use was experimental include: (a) the length of the test period; (b) whether the inventor received payment for the testing; (c) any agreement by the user to maintain the use confidentially; (d) any records of testing; (e) whether persons other than the inventor performed the testing; (f) the number of tests; and (g) the length of the test period in relation to tests of similar devices.³⁴⁹

Furthermore, objective evidence “indicating a purpose for such testing and experiment is generally preferred” where such evidence may include: (a) whether the inventor inspected the invention regularly; (b) whether the inventor retained control over the invention; and (c) whether any commercial exploitation was merely incidental to the primary purpose of experimentation.³⁵⁰

As indicated above, some courts maintain the distinction between the two questions. Again, to the extent that some inconsistency exists among Federal Circuit cases, a better approach would be to adopt a bright line rule that places the burden of proving experimental use squarely on the patentee’s shoulders because many of the experimental use factors are similar to the public use factors. Eliminating such duplication would conserve scarce judicial resources. The infringer should bear the burden of proving public use by clear and convincing evidence. To the extent that experimental use is an issue, the burden should shift to the patentee (upon alleging the *prima facie* case) to prove that any use was experimental. This is proper because, as explained above, most of the factors concern the patentee’s own conduct, and who is better able to police a patentee’s conduct than the patentee himself?

In summary, in the medical arts, testing drugs and devices *in vivo* and *in vitro* prior to filing the patent application may create significant problems. Associating with physicians to

1423 (Fed. Cir. 1988) (citing *UMC Elecs. Co. v. United States*, 816 F.2d 647, 652 n.6, 2 U.S.P.Q.2d 1465, 1467 n.7 (Fed. Cir. 1987)).

349. See *TP Labs.*, 724 F.2d at 971-72; *In re Brigance*, 792 F.2d 1103, 1108, 229 U.S.P.Q. 988, 991 (Fed. Cir. 1986).

350. *In re Smith*, 714 F.2d 1127, 1135, 218 U.S.P.Q. 976 (Fed. Cir. 1983).

conduct trials can create a panoply of problems based on the sheer number of people involved and the very public nature of the testing. The existence of confidentiality agreements and/or the degree of control over the testing will help insulate the patentee from a charge of invalidity – as demonstrated by the trend in recent cases. Thus, in a multi-site clinical trial, a prudent inventor or medical company should have confidentiality agreements with the trial administrators, attending doctors, and each enrolled patient. Furthermore, for medical devices, confidentiality agreements should be executed with all the attending surgical staff; otherwise, a public use may be demonstrated when the attending parties are not under confidence. These comprehensive confidentiality agreements may seem unduly burdensome, but such agreements may be necessary given the broad construction courts give the public use bar.

VII. SHOULD THE PUBLIC USE/EXPERIMENTAL USE EXCEPTION BE LIBERALLY OR NARROWLY CONSTRUED?

The ultimate question is whether a court should construe the public use bar liberally or narrowly.³⁵¹ Arguments exist for both views. One court stated the public use bar is to be broadly construed. One commentator suggests a narrow or strict construction ought to apply.³⁵² He suggests that the existence of the patent term restoration provisions³⁵³ means pre-patent-application public activity should be narrowly construed.³⁵⁴

351. For the remainder of this article, a “liberal construction of public use” means that more uses would qualify as either non-public uses or as experimental use and thus be “safe harbored.” Accordingly, most patentees will desire a liberal construction because liberality would shield more uses as non-public uses. In contrast, a “narrow construction of public use” means fewer uses would be safe; more uses would qualify as public uses. Most infringers will desire a narrow construction because the patentee could not shield his uses under the guise of “safe uses.”

352. Eric M. Lee, *Public Use and On Sale Issues Arising from Clinical Testing of Medical Devices*, 75 J. PAT. & TRADEMARK OFF. SOC'Y 364, 375 n.62 (May 1993).

353. See 35 U.S.C. § 156 (2000). This provision permits a patentee to recoup some of the lost time spent embroiled in the FDA regulatory process.

354. Lee, *supra* note 352, at 375 n.62; *Merck & Co. v. Kessler*, 80 F.3d 1543, 1546-47, 38 U.S.P.Q.2d 1347 (Fed. Cir. 1996); *cf. Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 5 F.Supp. 2d 399, 400, 46 U.S.P.Q.2d 1831 (N.D. W. Va. 1998) (contending that during the patent process, Upjohn's reliance on a critical limiting element of the claim meant that a reasonable competitor could

This avoids the situation in which the patentee enjoys protection on both ends of the time-line – the public use activity at the beginning and the statutory patent term restoration at the end. However, the argument regarding patent term extension for FDA entanglements only applies to medical devices approved under the PMA process; it does not apply to medical devices cleared under the § 510(k) process.³⁵⁵

Another argument for a strict construction of the public use bar is the modest fact that drafting and filing a patent application on a device or drug reduced to practice is relatively simple compared to a full-scale clinical trial. From a purely economic perspective, detailed patent applications describing a drug or device can be accomplished for \$5,000 to \$20,000 in attorney's fees.³⁵⁶ The U.S. Patent Office charges a filing fee for submitting a patent application, which varies if the patent applicant is a small or large entity.³⁵⁷ Small entities enjoy a 50% fee reduction.³⁵⁸

In addition to a fee reduction, fees are different depending on the type of patent application filed. That is, if the patent application is a "provisional" patent application³⁵⁹ then the current fee is substantially smaller than a "non-provisional" fee.³⁶⁰ Table 1 shows the current fee structure charged by the U.S. Patent Office.³⁶¹

have concluded that Upjohn had relinquished control over claims outside that limitation – thus implying that formal reliance on a technical element to earn a patent *limits* the ways that the technical element can be construed).

355. *In re Nitinol Med. Tech., Inc.*, 17 U.S.P.Q.2d 1492 (Comm'r Patents 1990), *aff'g denial of extension*. For a complete description of the differences between devices approved under the PMA versus 510(k) processes, see Upadhye, *supra* note 1, at 1-28.

356. AILPA LAW PRACTICE MANAGEMENT COMMITTEE, AIPLA: REPORT OF ECONOMIC SURVEY 2001 78 (2001) (reporting a median price of \$9,967 for preparing a complex biotech or chemical application).

357. 35 U.S.C. § 41, 41(h) (2000); 37 C.F.R. §§ 1.16-1.21 and 1.27 (2001).

358. *Id.*

359. Provisional patent applications are governed by 35 U.S.C. § 111(b) (2000). Provisionals are not examined substantively and essentially sit at the Patent Office until its expiry. Provisionals never mature into an issued patent but serve as a hook upon which later non-provisionals can hang.

360. Non-provisional patent applications are governed by 35 U.S.C. § 111(a). Non-provisionals are "normal" or "regular" patent applications. Non-provisionals can mature into issued patents.

361. See <http://www.uspto.gov/web/offices/ac/qs/ope/1999/fee20021001.htm> (last visited Nov. 15, 2002). It is also understood that other fees may apply as circumstances dictate.

<u>Applicant Company Size</u>	<u>Provisional Application Filing Fee</u>	<u>Non-Provisional Application Filing Fee</u>
Small Entity (e.g., individuals, small businesses, not-for-profits, universities, etc.)	\$80.00	\$370.00
Large Entity (e.g., large companies)	\$160.00	\$740.00

Clearly the price of a patent application is nominal.³⁶²

A. THE PROVISIONAL PATENT APPLICATION AS A TOOL FOR REFORM

In the circumstance of an individual inventor, the small entity provisional application filing fee is affordable. Any entity may benefit from the provisional patent application process.³⁶³ A provisional patent application provides the means to establish an early effective filing date for a later 35 U.S.C. § 111(a) non-provisional patent application. A provisional patent application has a pendency lasting 12 months from the initial filing.³⁶⁴ The 12-month pendency period cannot be extended.³⁶⁵ Therefore, an applicant who files a provisional application must file a corresponding non-provisional application during the 12-month pendency period of the provisional application in order to benefit from the earlier filing of the provisional application.³⁶⁶ Thus, if one were to assume that the public use

362. Even factoring in attorney's fees – which are not necessarily expended if inside counsel draft the application (ignoring the inside counsel resource expenses) – the application fee is nominal compared to the potential future benefit.

363. 35 U.S.C. § 111(b).

364. 35 U.S.C. § 111(b)(5) (“[T]he provisional application shall be regarded as abandoned 12 months after the filing date of such application and shall not be subject to revival after such 12-month period.”).

365. 35 U.S.C. § 119(e)(3) (2000).

366. 35 U.S.C. § 119(e)(1).

An application for patent filed under section 111(a) or section 363 of this title for an invention . . . shall have the same effect, as to such invention, as though filed on the date of the provisional application . . . if the application for [non-provisional] patent . . . is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application.

started on Month 0, the inventor would have until Month 12 to file a provisional patent application (or non-provisional patent application for that matter) because of the § 102(b) one-year grace period. Then, because the inventor now has a patent application on file, the inventor can publicly use, sell, demonstrate, or publish the invention.³⁶⁷ The caveat is that the inventor must file the corresponding non-provisional application by Month 24 – within twelve months of the provisional application filing date. If the inventor does so, the patent application then proceeds to examination and subsequent issuance.

If the inventor seeks to establish the commercial viability of the invention, the inventor has almost 24 months to do so, as long as the inventor is willing to pay the costs of the attorney's fees in preparing the provisional patent application and the nominal U.S. Patent Office filing fee.³⁶⁸ As a result, the inventor is assured of patent validity, assuming no third party public use. It is hard to argue that the public use bar ought to be liberally construed when this filing strategy is available.

A counterpoint to this strategy is that any patent application filed (provisional or non-provisional) must embody the statutory utility requirement.³⁶⁹ The utility requirement embodies the question of whether the device will work for its intended purpose; something that does not work cannot be "useful" within the meaning of the statute.³⁷⁰ It is tempting to

Id.

367. Recall that the filing date freezes the universe of prior art that can be used against a patent application. Accordingly, post-filing date activity is not prior art against the patent application (irrespective of whether the application is provisional or non-provisional). See *supra* note 10 and accompanying text.

368. This situation can also be shown using days as the benchmarks. Suppose the public use occurs on 01 Jan. Year 1. The inventor would have until 31 Dec. Year 1 to file the provisional application. By filing the provisional by 31 Dec., then the 01 Jan. use is not a § 102(b) bar. The inventor now has until 31 Dec. Year 2 to file the non-provisional application. Therefore, the inventor can start using and marketing the invention two years before investing time, money, and energy to push the patent application process forward. All that remains is to file the provisional by 31 Dec. Year 1 to avoid public use issues.

369. 35 U.S.C. § 101 (2000) ("Whoever invents or discovers any new and *useful* process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.") (emphasis added).

370. See, e.g., *Newman v. Quigg*, 877 F.2d 1575, 1581, 11 U.S.P.Q.2d 1340, 1345 (Fed. Cir. 1989) (court declined to issue the patent on a "perpetual

argue medical devices or drugs deserve special treatment because one can never be certain the invention works and thus satisfies the utility requirement. Courts have held, however, that utility of medical inventions is measured under the same legal constructs as “regular” inventions.³⁷¹ It is tempting to argue that drugs alone deserve special treatment because of the unique biochemistry and pharmacology of the drugs reacting within the body. The inventor would argue that because of the unique biochemical interactions, the utility must be measured only when the invention is so complete that it is determined to fully work for its intended use. Nonetheless, the courts have

motion” machine because “[the machine] does not operate to produce what [the inventor] claims it does”); *In re Harwood*, 390 F.2d 985, 989, 156 U.S.P.Q. 673, 676 (C.C.P.A. 1968) (“An inoperative invention, of course, does not satisfy the requirement of 35 U.S.C. § 101 that an invention be useful.”). The Federal Circuit stated “[t]o violate [35 U.S.C.] § 101 the claimed device must be *totally incapable* of achieving a useful result.” *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992) (emphasis added); see *E.I. du Pont de Nemours & Co. v. Berkeley & Co.*, 620 F.2d 1247, 1260 n.17, 205 U.S.P.Q. 1, 10 n.17 (8th Cir. 1980). The *du Pont* court noted that:

A small degree of utility is sufficient. The claimed invention must only be capable of performing *some* beneficial function. An invention does not lack utility merely because the particular embodiment disclosed in the patent lacks perfection or performs crudely. A commercially successful product is not required. Nor is it essential that the invention accomplish all its intended functions, . . . or operate under all conditions, . . . partial success being sufficient to demonstrate patentable utility[.] . . . In short, the defense of non-utility cannot be sustained without proof of total incapacity.

Id. (emphasis in original, citations omitted). If an invention is only partially successful in achieving a useful result, a rejection of the claimed invention as a whole based on a lack of utility is not appropriate. See *In re Brana*, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995); *In re Gardner*, 475 F.2d 1389, 177 U.S.P.Q. 396 (C.C.P.A. 1973); *In re Marzocchi*, 439 F.2d 220, 169 U.S.P.Q. 367 (C.C.P.A. 1971).

371. *In re Chilowsky*, 229 F.2d 457, 461-62, 108 U.S.P.Q. 321, 325 (C.C.P.A. 1956). The *Chilowsky* court reasoned that:

There appears to be no basis in the statutes or decisions for requiring any more conclusive evidence of operativeness in one type of case than another. The character and amount of evidence needed may vary, depending on whether the alleged operation described in the application appears to accord with or to contravene established scientific principles or to depend upon principles alleged but not generally recognized, but the degree of certainty as to the ultimate fact of operativeness or inoperativeness should be the same in all cases.

Id.; *In re Gazave*, 379 F.2d 973, 978, 154 U.S.P.Q. 92, 96 (C.C.P.A. 1967) (“Thus, in the usual case where the mode of operation alleged can be readily understood and conforms to the known laws of physics and chemistry, operativeness is not questioned, and no further evidence is required.”).

held that the threshold for drug utility is whether the drug provides *any* immediate benefit to the public.³⁷²

To this end, the inventor may also be foreclosed from arguing that *in vivo* testing is necessary because satisfactory utility may be found by the prior *in vitro* testing or early stage testing.³⁷³ The Federal Circuit has made it quite clear that therapeutic utility sufficient under the patent laws is not to be confused with the requirements of the FDA with regard to safety and efficacy of drugs to be marketed in the United States.³⁷⁴ Accordingly, because the threshold for utility is relatively low, the patent laws permit the inventor to file patent applications with a modicum of utility. This means that

372. *Nelson v. Bowler*, 626 F.2d 853, 856, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980). The court concluded that:

Knowledge of the pharmacological activity of any compound is obviously beneficial to the public. It is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible, we conclude that adequate proof of any such activity constitutes a showing of practical utility.

Id.

373. *Cross v. Iizuka*, 753 F.2d 1040, 1051, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985).

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 provided by the showing of an *in vivo* utility.

Id.

374. *Brana*, 51 F.3d at 1568. The court noted that:

FDA approval, however, 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.

Id. (internal citations omitted); see also *In re Sichert*, 566 F.2d 1154, 1159, 196 U.S.P.Q. 209 (C.C.P.A. 1977); *In re Watson*, 517 F.2d 465, 474, 186 U.S.P.Q. 11 (C.C.P.A. 1975); *In re Anthony*, 414 F.2d 1383, 1397, 162 U.S.P.Q. 594 (C.C.P.A. 1969); *In re Hartop*, 311 F.2d 249, 252-53, 135 U.S.P.Q. 419 (C.C.P.A. 1962).

the inventor need not engage in full-scale trials to show that the invention can work. It follows that the public use ought to be narrowly construed. Because provisionals provide a lower cost alternative to patent applicants coupled with the debunked myth that full FDA type therapeutic utility must be shown before filing a patent application, the public use bar ought to be narrowly construed.

A counterargument to this strategy is that any provisional patent application must fully support the later filed non-provisional patent application. Although provisional patent applications have been around since 1995,³⁷⁵ few cases exist in which the court rigidly examined the sufficiency of the provisional compared to the non-provisional. By way of background, it is axiomatic that the subject matter of the patent application is fixed on its filing date. Matter in a provisional patent application is given that effective filing date. The filing date is important because it fixes or freezes the universe of prior art that can be used against the application. Accordingly, having the earliest filing date is critically important. In later applications that claim the benefit of the filing dates of the earlier applications or claim priority to earlier applications,³⁷⁶ the subject matter of the later application is given the earlier filing date only for matter common to both the earlier and later applications. So, any “new matter” in the later application is only given a filing date of the later application. The maxim is “old matter gets the old filing date and new matter gets the new filing date.” Therefore, if the claimed invention is a hybrid between old and new matter, then the filing dates are different and thus the universe of prior art is different as well.

For example, suppose a provisional patent application discloses subject matter *X*. Within one year, the applicant files

375. Congress authorized provisional patent applications effective June 8, 1995, as part of the Uruguay Round Agreement Act (URAA). Pub. L. No. 103-465, 108 Stat. 4809 (1994).

376. See *e.g.*, 35 U.S.C. §§ 119, 120, and 121 (2000). Section 119(a)-(d) relates to U.S. applications claiming the benefit of earlier foreign patent application filing dates. Section 119(e) relates to the creation and administration of U.S. provisional patent applications. Section 120 relates to the continuing patent application process. Continuing applications can be further subdivided into continuations, continuations-in-part (CIP), and divisionals. Section 121 relates to the divisional applications only. Essentially, continuing applications permit a later filed application to claim the benefit of the earliest effective filing date.

a non-provisional patent application disclosing and claiming subject matters $X + Y$. Subject matter X has the provisional filing date and subject matter Y has the new filing date. Here, the non-provisional application contains new matter that was not taught in the provisional.

Returning to the timeline hypothetical just discussed, suppose an inventor on Month 0 publicly used the invention of $X + Y$. On Month 12, the inventor filed a provisional patent application teaching only X or insufficiently describing Y in the necessary detail. On Month 24, the inventor files the non-provisional patent application claiming $X + Y$. The patent issues. Now, an infringer may defend on the grounds that the claim to $X + Y$ is invalid because the subject matter Y has a filing date of Month 24, and the public use of $X + Y$ occurred almost 2 years earlier (i.e., Month 0). While any claim to subject matter X only could chain its way from Month 24 to Month 12 properly, the subject matter Y chain stops at Month 24. So, the failure to adequately describe subject matter Y in the provisional means that it cannot serve as an anchor to subject matter Y in the later non-provisional application.

Recently, in *New Railhead Manufacturing v. Vermeer Manufacturing Co.*³⁷⁷ the Federal Circuit found that the critical part of the invention was not adequately described in the provisional patent application.³⁷⁸ Although the provisional patent application was timely filed within one year of the public use, the later non-provisional patent application was filed well after the one year grace period.³⁷⁹

The Federal Circuit agreed that under 35 U.S.C. § 119(e)(1), the old matter got the old date and new matter got the new date.³⁸⁰ The court noted that the provisional application text failed to adequately describe the angled bit body and the drawings did not illustrate any angled relationship.³⁸¹ Because the claim now called expressly for the angled bit body, that claim element had the non-provisional filing date. Thus the invention was in public use for more than one year prior to the provisional filing date and was invalid.³⁸²

One may argue that the provisional patent application is

377. 298 F.3d 1290, 63 U.S.P.Q.2d 1843 (Fed. Cir. 2002).

378. *Id.* at 1292-93 (noting the lack of description of the angled bit body).

379. *Id.* at 1293.

380. *Id.* at 1294.

381. *Id.* at 1294-95.

382. *Id.* at 1295.

designed for “quick and dirty” descriptions to secure filing dates. But inventors may still utilize the provisional patent application process to secure step-wise improvements and yet protect themselves fully. For example, an inventor may capitalize on the cheap provisional application filing fee by using a “rolling provisional” procedure.

The rolling provisional procedure is best illustrated by example. Suppose on January 1, Year 1, the inventor files a provisional patent application describing subject matter A. As the inventor further develops improvements in January, the inventor files another provisional patent application on the improvement B on February 1, fully teaching base subject matter A and the improvement B. Similarly, the inventor continues improvements and on March 1, the inventor files another provisional application on subject matter A, B, and C. This continues until December 31 of Year 1, when 12 provisional patent applications will be on file, each teaching various subject matter such that the December 1 provisional patent applications contain subject matter for A through L. By December 31 Year 1, the inventor may file a non-provisional patent application containing subject matter A to L. This way, the non-provisional application fully contains all improvements made during that year and any public uses that occurred during that year are of no consequence.

If the inventor feels that he is not yet ready to file a non-provisional, he can delay the filing into Year 2. The only caveat is that on each first of the month of Year 2, a previously filed provisional patent application will expire. That is of no consequence, however, if there was no public use or other invalidating prior art. Under this rolling provisional procedure, as improvements are made, the inventor may adequately protect himself by filing provisionals right away and using that year to perfect more improvements. What more can an inventor ask for if the theories are that improvements or refinements are made during clinical testing? Here, the rolling model adequately protects the inventor and the public. Issues of prior public use do not arise, and because they do not arise, there is never a real inquiry into whether any putative public use was experimental.

B. A NARROW CONSTRUCTION MAY AVOID ANTITRUST CONCERNS

Antitrust issues arise in the context of enforcing a patent

procured by fraud, in violation of Rule 56's duty of candor by failing to submit relevant and material prior art during examination.³⁸³ This fraud on the Patent Office is also known as inequitable conduct.³⁸⁴ Accordingly, when the inventor engages in questionably public use, the inventor enters a dilemma of whether to submit that test information to the examiner – to comply with Rule 56 – or to unilaterally determine that the use was not public and thus not submit it to the examiner. If the inventor's assertion that the use was not public is objectively wrong, the inventor could be guilty of inequitable conduct.³⁸⁵

There must be encouragement for the inventor to disclose a potential prior public use. Narrowing the scope of public use provides this encouragement. If the public use is narrowly construed, then there is less subjective belief by the inventor that certain activities may be safe. That is, if the scope is narrow, then it is less likely that the inventor will believe his activities are safe. If he believes that his use is no longer safe, he will be encouraged to disclose the use and let the Patent Office decide whether it is safe or not. So by reducing the scope, an inventor who is not sure whether the use is safe will be motivated to disclose it to the Office. When the issue of disclosure is a close call, the inventor should err on the side of disclosure.³⁸⁶ When the Office examines that use and still issues the patent, the inventor cannot be guilty of inequitable conduct, as he did not fraudulently withhold the prior public use. Accordingly, where there is no fraudulent procurement, there can be no antitrust violation. Moreover, his patent will be stronger because the Office would have already examined that use and determined that it did not significantly affect patentability.

383. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 174, 147 U.S.P.Q. 404, 406 (1965); *see also* 37 C.F.R. § 1.56 regarding the duty of candor to submit relevant and material prior art to the examiner during patent examination.

384. *In re Hayes Microcomputer Prod., Inc. Patent Litig.*, 982 F.2d 1527, 1546, 25 U.S.P.Q.2d 1241, 1255-56 (Fed. Cir. 1992).

385. *Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529, 1538-40, 222 U.S.P.Q. 553, 561-62 (Fed. Cir. 1984).

386. *LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1076, 22 U.S.P.Q.2d 1025, 1033 (Fed. Cir. 1992).

VIII. CONCLUSION

It is still better policy to apply the experimental use/public use bar narrowly. The above discussion illustrates that application of the multifactor test is fraught with problems. As most factors are generally in the control of the patentee, it makes sense to hold the patentee strictly to the test. In addition, the new provisional patent application procedure means that the patentee is in the best position to draft fully comprehensive and detailed patent applications. The cost of doing so remains less costly than drafting full non-provisional applications. Furthermore, because rolling provisionals provide a vehicle to protect an inventor for all improvements, the public use should be strictly construed against an inventor who fails to capitalize on the tools now available. In complicated areas of law, such as patent law, bright line rules will foster the competitive system that the Constitutional framework set out to establish. While many cases of the previous era retained a flexible approach to the public use bar, new cases and new legislation beg for reform in this area and stricter application of the public use bar.