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Environmentally Dependent Inventions and the "On Sale" and "Public Use" Bars of § 102(b): A Proffered Solution to a Statutory Dichotomy

James A. Jorgensen

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Environmentally Dependent Inventions and the “On Sale” and “Public Use” Bars of § 102(b): A Proffered Solution to a Statutory Dichotomy

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I. INTRODUCTION

The United States Constitution empowers Congress “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries”¹ Pursuant to this Constitutional authorization, Congress enacted the federal patent laws² under which the owner of a patent is granted the “right to exclude others from making, using, or selling [the patented] invention throughout the United States” for a period of seventeen years.³

1. U.S. CONST. art. I, § 8, cl. 8.

2. Codified at Title 35 U.S.C. § 1 et seq.

3. 35 U.S.C. § 154 (1988).

In return for this limited monopoly, the inventor must disclose to the public methods by which one skilled in the art can make and use the patented invention.⁴ This quid pro quo arrangement encourages technological innovation by benefitting the inventor with exclusive rights in his patented device while providing new ideas to others who can, in turn, develop them further.

In order for an inventor to receive patent protection, however, he must first meet several conditions set forth by Congress. Two of these prerequisites are: (1) that the invention be new and "useful";⁵ and (2) that the invention *not* have been "on sale" or in "public use" within the United States more than one year prior to the filing of the application for patent.⁶ The former is commonly referred to as the "utility" requirement of the patent law.⁷ The latter are known, respectively, as the "on sale" and "public use" bars to patentability.⁸ Specifically, if an inventor is found to have transgressed the on sale or public use provisions of section 102(b), he will be forever denied the right to receive a patent for the offending invention. The "critical date,"⁹ the date one year prior to the inventor's filing of his application for patent, is decisive in this regard. It is therefore particularly important that the inventor not place his device on sale or in public use prior to the critical date if he wishes to preserve the right to a patent for his invention.

The dilemma posed by these prerequisites to patentability is that there exists an intrinsic tension between the requirement of utility, on one hand, and the on sale and public use bars on the other. This tension is clearly illustrated when the invention sought to be patented involves the design and testing of pharmaceutical compositions, medical devices, and environmentally dependent inventions ("EDIs") generally. The term "environmentally dependent invention" is used throughout this Comment to refer to any of a class of patentable devices or compositions

4. *Id.* § 112.

5. "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 therefor, subject to the conditions and requirements of this title." *Id.* § 101 (emphasis added).

6. "A person shall be entitled to a patent unless . . . (b) the invention was . . . 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" *Id.* § 102(b) (emphasis added).

7. See *Brenner v. Manson*, 383 U.S. 519, 528-29 (1966). See generally Note, *The Utility Requirement in the Patent Law*, 53 GEO. L.J. 154 (1964).

8. See *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1265 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1030 (1987). See generally William C. Rooklidge & W. Gerard von Hoffman III, *Reduction to Practice, Experimental Use, and the "On Sale" and "Public Use" Bars to Patentability*, 63 ST. JOHN'S L. REV. 1 (1988).

9. *Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1563 (Fed. Cir. 1987) ("The 'critical date,' the date one year before the filing date of the patent application, is determined retrospectively.").

which vary in effectiveness and result depending upon their operative setting (i.e., working environment). Such devices are to be distinguished from strictly "autonomous" inventions which tend to function in a consistent and efficacious manner irrespective of their surrounding environment or setting.

The inventor of an environmentally dependent invention finds himself caught in a Catch-22; he must adequately test his invention to demonstrate its utility and effectiveness without placing it on sale or in public use more than one year prior to his application for patent. Although this may not appear to be a problem for inventors of autonomous inventions, experimentation involving EDIs, because of their very nature, often emulates the statutorily proscribed on sale or public use activities. Such inventions typically require some form of public testing to establish and adequately demonstrate the utility required by section 101. For example, a pharmaceutical composition must generally be tested on a group of individuals (i.e., members of the public at large) before it can be proven effective for the treatment of disease in humans and thus sufficiently "useful" to be patentable for that purpose.¹⁰

To deal with this dilemma, courts have adopted an "experimental use" doctrine,¹¹ whereby experimental use of an invention for the purpose of bringing it to perfection negates the on sale and public use bars.¹² Application of this doctrine by the courts, however, has proven inadequate towards resolving the inherent statutory tension between sections 101 and 102(b). As a result, both inventors and patent attorneys have very little guidance concerning when to file patent applications for EDIs. An indirect consequence of this uncertainty is that, contrary to Constitutional mandate, progress in the sciences and useful arts is discouraged.

This Comment discusses pertinent precedent of the United States Court of Appeals for the Federal Circuit ("Federal Circuit")¹³ with regard to both the utility requirement of section 101 and the on sale and

10. See *infra* note 31.

11. See, e.g., *Elizabeth v. Pavement Co.*, 97 U.S. 126 (1877); see also discussion *infra* part III.B.3.

12. See *Elizabeth*, 97 U.S. at 137; *T.P. Labs., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 971 (Fed. Cir.), *cert. denied*, 469 U.S. 826 (1984).

13. The Federal Circuit was created under the Federal Courts Improvement Act, Pub. L. No. 97-164, 96 Stat. 25 (1982) (current version at 28 U.S.C. § 1295 (1988 & Supp. IV 1993)). Effective October 1, 1982, the jurisdiction of the regional circuit courts of appeals was transferred to the Federal Circuit over appeals from U.S. district court cases arising under the federal patent, copyright, and trademark laws. See 28 U.S.C. § 1295(a)(1) (1988 & Supp. IV 1993). In addition, the Federal Circuit hears all appeals by patent applicants from adverse decisions of the Board of Patent Appeals and Interferences of the Patent and Trademark Office. See *id.* § 1295(a)(4). One of the primary Congressional goals in granting the Federal Circuit exclusive jurisdiction over appeals in patent cases was to establish uniformity and certainty in the area of patent law. See S.

public use bars of section 102(b). An emphasis is placed on the law as it relates to the testing of EDIs generally.

Part II provides a rudimentary understanding of the patent law concept of "utility" so that the reader may begin to understand the problems created when the utility requirement is considered in conjunction with the on sale and public use bars of section 102(b). Emphasis is placed on chemical and pharmaceutical compositions for two reasons. First, chemical compositions, in general, are recognized as one of the more problematic categories in the area of utility.¹⁴ Second, pharmaceutical compounds are paradigmatic EDIs and will thus best serve to illuminate the points made throughout this Comment.

The Federal Circuit's application of the on sale and public use bars of section 102(b) and the judicially created experimental use doctrine are detailed in Part III. Several of the court's decisions—which address a variety of EDIs—have been selected for discussion in order to illustrate some of the inconsistencies in the court's application of the statutory bars and the experimental use doctrine. It is hoped that the reader will acquire a greater appreciation of the types of problems faced by inventors of EDIs who, as a necessary prerequisite to patent protection, seek to establish their inventions' practical utility through various methods of public experimentation. Additionally, Part III examines various factors underlying the court's apparent failure to equitably and predictably apply the experimental use doctrine.

Part IV endeavors to cut to the heart of the intrinsic tension between the utility requirement of section 101 and the on sale and public use bars of section 102(b), placing particular emphasis on the impact to inventors of EDIs.

The purported policy considerations underlying section 102(b) and the reasons behind the statute's failure to effectively realize those policies are discussed in Part V. Finally, a proposal for statutory reformation of section 102(b) is set forth with the intent of achieving the Constitutional goal of promoting the progress of science and the useful arts,¹⁵ while remaining faithful to the policies underlying the statutory bars of section 102(b).¹⁶

REP. NO. 275, 97th Cong., 2d Sess. 5-6, reprinted in 1982 U.S.C.C.A.N. 11, 15-16; H.R. REP. NO. 312, 97th Cong., 1st Sess. 20-23 (1981).

14. See 1 DONALD S. CHISUM, PATENTS §§ 4.01-02, at 4-2, 4-3 (rel. 42, 1992) ("The problem of finding a sufficient [utility] is encountered most often with chemical compounds and processes."). For a discussion of the utility requirement of section 101 as it relates specifically to pharmaceutical compositions, see generally Deborah H. Brand, *Utility in a Pharmaceutical Patent*, 39 FOOD DRUG COSM. L.J. 480 (1984).

15. See U.S. CONST. art. I, § 8, cl. 8.

16. See discussion *infra* part V.A.

II. THE "UTILITY" REQUIREMENT OF 35 U.S.C. § 101

A. *The Basic Concept of Utility*

The utility requirement in patent law is set forth at 35 U.S.C. § 101, which states: "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 therefor"¹⁷ In other words, one may only patent that which is deemed "useful."¹⁸ To be minimally useful within the meaning of section 101, the invention must "(1) be operable and capable of use, i.e., it must perform a designed function; (2) achieve some minimum human purpose; and (3) that purpose must not be illegal, immoral or contrary to public policy."¹⁹ Commercial usefulness, however, to the extent that the invention is commercially salable in the marketplace, is not a prerequisite of utility under section 101.²⁰ In addition to fulfilling the utility requirement, the inventor must further satisfy the disclosure requirement of section 112.²¹ The inventor's disclosure, which includes a statement of practical utility made within the patent application, must describe the invention in sufficient detail to enable one skilled in the art to which the invention pertains to make and use the invention as of its filing date.²²

B. *Utility of Chemical and Pharmaceutical Compositions*

The utility requirement, as it pertains to chemical processes, was directly addressed by the United States Supreme Court in the seminal case of *Brenner v. Manson*.²³ At issue in *Brenner* was the utility of a chemical process found to produce a particular steroid that demonstrated a tumor-inhibiting effect in mice. In affirming the Patent and Trademarks Office's finding that the inventor had failed to produce sufficient evidence of utility, the Court set forth its rationale for requiring a clear showing of specific utility:

[A] process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly

17. 35 U.S.C. § 101 (1988) (emphasis added).

18. *Brenner v. Manson*, 383 U.S. 519, 528-29 (1966). The Court, however, noted that such a simple word as "useful" can be "pregnant with ambiguity when applied to the facts of life." *Id.* at 529.

19. *Phillips Petroleum Co. v. U.S. Steel Corp.*, 6 U.S.P.Q.2d 1065, 1101-02 (D. Del. 1987) (citing 1 CHISUM, *supra* note 14, § 4.04[1]), *aff'd*, 865 F.2d 1247 (Fed. Cir. 1989).

20. *Application of Langer*, 503 F.2d 1380, 1393 (C.C.P.A. 1974); *Application of Anthony*, 414 F.2d 1383, 1396 (C.C.P.A. 1960).

21. 35 U.S.C. § 112 (1988).

22. *See Application of Glass*, 492 F.2d 1228 (C.C.P.A. 1974); 1 CHISUM, *supra* note 14, § 4.04, at 4-24, 4-25.

23. 383 U.S. 519 (1966).

of knowledge which should be granted only if clearly commanded by [section 101]. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

....

... [A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. "[A] patent system must be related to the real world of commerce rather than to the realm of philosophy" ²⁴

The Court's principal concern was that if the inventor were permitted to receive a patent on a chemical process, whose specific utility had not been narrowed within the patent application to a particular use or function, then the inventor could unjustifiably control a monopoly over all possible uses of that process, including both those known at the time of filing and those yet to be discovered. For this reason, the court made clear that an invention's demonstrable and substantial utility must be set forth with specificity within the application for patent in order to satisfy the useful (i.e., utility) requirement of section 101.

1. MANIFESTATION OF UTILITY THROUGH CLINICAL TESTING

That an inventor must designate his invention's *specific* utility within the application for patent means that inventors of pharmaceutical compositions (and medical devices generally) typically need to perform some form of preliminary clinical testing. These tests ordinarily involve human subjects where the composition is to be utilized solely for the treatment of human disease.²⁵ Under certain circumstances, however, clinical testing on humans is not necessary and *in vivo* (i.e., on lab animals) or *in vitro* (i.e., in an artificial environment such as a test tube) testing may be sufficient to establish the practical utility required by section 101.²⁶ This particular issue was addressed, and at least partially

24. *Id.* at 534-36 (footnotes and citations omitted).

25. *See infra* note 31.

26. *See infra* note 29.

resolved, by the Federal Circuit in *Cross v. Iizuka*.²⁷

In *Cross*, the Federal Circuit's most notable decision concerning the utility of pharmaceutical compositions, the court held, on the facts of the case,²⁸ that *in vitro*²⁹ utility was sufficient to establish the practical utility required by section 101. The invention at issue in the interference proceeding was an imidazole derivative compound used to inhibit the synthesis of thromboxane synthetase from human or bovine platelet microsomes. The challenging party (*Cross*), in an attempt to convince the court that *Iizuka*'s claimed compound lacked practical utility at the time its priority application was filed, argued that the minimum level of utility disclosed in a patent application claiming a pharmaceutical compound must be directed to *in vivo* utility to satisfy the practical utility requirement of section 101. The court, however, disagreed, recognizing that each case involving a question of utility under section 101 must be decided on its own unique facts and circumstances.³⁰ The court concluded, based upon the evidence before it, with specific emphasis on the fact that the *in vitro* utility of the compound in question was supplemented by *in vitro* and *in vivo* activity of *structurally similar compounds* (i.e., prior art), that *in vitro* utility was sufficient to establish utility under section 101.³¹

The question raised by this case, and as of yet remaining unan-

27. 753 F.2d 1040 (Fed. Cir. 1985).

28. *Id.* at 1051 ("Today, under the circumstances of the instant case, . . . *in vitro* utility is sufficient to comply with the practical utility requirement of § 101.").

29. *In vitro* refers to an environment outside a living organism, such as a test tube or culture, whereas *in vivo* refers to an environment within a living organism, such as an animal or a plant. *Id.* at 1043 n.6.

30. *Id.* at 1048.

31. The initial determination, however, as to whether an invention possesses practical utility for purposes of section 101 is made by the Patent and Trademark Office ("PTO"). Although the PTO is bound by decisions of the Federal Circuit, its application of the utility requirement in practice tends to be more rigorous than that of the Federal Circuit, particularly with respect to pharmaceutical compositions. In particular, the PTO seldom finds *in vitro* testing by itself to be sufficient to establish practical utility. See, e.g., *Hoffman v. Klaus*, 9 U.S.P.Q.2d 1657, 1660 (Bd. Pat. App. & Int. 1988) (finding that practical utility had not been established where there was a lack of correlation between *in vitro* tests and the treatment of arthritis); *Ex Parte Maas*, 9 U.S.P.Q.2d 1746, 1747-48 (Bd. Pat. App. & Int. 1987) (finding that practical utility had not been established where there was "no correlation . . . between *in vitro* experiments and a practical utility in currently available form for humans or animals"). The PTO's stated position on pharmaceutical utility as concerns clinical testing is as follows:

Proof of utility . . . may be established by clinical or *in vivo* or *in vitro* data, or combinations of these which would be convincing to those skilled in the art. More particularly, if the utility relied on is directed *solely* to the treatment of humans, evidence of utility, if required, must generally be clinical evidence although animal tests may be adequate where the art would accept these as appropriately correlated with human utility or where animal tests are coupled with other evidence, including clinical evidence and a structural similarity to compounds marketed commercially for the same indicated uses. If there is no assertion of human utility, or if there is an

swered, is whether a pharmaceutical compound, not structurally similar to pre-existing compounds of proven *in vivo* utility, may, with respect to pharmacological activity, satisfy the practical utility requirement of section 101 following mere *in vitro* testing.³² The issue, however, is even broader. Because the court deemed utility a question of fact,³³ any case involving a determination of practical utility under section 101 will be decided on the facts and circumstances particular to that individual case. Such fact based analysis tends to promote unpredictability and confusion in the area of practical utility and, accordingly, stimulates increased litigation over the issue.³⁴ This result runs counter to the basic premise underlying the patent system—that innovation, not litigation, is to be promoted and rewarded.

2. SAFETY AS A REQUIREMENT OF PHARMACEUTICAL UTILITY

Although an inventor must establish a specific and substantial use for a pharmaceutical compound, he need not demonstrate its absolute safety through a process of clinical testing in order to receive patent protection for the invention.³⁵ In other words, absolute safety is not a prerequisite to a finding of utility in drugs designed for therapeutic use in humans. All that is required is a "sufficient probability" of safety in human therapy and such probability need not necessarily be established

assertion of animal utility, operativeness for use on standard test animals is adequate for patent purposes.

U.S. PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 608.01(p), at 600-41 (5th ed. 1983, rev. 15, Aug. 1993) (citations omitted).

32. Thus, *Cross* does little to resolve the dilemma faced by inventors of pharmaceutical compounds in determining the proper method by which to ascertain their inventions' specific usefulness. It remains unclear when *in vitro*, or even *in vivo*, testing alone will be sufficient to establish the practical utility of a given pharmaceutical composition. Accordingly, if such a composition is to be utilized in the medical treatment of humans (and is so claimed in the application for a patent), the inventor is well-advised to perform preliminary clinical testing on human subjects (i.e., beyond mere *in vivo* or *in vitro* experimentation) in order to ensure the compound's utility. Such testing may, however, create difficulties for the inventor when viewed in conjunction with the public use or on sale bars of section 102(b). See *infra* part IV.

33. 753 F.2d at 1044 n.7 (noting, in dictum, that "[u]tility is a fact question").

34. One commentator, arguing that practical utility should properly be decided as a question of law, has asserted that categorization of utility as a question of fact will heighten unpredictability in the field of pharmaceutical research, thus making such risky investments even more uncertain and speculative. See generally, Kenneth D. Sibley, *Practical Utility: Evolution Suspended*, 32 J.L. & TECH. 203 (1992).

35. The position of the Patent Office with respect to the safety of pharmaceutical compounds is:

[A] drug which is not sufficiently safe under the conditions of use for which it is said [sic] be effective will not satisfy the utility requirement. Proof of safety shall be required only in those cases where adequate reasons can be advanced by the examiner for believing that the drug is unsafe, and shall be accepted if it establishes a reasonable probability of safety.

U.S. PATENT AND TRADEMARK OFFICE, *supra* note 31, § 608.01(p), at 600-42 (citations omitted).

by clinical evidence of use on human subjects.³⁶ In fact, a pharmaceutical compound may be useful within the meaning of section 101, and thus patentable, even though it has not yet been approved by the Food and Drug Administration.³⁷

III. THE "ON SALE" AND "PUBLIC USE" BARS OF 35 U.S.C. § 102(b)

Of particular concern to the inventor seeking to establish, through the process of clinical testing, a specific practical utility for a pharmaceutical compound or medical device are the on sale and public use bars of 35 U.S.C. § 102(b). Such concerns, however, are not unique to the field of medical inventions. They are also shared by inventors of most types of EDIs whose inventions often require testing in the "public" domain to ensure their practical utility.

A. Legislative History of the Statutory Bars

In the Patent Act of 1790, the earliest of the United States Patent Acts, Congress authorized the issuance of a patent to one who had "invented or discovered any useful art . . . or any improvement therein not before known or used"³⁸ It was not until passage of the Patent Act of 1836, however, that Congress enacted the first on sale and public use bar provisions.³⁹ Congress's principal objective in implementing the statutory bars was to prevent inventors from commercially exploiting their inventions, and thus extending their effective monopolies, beyond the statutory patent term prescribed by Congress.⁴⁰ The bars, as set forth in the 1836 Act, were not qualified by any grace period whatsoever.

36. See *Application of Hartop*, 311 F.2d 249, 260 (C.C.P.A. 1962) (holding that anesthetic efficiency tests performed on rabbits using the claimed invention established a sufficient probability of safety in human therapy but noting that it did not mean to imply that evidence of clinical testing should not be demanded by the Patent Office under different factual circumstances).

37. See *id.*; *Application of Anthony*, 414 F.2d 1383, 1393 (C.C.P.A. 1969). See also *Application of Krimmel*, 292 F.2d 948 (C.C.P.A. 1961). The court in *Anthony* explained:

Congress has given the responsibility to the FDA, not to the Patent Office, to determine in the first instance whether drugs are sufficiently safe for use that they can be introduced in the commercial market, under the conditions prescribed, recommended, or suggested in the proposed labeling thereof

. . . [T]he FDA need not necessarily determine that a drug be commercially useful or usable before it may be "useful" in the patent law sense.

414 F.2d at 1395.

38. Patent Act of 1790, ch. 7, § 1, 1 Stat. 109.

39. See Patent Act of 1836, ch 357, § 6, 5 Stat. 117. The statute provided that an inventor could be granted a patent if his invention was "not, at the time of his application for a patent, in public use or on sale, with his consent or allowance." *Id.*

40. This concern stems from the fact that the United States utilizes a first-to-invent, and not a first-to-file, patent system. See 35 U.S.C. § 102(g) (1988). Thus, if it were not for the statutory bars, the first to invent could extend, indefinitely, a virtual monopoly over the *prospective* patent

Accordingly, an inventor was required to file his application for patent before initially placing his invention on sale or in public use. As part of the Patent Act of 1939, however, Congress added a two year grace period to the bars, allowing an inventor to apply for a patent within two years after first placing his invention on sale or in public use.⁴¹ This grace period evolved out of a Congressional recognition that an inventor requires time to adequately perfect his invention prior to applying for a patent.⁴²

In 1939, Congress reduced the statutory grace period from two years to one year.⁴³ The reason for this change was set forth in a Senate Report accompanying the measure:

In 1839, when the period of 2 years was first developed, it may have been a proper length of time for an inventor to make up his mind whether or not to file an application for a patent. Under present conditions 2 years appears unduly long and operates as a handicap to industry. Reduction of the period would serve to bring the date of patenting closer to the time when the invention is made, and would expedite applications, not only in their filing but also in their progress through the Patent Office. One year is believed to be a very fair period for all concerned.⁴⁴

Implicit in this statement is the belief that an inventor's only consideration in determining when to file his application for a patent is whether he should do so at all.

All inventions, however, are not created equally. Some devices and compositions, by their very nature, require a period of time significantly longer than one year to perfect.⁴⁵ This is particularly true of inventions that possess the quality of durability as an essential part of their claimed utility⁴⁶ or of inventions whose effectiveness cannot be reliably or ade-

rights in an invention, even though he himself had never filed a patent application for such an invention.

41. See Patent Act of 1839, ch. 88, § 7, 5 Stat 353. The Act provided in pertinent part:

[N]o patent shall be held to be invalid by reason of such purchase, sale, or use prior to the application for a patent as aforesaid, except . . . that such purchase, sale, or prior use has been for more than two years prior to such application for a patent.

Id.

42. See S. REP. NO. 338, 24th Cong., 1st Sess. 6 (1836).

43. See Act of August 5, 1939, ch. 450, § 1, 53 Stat. 1212.

44. S. REP. NO. 876, 76th Cong., 1st Sess. 1-2 (1939); H.R. REP. NO. 961, 76th Cong., 1st Sess. 1-2 (1939).

45. See, e.g., *Elizabeth v. Pavement Co.*, 97 U.S. 126 (1877) (upholding the inventor's patent where he had publicly tested his invention, a method of constructing pavement from wooden blocks and tar paper, for six years prior to seeking a patent).

46. See, e.g., *id.*; *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544 (Fed. Cir. 1990) (luminaire assembly for use on outdoor light poles—new design's durability in weather conditions was unknown).

quately determined within a one-year period.⁴⁷ When such devices or compositions further require that testing be performed in a public setting—that is, outside of a confidential laboratory environment—the one-year grace period, in conjunction with the public use and on sale bars, operates in a prohibitive fashion. This presents a significant obstacle for inventors of EDIs. Such inventors necessarily feel compelled to complete their experimental testing and subsequently apply for a patent within the one-year time frame. An inventor, however, cannot possibly feel confident in so applying for a patent, and thus incurring the associated expenses, until he is assured that his invention will function as intended. Accordingly, a blanket one-year bar provision for all classes of inventions, regardless of their complexity or inherent need for extended testing, is not truly an ideal solution to the perceived problem.

Nonetheless, the one-year blanket period for the on sale and public use bars was carried over from the 1939 Act into the current version of section 102(b),⁴⁸ which provides in pertinent part: “A person shall be entitled to a patent unless . . . (b) the invention was . . . 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”⁴⁹ Consequently, in order to provide inventors additional time where necessary to perfect their inventions, the Federal Circuit has remedially applied the experimental use doctrine to circumvent the statutory one year mandate. In a sense, the court is acting in a quasi-legislative fashion to repair what Congress has not.⁵⁰

B. *The Federal Circuit's Application of Section 102(b)*⁵¹

The principles enunciated below are consistently set forth by the Federal Circuit as generally accepted “rules” of law. It should be noted,

47. See, e.g., *TP Labs., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965 (Fed. Cir.), cert. denied, 469 U.S. 826 (1984) (orthodontic tooth positioning appliance).

48. See Act of July 19, 1952, ch. 950, 66 Stat. 797.

49. 35 U.S.C. § 102(b) (1988).

50. See Gerald T. Welch, *Patent Law's Ephemeral Experimental Use Doctrine: Judicial Lip Service to a Judicial Misnomer or the Experimental Stage Doctrine*, 11 U. Tol. L. Rev. 865, 866 (1980).

51. This Comment makes no attempt to discuss the historical development and interpretation of the on sale and public use bars in the United States Supreme Court and various federal circuit and district courts prior to the creation of the Court of Appeals for the Federal Circuit. The Federal Circuit, aside from infrequent and sporadic Supreme Court decisions, is now charged with establishing precedent in the field of patent law. See *supra* note 13. Accordingly, this Comment focuses primarily on decisions of the Federal Circuit. For detailed discussions on the historical evolution of the bars and the experimental use doctrine generally, see William K. West, Jr. & Nancy J. Linck, *The Law of “Public Use” and “On Sale”: Past, Present and Future*, 72 J. Pat. & Trademark Off. Soc'y 114, 129-151 (1990); Rooklidge & von Hoffman, *supra* note 8, at 11-23; 2 CHISUM, *supra* note 14, §§ 6.02[2],[5-7].

however, that some of these principles may appear less than consistent in their application when viewed in light of the specific facts and circumstances of individual cases.⁵²

1. ON SALE GENERALLY

The determination of whether an invention is on sale, for purposes of section 102(b), is a question of law.⁵³ A completed sale, in the sense that title passes from the seller to a buyer,⁵⁴ is not required to implicate the on sale bar. Instead, a mere *offer* to sell the invention prior to the critical date,⁵⁵ regardless of whether the offer is accepted or rejected, is enough to bar the issuance of a patent.⁵⁶ In fact, a *single* offer to sell prior to the critical date may be sufficient to invoke the on sale bar of section 102(b).⁵⁷ The inventor's offer to sell, however, must be objectively manifested as a definite offer to sell the invention. The subjective, uncommunicated, and ultimate intention of the offeror is not, in itself, sufficient to raise the bar.⁵⁸ In determining whether an offer to sell was made, the totality of the circumstances surrounding the offer must be examined⁵⁹ because the policies underlying the on sale bar, in effect, define it.⁶⁰

The actual sale or offer to sell, however, must occur between two legally separate entities for the bar to arise.⁶¹ An assignment or sale of *rights* in the invention or potential patent rights in the invention, prior to the critical date, is not a "sale" within the meaning of section 102(b).⁶² Conversely, the existence of a sales contract or the signing of a purchase agreement for the invention itself, prior to the critical date, is violative of

52. See discussion *infra* parts III.C-D.

53. *Paragon Podiatry Lab., Inc. v. KLM Lab., Inc.* 984 F.2d 1182, 1186 (Fed. Cir.), *cert. denied*, 113 S. Ct. 2346 (1993); *Envirotech Corp. v. Westech Eng'g, Inc.*, 904 F.2d 1571, 1574 (Fed. Cir. 1990); *Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1462 (Fed. Cir. 1988); *UMC Elec. Co. v. United States*, 816 F.2d 647, 657 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1025 (1988).

54. See, e.g., U.C.C. § 2-106(1) (1990).

55. See *supra* note 9 and accompanying text.

56. *UMC Elec.*, 816 F.2d at 653. See *Envirotech*, 904 F.2d at 1575; *In re Caveney*, 761 F.2d 671, 675 (Fed. Cir. 1985).

57. *Paragon Podiatry*, 984 F.2d at 1188; *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 836 (Fed. Cir. 1992); *A.B. Chance Co. v. RTE Corp.*, 854 F.2d 1307, 1311 (Fed. Cir. 1988); *In re Caveney*, 761 F.2d at 676.

58. *Envirotech*, 904 F.2d at 1575; *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1062 (Fed. Cir. 1989).

59. *Envirotech*, 904 F.2d at 1574; *UMC Elec.*, 816 F.2d at 656.

60. *Envirotech*, 904 F.2d at 1574; *RCA Corp.*, 887 F.2d at 1062; *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549 (Fed. Cir. 1990).

61. *Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1465 (Fed. Cir. 1988); *In re Caveney*, 761 F.2d 671, 676 (Fed. Cir. 1985).

62. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1267 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1030 (1987).

the on sale bar.⁶³ Even if an inventor loses money on a sale of the invention to another party, such a sale may nonetheless give rise to the on sale bar.⁶⁴

In contrast, a sale made primarily for experimental purposes, as opposed to one made predominantly for purposes of commercial profit, does not implicate the on sale bar.⁶⁵ Once an invention has been "reduced to practice,"⁶⁶ however, an offer to sell or an actual sale of the invention is no longer justifiable as an experimental use.⁶⁷ Reduction to practice, on the other hand, is not a prerequisite to operation of the on sale bar.⁶⁸ In other words, if an offer to sell was made prior to the critical date, the invention does not have to be in its complete and final form for the bar to operate.

To invoke the on sale bar, the challenger in an interference action or the defendant in an infringement suit must prove that the complete invention, as claimed, was embodied in or obvious in view of the item sold or offered for sale prior to the critical date.⁶⁹ The purchaser of the item sold, however, need not have actual knowledge of the embodied invention at the time of purchase in order for the bar to arise.⁷⁰

The challenger to a patent's validity bears the burden of proving that there was a definite sale or offer to sell more than one year prior to the filing of the patent application.⁷¹ If the underlying action is based on an interference or patent infringement, such sale or offer to sell must be proved by clear and convincing evidence.⁷² If, on the other hand, the

63. *Buildex*, 849 F.2d at 1464.

64. *United States Envtl. Prods., Inc. v. Westall*, 911 F.2d 713, 717 (Fed. Cir. 1990).

65. *Id.* at 716; *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 550 (Fed. Cir. 1990); *UMC Electronics Co. v. United States*, 816 F.2d 647, 657 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1025 (1988). The topic of experimental use is discussed in greater detail, *infra* part III.B.3.

66. "Reduction to practice" is a term of art which means that an actual physical embodiment of an invention has been built that contains *all elements* of the claim set forth in the application for patent. See *RCA Corp. v. Data Gen.*, 887 F.2d 1056, 1061 (Fed. Cir. 1989); *UMC Elec.*, 816 F.2d at 652.

67. *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 5 F.3d 1477, 1480 n.3 (Fed. Cir. 1993); *RCA Corp.*, 887 F.2d at 1061.

68. *UMC Elec.*, 816 F.2d at 656. The court, however, limited its holding to the on sale bar, noting that "[t]he public use bar of section 102(b) implicates different considerations and nothing said here should be construed to encompass that part of the statute." *Id.* at 652 n.5. Thus, the issue remains open as to whether reduction to practice is a prerequisite of the public use bar.

69. *Atlantic Thermoplastics*, 970 F.2d at 836 (Fed. Cir. 1992); *UMC Elec.*, 816 F.2d at 656.

70. *Envirotech Corp. v. Westech Eng'g., Inc.*, 904 F.2d 1571, 1576 (Fed. Cir. 1990); *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 860 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1016 (1986).

71. *Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1462 (Fed. Cir. 1988); *UMC Elec.*, 816 F.2d at 656.

72. *Atlantic Thermoplastics*, 970 F.2d at 836; *Sonoscan, Inc. v. Sonotek, Inc.*, 936 F.2d 1261, 1263 (Fed. Cir. 1991); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549 (Fed. Cir.

inventor is challenged by the Patent and Trademark Office during the prosecution of his patent application, the appropriate burden of proof is the lower preponderance of the evidence standard.⁷³ Once facts evidencing prior on sale activity are established by the challenging party, the patent owner has the burden of coming forward to explain the circumstances which otherwise appear to be motivated by commercial objectives outside the one-year grace period provided by section 102(b).⁷⁴

Notwithstanding the above rules of law, there is undoubtedly a degree of uncertainty, on the inventor's part, as to which activities the court will deem to place an invention on sale within the meaning of section 102(b).⁷⁵ At least one judge on the Federal Circuit has made note of this incertitude, recognizing that the court itself tends to complicate the matter by applying any one of three different tests to determine whether on sale activity has occurred.⁷⁶ These alternative inquiries are as follows:

1. (A) the claimed invention must have been embodied in or obvious in view of the subject matter of the sale;
- (B) the invention must have been tested sufficiently to verify its operability; and
- (C) the sale must have been primarily for profit rather than experimental purposes.⁷⁷ Or,

1990); *Envirotech*, 904 F.2d at 1574. The rationale for applying the clear and convincing standard of proof arises from 35 U.S.C. § 282 (1988 & Supp. IV 1993), which provides in pertinent part: "A patent shall be presumed valid. . . . The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." See *Buildex*, 849 F.2d at 1463.

73. *In re Caveney*, 761 F.2d 671, 674 (Fed. Cir. 1985).

74. *UMC Elec.*, 816 F.2d at 656.

75. See David W. Carstens & Craig Allen Nard, *Conception and the "On Sale" Bar*, 34 WM. & MARY L. REV. 393, 398 (1993) (each Federal Circuit decision analyzing the on sale bar "involved a different panel of three judges, and each panel analyzed the 'on sale' bar differently"); West & Linck, *supra* note 51, at 115 (the Federal Circuit's totality of the circumstances approach tends to result in unpredictability); Stephen R. Schaefer, Comment, *Envirotech Corp. v. Westech Engineering, Inc.: The On-Sale Bar to Patentability and Executory Sales Offers*, 75 MINN. L. REV. 1505, 1508 (1991) (noting that some commentators criticize the Federal Circuit's application of the on sale bar because it lacks predictability, fails to inform inventors how to behave, fails to inform lower courts how to invoke the bar, and thus generally encourages litigation); Michael R. Schacht, Note, *UMC Electronics v. United States: Should Reduction to Practice be a Requirement of the On Sale Bar?*, 12 U. PUGET SOUND L. REV. 131, 152-53 (1988) (the Federal Circuit's use of the totality of the circumstances test to determine on sale activity fails to provide lower courts, patent attorneys, and inventors with guidance as to when the on sale bar is triggered). *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 5 F.3d 1477, 1483 n.1 (Fed. Cir. 1993) (Rader, J., dissenting).

76. See, e.g., *Atlantic Thermoplastics*, 5 F.3d at 1482-83 (Rader, J., dissenting).

77. See *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 859-60 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1016 (1986); see also *Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.*, 731 F.2d 831, 835-37 (Fed. Cir. 1984).

2. (A) there must have been a sale or definite offer to sell the invention more than one year prior to the critical date;

(B) there must be evidence that the thing sold or offered for sale anticipates or renders obvious the later-claimed invention; and

(C) the court will weigh all of the circumstances surrounding the sale or offer in light of the underlying policies.⁷⁸ Or,

3. the court will go straight to a weighing of the "totality of the circumstances" because the policies underlying the "on sale" bar, in effect define it.⁷⁹

It becomes apparent after contemplating these various tests that the inventor is placed in a considerable dilemma when attempting to predict what the court will consider to be on sale activity or even how the court will go about reaching such a decision. Nevertheless, he must make such a prediction if he intends to publicly distribute his invention in any fashion prior to the critical date, or risk being barred from obtaining a patent or having his patent subsequently invalidated in a later interference or infringement action.

2. PUBLIC USE GENERALLY

"The essence of 'public use' is the free and unrestricted giving over of an invention to a member of the public or to the public in general."⁸⁰ In other words, if an inventor gives or sells his device to another without limitation, restriction, or injunction of secrecy, the use of such invention will be considered public, even though the use and knowledge of the use may be confined to only one person.⁸¹ The mere presence or absence of an express confidentiality agreement, however, is not determinative of whether a given use will or will not be considered public within the meaning of section 102(b).⁸² Private use of one's own invention, on the other hand, will not be deemed a public use.⁸³ It must be made clear that it is not public *knowledge* of the invention that precludes the inventor from obtaining a patent, but rather a public *use* or *sale*.⁸⁴ In fact, a

78. *Atlantic Thermoplastics*, 5 F.3d at 1483; see *UMC Elec.*, 816 F.2d at 656.

79. *Atlantic Thermoplastics*, 5 F.3d at 1483; see, e.g., *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549-50 (Fed. Cir. 1990).

80. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1265 (Fed. Cir. 1986) (quoting, with approval, the district court below, 594 F. Supp. 1420, 1427 (D. Del. 1984), *cert. denied*, 479 U.S. 1030 (1987)).

81. *Egbert v. Lippman*, 104 U.S. 333, 336 (1881); *Grain Processing Corp. v. American Maize-Prods.*, 840 F.2d 902, 906 (Fed. Cir. 1988) (quoting *In re Smith*, 714 F.2d 1127, 1134 (Fed. Cir. 1983)); *Moleculon*, 793 F.2d at 1266 (quoting *Egbert*, 104 U.S. at 336).

82. *Moleculon*, 793 F.2d at 1266; *TP Labs. v. Professional Positioners, Inc.*, 724 F.2d 965, 972 (Fed. Cir.), *cert. denied*, 469 U.S. 826 (1984).

83. See *Moleculon*, 793 F.2d at 1265-66.

84. *Elizabeth v. Pavement Co.*, 97 U.S. 126, 136 (1877); *TP Labs.*, 724 F.2d at 970 (quoting *Elizabeth*, 97 U.S. at 136).

commercial use of the invention, even if the invention is kept secret, will generally be considered public for purposes of the statute.⁸⁵

As with on sale activity, the totality of the surrounding circumstances must be taken into consideration in determining whether a given use should be deemed public for purposes of section 102(b).⁸⁶ In addition, the party challenging the patent's validity in an interference proceeding or infringement action bears the burden of proving, by clear and convincing evidence, that the invention was in public use prior to the critical date.⁸⁷

3. THE EXPERIMENTAL USE DOCTRINE

The essence of the experimental use doctrine is that the pre-critical date use of an invention by the inventor himself, or anyone under his direction and control, in order to bring the invention to perfection or to ascertain whether it will answer its intended purpose, should not be deemed a transgression of the statutory on sale or public use bars.⁸⁸ In other words, the doctrine's principal function is to mitigate the inflexible nature of the statutory one-year grace period of section 102(b). The United States Supreme Court fully embraced this doctrine in the time-honored case of *Elizabeth v. Pavement Co.*⁸⁹

The invention at issue in *Elizabeth* was a method of constructing pavement utilizing wooden blocks on a base foundation of tar paper. In order to test the durability and usefulness of the pavement, the inventor constructed a seventy-five foot length of the pavement near a toll booth on a public road. This location was chosen because the inventor knew it to be well travelled by heavily loaded wagons. The inventor observed the area where the test pavement was placed on a near daily basis, for a period of approximately six years. The Court, in upholding the validity of the patent, held such use to be wholly experimental and thus not a "public use" within the meaning of the statute. Of particular importance to the Court was the *nature* of the invention. It noted that the nature of

85. *Kinzenbaw v. Deere & Co.*, 741 F.2d 383, 390 (Fed. Cir. 1984), *cert. denied*, 470 U.S. 1004 (1985).

86. *United States Envtl. Prods., Inc. v. Westall*, 911 F.2d 713, 716 (Fed. Cir. 1990); *Kinzenbaw*, 741 F.2d at 391 (quoting *TP Labs.*, 724 F.2d at 972).

87. *Manville Sales Corp. v. Paramount Systems, Inc.*, 917 F.2d 544, 549 (Fed. Cir. 1990); *Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1563 (Fed. Cir. 1987); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1266 (Fed. Cir. 1986).

88. See *Elizabeth*, 97 U.S. at 134-37; *Labounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1071 (Fed. Cir. 1992); *Baker Oil Tools*, 828 F.2d at 1563; *Pennwalt Corp. v. Akzona, Inc.*, 740 F.2d 1573, 1580 (Fed. Cir. 1984).

89. 97 U.S. 126 (1877). This case continues to have a lasting influence on the Federal Circuit. See, e.g., *Manville*, 917 F.2d at 551; *Baker Oil Tools*, 828 F.2d at 1563; *TP Labs. v. Professional Positioners, Inc.*, 724 F.2d 965, 970-71 (Fed. Cir.), *cert. denied*, 469 U.S. 826 (1984).

street pavement is such that it cannot be experimented upon satisfactorily except in public.⁹⁰

The Court set forth the following rationale for the experimental use doctrine:

When the subject of invention is a machine, it may be tested and tried in a building, either with or without closed doors. In either case, such use is not a public use, within the meaning of the statute, so long as the inventor is engaged, in good faith, in testing its operation. He may see cause to alter it and improve it, or not. His experiments will reveal the fact whether any and what alterations may be necessary. If durability is one of the qualities to be attained, a long period, perhaps years, may be necessary to enable the inventor to discover whether his purpose is accomplished. And though, during all that period, he may not find that any changes are necessary, yet he may justly be said to be using his machine only by way of experiment; and no one would say that such a use, pursued with a *bona fide* intent of testing the qualities of the machine, would be a public use, within the meaning of the statute. So long as he does not voluntarily allow others to make it and use it, and so long as it is not on sale for general use, he keeps the invention under his own control, and does not lose his title to a patent.

It would not be necessary, in such a case, that the machine should be put up and used only in the inventor's own shop or premises. He may have it put up and used in the premises of another, and the use may inure to the benefit of the owner of the establishment. Still, if use under the surveillance of the inventor, and for the purpose of enabling him to test the machine, and ascertain whether it will answer the purpose intended, and make such alterations and improvements as experience demonstrates to be necessary, it will still be a mere experimental use, and not a public use, within the meaning of the statute.⁹¹

The Federal Circuit continues to employ the experimental use doctrine, as set forth in *Elizabeth*, for the purpose of giving inventors time to perfect their inventions, where legitimately necessary, beyond the express one-year grace period permitted by section 102(b). The court, however, rarely extends the doctrine for the benefit of inventors,⁹² typically finding some commercial motivation—and accordingly, a violation of section 102(b)—in a majority of situations. The following is a brief synopsis of the Federal Circuit's law of experimental use.

90. *Elizabeth*, 97 U.S. at 134.

91. *Id.* at 134-35.

92. See 2 CHISUM, *supra* note 14, § 6.02[7], at 6-83 ("The [experimental use] doctrine is a difficult one to apply in actual cases. It is frequently evoked by patent holders to avoid the statutory bar but is rarely sustained by the courts.").

In order to determine whether a given use was experimental, the court will generally consider the totality of the circumstances relating to the character and extent of commercial activities along with the character and extent of bona fide experimentation.⁹³ The court, in weighing these two factors, requires that the public use, sale, or offer to sell is "substantially for the purpose of experiment" as opposed to "mainly for the purposes of trade or profit."⁹⁴

The factors which the court generally accords the most weight in making a determination as to whether the public use or on sale activity was "substantially for the purpose of experiment" are: (1) the amount of control retained by the inventor over the operation; (2) the extent of public testing in relation to the nature of the invention; (3) the length of the test period; (4) whether any payment was made;⁹⁵ (5) whether there was a secrecy obligation involved; (6) whether progress records were kept; (7) who conducted the experiments; and (8) the degree of commercial exploitation during the tests in relation to the purpose of the experimentation.⁹⁶ The most significant and heavily weighted of the above factors is the first, the amount of control that the inventor maintains over the use and operation of his invention.⁹⁷

A use or sale will not be considered experimental unless those using or purchasing the invention are aware of the experimentation at the time of the use or sale.⁹⁸ Additionally, the inventor's subjective belief that his activities were carried out for experimental purposes is considered irrelevant by the court in making a subsequent determination of whether the use was experimental.⁹⁹

The Federal Circuit has recognized that an inventor may need to

93. See *Baker Oil Tools*, 828 F.2d at 1563; *Western Marine Elec., Inc. v. Furuno Elec. Co.*, 764 F.2d 840, 845 (Fed. Cir. 1985).

94. *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 256 (1887); see *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1187 (Fed. Cir. 1993); *Labounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1071 (Fed. Cir. 1992); *Baker Oil Tools*, 828 F.2d at 1563 (quoting *Smith & Griggs*, 123 U.S. at 256).

95. Although payment is an important factor to be taken into account, it does not *per se* give rise to the on sale or public use bars of section 102(b). See *Baker Oil Tools*, 828 F.2d at 1564; *TP Labs., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 971-72 (Fed. Cir.), *cert. denied*, 469 U.S. 826 (1984).

96. *Baker Oil Tools*, 828 F.2d at 1564 (citations omitted); see also *Labounty Mfg.*, 958 F.2d at 1071; *United States Envtl. Prods., Inc. v. Westall*, 911 F.2d 713, 717 (Fed. Cir. 1990).

97. See *Elizabeth v. Pavement Co.*, 97 U.S. 126, 136 (1877); *Paragon Podiatry*, 984 F.2d at 1187; *Envtl. Prods.*, 911 F.2d at 717; *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1266 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1030 (1987).

98. See *Paragon Podiatry*, 984 F.2d at 1186; *Labounty*, 958 F.2d at 1072 (The "[i]nventor's failure to communicate to any of the purchasers or prospective purchasers of his device that the sale or offering was for experimental use is fatal to his case.") (citation omitted).

99. *Paragon Podiatry*, 984 F.2d at 1186 (quoting *TP Labs.*, 724 F.2d at 972); *Labounty Mfg.*, 958 F.2d at 1071; *TP Labs.*, 724 F.2d at 972.

engage in customer testing¹⁰⁰ to perfect his invention but has limited the types of permissible testing. The court will not forgive as experimental the testing of a device to determine suitability for a particular customer's specific needs.¹⁰¹ Furthermore, the experimental use doctrine does not encompass market testing, as such testing is presumed to be commercially motivated.¹⁰² Even testing to satisfy federal regulatory procedures is not *per se* experimental for the purpose of avoiding the statutory bars.¹⁰³

The court has recognized that an invention can exist at the critical date for purposes of applying the statutory bars even though the invention may need to be later refined or improved.¹⁰⁴ The period of permissible experimental use, however, ends once the invention has been reduced to practice.¹⁰⁵ In other words, the one-year grace period may begin to run even before the invention is complete to the inventor's satisfaction. Once the inventor is convinced, or the court finds that he should have been convinced, that his invention will "answer the purpose intended," he may no longer be protected by the experimental use doctrine. Additionally, the experimental use doctrine does not apply to experiments performed with respect to unclaimed features of an invention.¹⁰⁶ That is, the experimentation must be related solely to claimed attributes of the invention which are included in the inventor's application for patent.

100. *Env'tl. Prods.*, 911 F.2d at 717 ("We recognize that an inventor may need to have a customer test the invention to determine that it works as intended.").

101. *Labounty Mfg.*, 958 F.2d at 1074 ("It is well settled that 'testing' of a device to determine suitability for a customer's particular (unclaimed) need is not experimental use which negates commercialization by the inventor.").

102. *In re Smith*, 714 F.2d 1127, 1135, 1137 (Fed. Cir. 1983). For a discussion on the interrelationship between the experimental use doctrine and market testing and the general need for a less restrictive public use bar as applied to market testing of inventions, see generally Jay David Schainholz, *The Validity of Patents After Market Testing: A New and Improved Experimental Use Doctrine?*, 85 COLUM. L. REV. 371, 383-86 (1985).

103. See *Pennwalt Corp. v. Akzona, Inc.*, 740 F.2d 1573, 1580 (Fed. Cir. 1984) ("The fact that a sale or use occurs under a regulatory testing procedure, such as a FIFRA [Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 135] experimental use permit, does not make such uses or sales *per se* experimental for purposes of 35 U.S.C. § 102(b).") (citations and footnote omitted). For a discussion of the effects of the public use and on sale bars of section 102(b) on clinical testing of medical devices during the FDA approval process, see generally Eric M. Lee, *Public Use and On Sale Issues Arising From Clinical Testing of Medical Devices*, 75 J. PAT. & TRADEMARK OFF. SOC'Y 364 (1993).

104. *Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1563 (Fed. Cir. 1987) (citations omitted).

105. *RCA Corp. v. Data General Corp.*, 887 F.2d 1056, 1061 (Fed. Cir. 1989).

106. *In re Smith*, 714 F.2d at 1136.

C. *An Exposition of Federal Circuit Cases*

In practice, the Federal Circuit has had difficulty applying the on sale and public use bars—and more specifically, the experimental use doctrine—in a predictable manner. The ensuing case discussions are structured to provide the reader with an insight into the court's inconsistent treatment of various types of EDIs.

1. ENVIRONMENTALLY DEPENDENT INVENTIONS AND THE NECESSITY OF PUBLIC TESTING

a. Experimentation or Commercialization? A Very Fine Line

One of the most significant dilemmas faced by inventors of EDIs is that the testing necessary to establish their inventions' utility often emulates the kinds of on sale or public use activity proscribed by section 102(b). Accordingly, it becomes quite difficult to distinguish between those endeavors which are commercially motivated and those which are predominantly experimental in character. If the court recognizes that an invention, by its nature, requires public testing to perfect, such invention will likely be sheltered from operation of the statutory bars by the experimental use doctrine. If, however, the court fails to perceive or consider the environmentally dependent quality of the concerned invention, such testing will likely be deemed commercially motivated, and hence violative of section 102(b). The following cases are illustrative.

In *Grain Processing Corp. v. American Maize-Products*,¹⁰⁷ for instance, the inventor had shipped, prior to the pertinent critical date, samples of certain starch hydrolysates to food manufacturers for testing and ultimately for determination of the product's "utility." The court found such testing necessary, as "starch hydrolysates may interact adversely with other food ingredients in the manufacturers' products."¹⁰⁸ Additionally, the court noted that the testing period was short, small quantities of the samples were shipped, and the samples had been provided free of charge.¹⁰⁹ Ultimately, the court, in upholding the patent at issue, found such testing consistent with experimentation and determined that there had been no public use in violation of section 102(b).

Conversely, in *In re Smith*,¹¹⁰ the Federal Circuit affirmed a decision of the Patent and Trademark Office rejecting the inventor's claims for patent pursuant to the public use bar of section 102(b). The invention at issue was a powdered composition for use as a carpet and room

107. 840 F.2d 902 (Fed. Cir. 1988).

108. *Id.* at 906.

109. *Id.*

110. 714 F.2d 1127 (Fed. Cir. 1983).

deodorizer, commonly known as "Carpet Fresh." The inventor had conducted, prior to the critical date, a two-stage consumer test of the product involving seventy-six participants. In the first stage of the testing, the participants viewed a video presentation of the product's intended application and were subsequently asked various questions about their perception of the product. The second stage of the test involved actual in-home usage by the consumers of two different formulations of the product. The participants were then interviewed for their opinions as to the product's overall effectiveness, particularly with regard to its vacuumability.

The majority rejected the inventor's arguments that the testing was carried out for experimental reasons, finding instead that the dominant purpose of the tests was market testing, not technological improvement. The court determined that the operability of the product could have been sufficiently verified in the laboratory without the assistance of consumer "housewives."¹¹¹ In reaching its holding that, prior to the critical date, the product had been in public use within the meaning of section 102(b), the majority emphasized the fact that no restrictions had been placed on the consumers' use of the product.¹¹²

Judge Nichols, in dissent, sharply criticized the majority's reasoning,¹¹³ contending:

What the court is really saying is that the inventor of a product for use by amateur engineers in the home cannot test the product by amateur engineers in the home without the occurrence of a 'public use' starting the year of § 102(b) to run. It appears to me such a rule is well calculated to thwart and nullify, in the consumer product category, the experimental use exception itself.¹¹⁴

In particular, Judge Nichols took exception to the majority's determination that testing of the product could have occurred entirely within the laboratory. He felt it "improbable" that such testing would truly reflect the conditions of consumer home usage.¹¹⁵ Additionally, the dissent

111. *Id.* at 1135-36.

112. *Id.* at 1136.

113. *Id.* at 1137-39 (Nichols, Cowen, J.J., dissenting).

114. *Id.* at 1138.

115. On this point Judge Nichols noted:

The majority assumes that all this could have been duplicated in the laboratory The idea that the other tests could have been duplicated in the laboratory seems highly improbable It seems to be supposed that the laboratory technician could anticipate all the varieties of carpets used in St. Louis homes . . . , all the varieties of vacuum cleaners, with their variegated workings and degree of wear and tear; and all the ways the householder could produce malfunctions by dealing with the product in an unforeseen manner, with all the brands of engineering ineptitude to be anticipated in the average home.

Id.

recognized that market testing and product testing, in this instance, were "inseparable, and each was useless without the other."¹¹⁶ Judge Nichols concluded: "It is the refusal to recognize the existence of these problems here that divorces the court from reality and produces a decision that will be quite harmful in its effect."¹¹⁷

b. Establishing Durability, An Environmentally Dependent Quality

Durability is an ideal example of an environmentally dependent quality; it is the type of characteristic that can be adequately tested only in an invention's ultimate operating environment. Additionally, durability may be an essential aspect of an invention's claimed usefulness and effectiveness. This statement is particularly true of devices which are to be used outdoors, subject to, among other things, changing weather conditions. Problems thus arise where an invention must be publicly tested in order to establish its durability, and hence, utility. Accordingly, whether such an invention's patent can withstand a challenge under section 102(b) may turn on the court's recognition of durability as an inherent and necessary attribute of the device.

Illustrative of the foregoing is *Manville Sales Corp. v. Paramount Systems, Inc.*,¹¹⁸ which addressed the validity of a patent for a self-centering luminaire assembly for use on lighting poles. After the device initially proved operable on a test pole, the inventor contacted a Wyoming State official for possible use of the device at a State rest area. The inventor sought to establish the device's durability by testing it under the "wind, cold and corrosive atmospheric conditions"¹¹⁹ of its intended working environment.¹²⁰ After receiving permission to do so, the inventor installed the device at the rest area prior to the critical date. The rest area, significantly, was opened to the public subsequent to the critical date.

The court upheld the patent for the lighting assembly on the basis that the policies underlying the section 102(b) bars¹²¹ did not support invalidation on the facts of the case. First, the court noted, the inventor had done nothing to lead the public to believe that the invention had

116. *Id.* at 1139.

117. *Id.*

118. 917 F.2d 544 (Fed. Cir. 1990).

119. *Id.* at 548.

120. It should be noted that the inventor here was under a contractual obligation to supply a luminaire assembly for installation at the particular Wyoming public rest stop involved and that another assembly (of different design) had previously been installed by the inventor at the same rest stop but had since failed. *Id.* at 547. The court, however, apparently did not find this sufficient to implicate the on sale bar.

121. See discussion *infra* part V.A.

entered into the "public domain."¹²² Second, the inventor had not attempted to extend his patent term by commercially exploiting the invention prior to the critical date. Additionally, the court found that the inventor's actions were consistent with the policy "favoring prompt and widespread disclosure of inventions."¹²³ Finally, the court indicated that when durability in an outdoor environment is inherent to the particular purpose of an invention, further testing to establish its durability will not implicate the section 102(b) bars.¹²⁴ Accordingly, the court concluded that experimentation was the inventor's primary motive and thus no public use or on sale activity had occurred. On this basis, the inventor's patent was upheld.

Another case in which an invention's durability was at issue, but for which its patent was invalidated pursuant to section 102(b), was *Kinzenbaw v. Deere & Co.*¹²⁵ The patented invention concerned a method of driving a seed ejector in a row planter.¹²⁶ After the device had been embodied in a prototype planter, yet prior to the critical date, it was tested for a period of three years, in several farmers' private lots. Through this testing, the inventor intended to ensure the "warrantability, durability, and acceptability of the planter."¹²⁷

In invalidating the patent pursuant to the public use bar of section 102(b), thereby affirming the jury verdict in the district court, the Federal Circuit set forth the following rationale:

In using the machines to test them for [the inventor], the farmers served [the inventor's] commercial purposes. [The inventor] has dis-

122. The court observed:

[T]he 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. We therefore conclude that there was no conduct by [the inventor] that would lead the "public" to reasonably believe the invention was in the public domain.

917 F.2d at 550.

123. *Id.* Of importance to the court's finding was the fact that "[p]rior to its 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." *Id.*

124. *Id.* at 551; see also *Elizabeth v. Pavement Co.*, 97 U.S. 126, 135 (1877) ("If durability is one of the qualities to be attained, a long period, perhaps years, may be necessary to enable the inventor to discover whether his purpose is accomplished. . . . So long as . . . he keeps the invention under his control, [the inventor] does not lose his title to a patent."). But see *Paragon Podiatry Lab., Inc. v. KLM Lab., Inc.*, 984 F.2d 1182, 1187 n.5 (Fed. Cir. 1993) ("Further testing simply to determine if the manufacturer/licensee had made the device sufficiently durable—not a requirement of the claim—is not the type of testing constituting testing to determine if the device as claimed would work for its intended purpose.").

125. 741 F.2d 383 (1984), *cert. denied*, 470 U.S. 1004 (1985).

126. A "row planter" is an agricultural machine that, when pulled by a tractor, opens a furrow in the soil, places seeds at appropriate intervals, and loosely covers the seeds with earth. *Id.* at 385.

127. *Id.* at 390 (emphasis added).

avowed any claim that such use was experimental. [The inventor] used the farmers as its agents, and the testing of the machines was a commercial use by [the inventor] of its patented invention.¹²⁸

Significantly, the court made no mention of any monetary transaction, concerning the invention, between the inventor and the farmers or between anyone else, yet managed to find such use commercially motivated.¹²⁹

c. Patient Testing of Medical Devices

Medical devices and pharmaceutical compounds, as previously noted, are paradigmatic EDIs. Such inventions will very often require testing in their intended working environment (i.e., on people) in order to establish their practical utility.¹³⁰ The obvious difficulty with such testing, however, is that it is undoubtedly public to a certain extent and may, to the detached observer, appear commercially motivated. Thus, whether such an invention's patent will be invalidated in an infringement action by a challenge under section 102(b) is likely to be determined by the court's assessment of the necessity of public testing of the device or composition.

For example, the court in *TP Laboratories v. Professional Positioners, Inc.*,¹³¹ in upholding the validity of the patent in dispute, determined that public testing was necessary because of the nature of the invention.¹³² The device at issue was a molded tooth positioning appliance to be worn by persons undergoing orthodontal treatment. An application for patent was not filed for the invention until six years after it was first conceived and embodied in a working prototype. During this six-year period and prior to the critical date, the invention had been employed in the treatment of three patients for terms ranging from two months to approximately fourteen months.

In reaching its decision that the invention had not been in public use prior to the critical date, the court emphasized that disclosure of the device could not be avoided because testing of an orthodontic device, by its nature, has to be public to some extent.¹³³ It was unimportant to the

128. *Id.* at 391.

129. In fact, the court recognized that the inventor would move the device amongst farmers, when it was not being used "for a couple of days" in order to keep the device in continuous use. *Id.* at 390. This control, retained by the inventor, tends to negate any inference that the farmers paid the inventor in order to use the device.

130. See discussion *supra* part II.B.

131. 724 F.2d 965 (Fed. Cir.), *cert. denied*, 469 U.S. 826 (1984).

132. See *infra* note 133 and accompanying text.

133. 724 F.2d at 972. The court further recognized that:

[T]he variable of patient cooperation cannot be checked by one patient alone. Use on three patients is not an obviously excessive number. . . . Again, as in *City of*

court that the doctor had not asked his patients to swear to secrecy as "it is beyond reasonable probability that a patient would show the device to others who would understand the function of the [device] or would want to duplicate the device."¹³⁴ The requisite control over the invention was found to have been established inherently by the dentist-patient relationship.¹³⁵ Accordingly, the court applied the experimental use doctrine—thus negating any purported public use of the device—finding that the inventor had been testing the device, not the market.

Conversely, the Federal Circuit, in *Sinskey v. Pharmacia Ophthalmics, Inc.*,¹³⁶ refused to find the inventor's use of his device experimental even though the underlying facts were quite similar to those in *TP Laboratories*. The invention with which the court was concerned was a surgical loop used to implant intraocular lenses in patients whose eyes had suffered natural lens damage. The inventor contacted an outside medical laboratory to prepare drawings of the device and later purchased three completed lenses from the lab prior to the critical date. The lenses, however, were not sold commercially until after the critical date. Additionally, the inventor had, prior to the critical date, implanted lenses utilizing the loop in question, in a total of eight patients.

Probably the most determinative factor to the outcome of this case was that the inventor admitted, in a deposition, that no animal testing of the device was necessary prior to implantation in human beings as he was sure that it would work as intended, even without such testing. He subsequently recanted this position in a declaration in opposition to the Defendant's motion for summary judgment, maintaining that he considered the implantations to have been primarily experimental.¹³⁷ The Federal Circuit, however, found his contradictory testimony insufficient to raise a genuine issue of material fact. The court determined that the evidence in the case weighed heavily against experimental use.¹³⁸ Accordingly it affirmed the district court's dismissal on summary judgment, thus invalidating the patent at issue.

Elizabeth, the test of necessity had to run for a considerable time and on several patients before the inventor could know whether "it was what he claimed it to be" and would "answer the purpose intended."

Id.

134. *Id.*

135. *Id.*

136. 982 F.2d 494 (Fed. Cir. 1992), *cert. denied*, 113 S. Ct. 2346 (1993).

137. *Id.* at 497.

138. The "objective" evidence which the court deemed relevant for determining the absence of experimental purpose was: the inventor's regular fee was charged for the implantation operations; he did not inform the patients that they were being treated with an "experimental" lens; he did not obtain any kind of secrecy agreement from the patients or the surgical staff; and the inventor's failure to make notations in the patients' medical records about the use of the device. *Id.* at 499.

2. TIME FRAMING OF THE INVENTOR'S COMMERCIAL MOTIVATION

The Federal Circuit's often demanding inquiry with respect to inventors' commercial motivations is not limited solely to the realm of EDIs.¹³⁹ It may, however, present a greater problem for inventors of such devices where the experimentation necessary to perfect their inventions closely emulates "commercial" activity. The following cases are illustrative of the court's inconsistent time framing in its application of the on sale and public use bars.¹⁴⁰ In certain instances, the court will employ a broad time frame analysis and strictly scrutinize pre-critical date non-sale transactions to determine whether the inventor possessed commercial objectives in violation of the statutory bars. In other instances, however, the court will apply a more narrow time frame analysis and disregard, as immaterial, such pre-critical date transactions.

The court, in *Moleculon Research Corp. v. CBS, Inc.*,¹⁴¹ utilized a fairly narrow commercialization time frame in upholding the inventor's patent in a challenge under section 102(b). The invention at issue was a three dimensional puzzle comprised of eight cubes in a two by two arrangement capable of rotational movement.¹⁴² Prior to the critical date, the inventor had constructed several paper models of his puzzle and subsequently showed the models to several close friends, explaining its operation to at least one of them. Later, but still prior to the critical date, the inventor assigned all of his rights in the puzzle to his employer. The employer then proceeded to solicit toy and game manufacturers in an effort to market the puzzle.

The court noted, based upon the personal relationships involved and other surrounding circumstances, that the inventor had retained sufficient control over the puzzle's use and circulation of information about the invention.¹⁴³ Furthermore, the court found the record to lack any "hard evidence" of commercialization.¹⁴⁴ The court determined that a

139. See, e.g., *supra* notes 54-57, 63-64 and accompanying text.

140. For a more in-depth discussion on the general concept of "time framing," see Mark Kelman, *Interpretive Construction in the Substantive Criminal Law*, 33 STAN. L. REV. 591, 600-16 (1981) (discussing the relevance and effect of broad/narrow time frames on various doctrines of the substantive criminal law).

141. 793 F.2d 1261 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1030 (1987).

142. The puzzle resembled a "Rubik's Cube" with only four squares per face, as opposed to nine. In fact, the defendant here was the manufacturer of the once popular Rubik's Cube puzzle.

143. 793 F.2d at 1266.

144. *Id.* at 1267. The court stated:

Although [the defendant] attempts to paint a picture of commercialization from the discussions between [the employer] and [the inventor], we see only the brush strokes of speculation. . . . Discussion between employer and employee does not by itself convert an employee's private pursuit into commercial enterprise with the employer. [The defendant] also makes much of a . . . phone call by [the employer] to [the potential manufacturer] to see if the latter was interested in receiving a

mere assignment of patent rights in the invention was not a "sale" within the meaning of section 102(b).¹⁴⁵ In sum, the court concluded that no public use or on sale activity involving the invention had occurred prior to the critical date.

In *UMC Electronics Co. v. United States*,¹⁴⁶ however, the court held that the on sale bar was implicated even though the invention, at the time of the inventor's offer for sale, had not been "reduced to practice." The device involved was an aviation counting accelerometer (ACA), which the inventor had designed for the United States Navy for use in its aircraft. The Navy, in seeking an improved ACA, requested proposals from various contractors to deliver such a device. The inventor here, five days prior to the critical date, responded to this request with an offer to supply over one and one-half million dollars worth of its improved ACA. It must be stressed, however, that at the time of this offer the invention had not yet been reduced to a physical embodiment. Nearly six months later the Navy canceled its earlier request and issued another. Subsequently, the contract was awarded to another company, with the inventor receiving no payment whatsoever from the Navy for his invention.

The court found that the inventor had made a definite offer to sell the device prior to the critical date and accordingly determined that it was a *prima facie* attempt to commercialize the invention. The majority concluded that there had been a violation of the underlying policy of preventing inventors from extending the effective length of their patent monopolies beyond the seventeen-year term granted by Congress. In determining that reduction to practice should not be an absolute requirement of the on sale bar, the majority stated: "We do not attempt here to formulate a standard for determining when something less than a complete embodiment of the invention will suffice under the on-sale bar."¹⁴⁷ Nevertheless, the majority found the device at issue to be sufficiently complete to warrant application of the on sale bar, thus invalidating the inventor's patent.

In a forceful dissent,¹⁴⁸ Judge Smith rebuked the majority opinion, asserting:

submission of a puzzle idea from an outside inventor. Nothing concerning the nature or workings of [the inventor's] puzzle was disclosed. [The employer] simply inquired whether and how an outsider could submit a puzzle for the potential manufacturer's consideration. We agree with the district court that those facts do not show commercialization.

Id.

145. *Id.*

146. 816 F.2d 647 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1025 (1988).

147. *Id.* at 657.

148. *Id.* at 658 (Smith, J., dissenting).

It is the users of the patent system who will suffer the impact of the panel majority decision. The question is not theoretical; it is of great practical importance.

Those inventors who have sought financing, or who have contacted potential customers, or who have engaged in other normal business activities before they have made a workable device will not know the time limit for filing a patent application will be measured or where the line will be drawn between raw idea and proved invention. Inventors do not normally try to patent something they have not yet found workable. . . . Most inventors do not hire a patent lawyer until they know they have something that works, by which time, according to the panel majority, it may be too late.

. . . .

As the technology community will attempt to cope with this decision, it perforce will file more "paper patents": patents on sketchy concepts, before they have been reduced to practice and before the inventor knows whether or how the invention will work, or whether it is worth developing.

It is the details of how to make and use an invention that are of value in the patent disclosure. Bare ideas are not patentable.¹⁴⁹

In considering the impact that the court's ruling would have on business generally within the technological community, Judge Smith continued:

Industry does not commit time and money to the development of a technological idea without some marketplace investigation. Many businesses, especially small ones, seek customers for future delivery, before or while they are working out the technological details. The patent system should accommodate the ways of the real world, not place new pitfalls in the way of normal business pursuits.¹⁵⁰

149. *Id.* at 664-65. Judge Smith further stated:

The long history of section 102(b), which effects the irretrievable loss of a valuable right, shows judicial and congressional recognition of this need for reasonable certainty.

It was never the purpose of section 102(b) to force premature entry into the patent system upon inventors who are still developing their inventions. The public interest is not served by a system that wastes the resources of inventors

. . . .

. . . This requirement for an operable invention is in tune with the purpose of the patent system to encourage and patent useful inventions, not bare ideas.

Id. at 660 (footnotes omitted).

150. *Id.* at 665.

D. *The Federal Circuit's Inconsistent Application of the On Sale and Public Use Bars: A Breakdown of the Experimental Use Doctrine*

As the preceding cases illustrate, the Federal Circuit has lacked consistency in its application of the on sale and public use bars of section 102(b), particularly in its mitigating application of the experimental use doctrine. The court's analysis of these issues has done little to elucidate an area of patent law which requires certainty and predictability to assist inventors in ensuring patent protection for their inventions, thus encouraging innovation and the promotion of technological advancement. Instead, confusion remains the central theme, as noted by Judge Nies in *UMC Electronics Co. v. United States*:¹⁵¹

Chief Judge Wright's comments in *Philco Corp. v. Admiral Corp.* . . . are as apt today as when made in 1961:

"The cases dealing with § 102(b) of the Patent Act are in a state of confusion resulting in part from an attempt to establish hard and fast rules of law based upon overly refined legal distinctions. The area sought to be governed by these rules, however, encompasses an infinite variety of factual situations which, when viewed in terms of the policies underlying § 102(b), present an infinite variety of legal problems wholly unsuited to mechanically-applied, technical rules."¹⁵²

Unfortunately, this statement remains as applicable today as it was in 1987, when cited by Judge Nies. The Federal Circuit continues, in general, to apply rigid rules in determining whether an invention has been on sale or in public use within the meaning of section 102(b).¹⁵³ Of particular importance within the context of this Comment, the court appears to perceive a bright-line distinction, even where the inventor himself cannot, between bona fide experimental use necessary to bring an invention to perfection and the non-experimental use or sale following the invention's reduction to practice (i.e., commercial exploitation).¹⁵⁴

151. 816 F.2d 647 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1025 (1988).

152. *Id.* at 654 (quoting *Philco Corp. v. Admiral Corp.*, 199 F. Supp. 797, 815 (D. Del. 1961)).

153. See generally discussion *supra* parts III.B.1-2. The irony here is that the court in *UMC Electronics* purportedly recognized the validity of Chief Judge Wright's statement that section 102(b) is "wholly unsuited to mechanically-applied" rules, yet in that case it proceeded to apply just such mechanical rules in determining that the inventor's device in that case had been on sale prior to the critical date. *UMC Elec.*, 816 F.2d at 654; see *infra* note 182 and accompanying text.

154. The problem with the court attempting to draw such bright-line distinctions is that there exists an inherent tension between the ideal set forth in *Elizabeth* that an inventor should have time "to ascertain whether [his invention] will answer the purpose intended and make such alterations and improvements as *experience* demonstrates to be necessary" and the Federal Circuit's belief that the inventor's subjective intent to experiment is irrelevant in determining whether the use was, in fact, experimental. See *supra* text accompanying note 91 and *supra* note

The reasons for the court's inconsistent and unpredictable application of the on sale and public use bars and, more specifically, for its indefinite and varying application of the experimental use doctrine, can generally be attributed to several underlying factors. The ensuing discussion highlights some of those factors which appear to contribute to the court's failure to set forth a body of consistent and reliable precedent in this area.

First, the court at times fails to distinguish between strictly autonomous and environmentally dependent inventions (and their divergent need for public testing) in determining whether an activity has been carried out primarily for experimental or commercial purposes. In the case of *In re Smith*,¹⁵⁵ for example, the court did not find significant the fact that the powdered carpet composition at issue was ultimately to be used in dissimilar environments and that it may, in fact, react adversely or ineffectively under such diverse working conditions (i.e., with varying carpets and vacuum cleaners). Rather, the court concluded that all testing necessary to perfect the composition should have been performed in the inventor's laboratory, instead of in the homes of participants involved in the study.¹⁵⁶

As the dissent in *Smith* emphasizes, the chief difficulty with the majority's position is its perfunctory assumption that all such testing could have been *adequately* performed in a laboratory setting.¹⁵⁷ This supposition may hold true with respect to certain autonomous inventions, such as stereos or television sets which function wholly independently of their environment, but is categorically untrue of EDIs which, by their nature, react dependently with their environment.¹⁵⁸

As a direct consequence of failing to perceive the composition as environmentally dependent, the *Smith* majority asserted that the "dominant" purpose of the study was market testing and hence, commercially

99 and accompanying text. "Experience" as used by the Court in *Elizabeth* undoubtedly implies the inventor's experience, not the Court's. Thus, it is the inventor's knowledge and experience which is relevant to determining whether additional experimentation is necessary to perfect his invention and, accordingly, the inventor's "subjective" intent is highly germane to a finding of experimental purpose.

155. 714 F.2d 1127 (Fed. Cir. 1988).

156. *Id.* at 1138.

157. *Id.* at 1138.

158. In other words, a battery operated radio (reception aside) will operate similarly in both the frozen wastelands of the North Pole and the jungles of Malaysia whereas a pharmaceutical (the paradigm example of an EDI) will function slightly, if not dramatically, differently on various individuals. In *In re Smith*, the carpet powder was an EDI in that it could vary in effectiveness depending on the type of carpet and/or vacuum cleaner used. To test all possible combinations in the laboratory would be both costly and time consuming. Thus, the most efficient method of assuring the invention's effectiveness in the breadth of settings in which it is to be used, is to perform the type of mass consumer testing that was carried out here.

exploitative. Implicit in this analysis is the court's unstated belief that any product testing outside of the laboratory and involving members of the public is predominantly motivated by commercial objectives. This, of course, is not necessarily true and altogether ignores the realities of experimental testing of EDIs.¹⁵⁹ The difficulty inherent in these situations is that such experimental testing may, at first glance, closely emulate on sale or public use activity—or, more specifically, market testing—in that seemingly subjective consumer responses are taken into account in determining the overall effectiveness and utility of the invention.¹⁶⁰ In some situations, market testing and experimental product testing truly are, as Judge Nichols stated, “inseparable.”¹⁶¹ This fact, however, as implicitly recognized by the court in *Grain Products*,¹⁶² should not deprive inventors of EDIs their right to patent protection.

In *Kinzenbaw v. Deere & Co.*,¹⁶³ as in *Smith*, the Federal Circuit failed to distinguish between the necessity of public testing for EDIs (where such testing may be essential to establishing the device's utility) from that necessary for strictly autonomous inventions (where such usage may simply be indicative of the inventor's commercial objectives). The invention in *Kinzenbaw*, a tractor-mounted planting device, was clearly one that's effectiveness with continued operation depended upon its surroundings. It could not be properly tested in a laboratory and necessarily required testing in its intended working environment to establish its utility. In fact, durability, which was at the heart of the inventor's testing here, is a paradigm example of an essential quality which is verifiable only in an actual, non-simulated working environment.¹⁶⁴

159. It is true that some EDIs may be fully tested in a laboratory setting where all situations critical to the device's effectiveness can be readily simulated, e.g., heat, cold, etc. However, such contrived situations are quite limited in scope and are generally not acceptable for determining the functionality of more complex inventions.

160. In essence, the consumers are, in Judge Nichols' words, “amateur engineers.” *In re Smith*, 714 F.2d at 1138. Their responses as to the perceived functionality of the invention are not necessarily less viable than responses of engineers or technicians in the laboratory, and in some circumstances may be more telling. At some level, any such determination as to the device's effectiveness, whether by engineer or consumer, will appear partially subjective in nature. Accordingly, there is no rational basis for distinguishing the resulting data by the actor who obtained the results. In other words, merely because the perceived operativeness of a device is determined by a consumer is no reason to automatically assert “market testing” as the primary objective.

161. *In re Smith*, 714 F.2d at 1139.

162. 840 F.2d 902 (Fed. Cir. 1988).

163. 741 F.2d 383 (Fed. Cir. 1984), *cert. denied*, 470 U.S. 1004 (1985).

164. See *Elizabeth v. Pavement Co.*, 97 U.S. 126, 135 (1877) (The Court, recognizing the importance of ensuring an invention's durability through extensive testing in its intended working environment, stated: “If durability is one of the qualities to be attained, a long period, perhaps years, may be necessary to enable the inventor to discover whether his purpose is accomplished.”). See discussion *supra* part III.C.1.b.

The most efficient method of performing such experimentation, in this instance, was to have independent farmers test the device in their own fields (i.e., the intended working environment). Only in this manner could the inventor be assured that the device would be functional and effective in every possible operating environment. Significantly, the court referred to the farmers as the inventor's "agents,"¹⁶⁵ which appears to cut against a finding that the farmers' use was commercially motivated and hence a public use within the meaning of section 102(b). Nevertheless, the *Kinzenbaw* court, in striking down the inventor's patent pursuant to section 102(b), apparently failed to recognize the importance of affording the inventor an opportunity to establish the durability and utility of its EDI in the invention's intended and ultimate working environment without being subject to the public use bar.¹⁶⁶

Likewise, the court in *Sinskey v. Pharmacia Ophthalmics, Inc.*,¹⁶⁷ in contrast to its earlier decision in *TP Laboratories*,¹⁶⁸ disregarded the environmentally dependent nature of the subject invention, holding that the circumstances surrounding the invention's implantation on patients did not support a finding of experimental use. In fact, the medical device at issue in *Sinskey* is an ideal example of an EDI which requires public testing to establish its utility and effectiveness.

The most troublesome aspect of the Federal Circuit's analysis in *Sinskey* is that it never actually specifies which section 102(b) bar, the on sale bar or the public use, was responsible for invalidating the inventor's patent.¹⁶⁹ This distinction clearly should have been made by the court because the facts of the case do not seem manifestly dispositive of either. There does not appear to be any activity by the inventor which would constitute a sale under section 102(b). Certainly, a purchase by the inventor of his own invention from an outside laboratory responsible for its fabrication cannot be deemed such a sale. The fee received for surgical implantations of the device was the inventor's standard service fee and not a sale of the invention itself; in fact, the nature of the pay-

165. See *supra* text accompanying note 128.

166. But see *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 551 (Fed. Cir. 1990) (where the court upheld the inventor's right to test his invention's durability in its intended working environment, stating: "[M]erely because [the inventor] also tested the invention briefly in Ohio does not mean [the inventor] had ascertained whether the invention was operable for its intended purpose in its intended environment.") (emphasis added).

167. 982 F.2d 494 (Fed. Cir. 1992), cert. denied, 113 S. Ct. 2346 (1993).

168. 724 F.2d 963 (Fed. Cir.), cert. denied, 469 U.S. 826 (1984).

169. The court simply stated: "[The challenging party] has thus met its burden of establishing a *prima facie* case of invalidity under section 102(b) because the patented lenses were in public use or on sale more than one year before the patent application was filed." *Sinskey*, 982 F.2d at 498 (emphasis added). The disjunctive form of this statement leaves it unclear which statutory bar, on sale or public use, the court considered applicable. This distinction is more than mere semantics as the applications of the two bars are different and apply in separate contexts.

ment was no different than that charged by the inventor in *TP Laboratories*, where no sale was found.¹⁷⁰ Accordingly, there does not appear to be any commercialization of the invention which would tend to implicate the underlying policies of the on sale bar. Furthermore, contrary to the opinion of the court, there does not appear to be a plainly obvious public use of the invention in this case. The facts here, with respect to the patient implantations, are virtually identical to those in *TP Laboratories*, where no public use was found.¹⁷¹

Although the court in *Sinskey* does not expressly indicate whether it is considering application of the public use or on sale bar, it nevertheless places the burden on the inventor of presenting sufficient evidence of experimental purpose to raise a genuine issue of material fact.¹⁷² This, however, seems an improper shifting of the burden of production as it appears questionable that the challenger had met its burden of establishing a *prima facie* case that the invention was, prior to the critical date, on sale or in public use within the meaning of section 102(b).¹⁷³ Thus, although no issue of material fact was raised by the inventor, the determination that the invention had been on sale or in public use as a matter of law remains questionable in light of the *TP Laboratories* decision.

Smith, *Kinzenbaw*, and *Sinskey* each illustrate an additional problem with the court's application of the experimental use doctrine. It appears evident that the court perceives itself, as opposed to the inventor, as the proper party to determine whether extensive public testing was necessary to perfect a given invention. The court essentially disregards the inventor's expertise and propinquity to his invention in ascer-

170. The court in *TP Laboratories* noted that "[t]here is no evidence that [the inventor] charged patients specifically for any [of the inventions]. With two of the three patients, [the inventor] followed its regular practice of setting a fixed fee for professional services, which included the necessary appliances." *TP Labs.*, 724 F.2d at 968. Thus, the court determined that use of an invention which is merely incidental to a professional service is not a sale for purposes of section 102(b). This is precisely the situation in *Sinskey*. Therefore, the surgical fee charged in *Sinskey*, in accordance with the precedent of *TP Laboratories*, should not have been deemed a sale for purposes of section 102(b).

171. See *TP Labs.*, 724 F.2d 985 (Fed. Cir. 1992).

172. *Sinskey*, 982 F.2d at 498.

173. As the court noted in *TP Laboratories*:

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

Thus, the [district] court should have looked at all the evidence put forth by both parties and should have decided whether the entirety of the evidence led to the conclusion that there had been "public use." . . . [I]f a *prima facie* case is made of public use [by the challenger], the patent owner must be able to point to or must come forward with convincing evidence to counter that showing.

724 F.2d at 971 (footnote omitted).

taining whether sufficient testing had been conducted to ensure that the invention will answer its intended purpose.¹⁷⁴ Such a retrospective and removed "objective" determination of experimental use by the court, however, cannot be considered an ideal method for ascertaining the validity of an inventor's patent or his right thereto.¹⁷⁵

Another reason underlying the court's apparent failure to equitably apply the experimental use doctrine is its overly broad time framing with respect to the inventor's commercial objectives. In other words, the court will, on occasion, look to the inventor's profit motive at some unspecified point in time following the critical date, instead of examining whether the inventor actually received any payment during the statutorily proscribed period prior to the critical date.

In *UMC Electronics v. United States*,¹⁷⁶ for instance, the court utilized an exceedingly broad commercialization time frame analysis. It looked far beyond the date of the inventor's initial proposal to the Navy to determine whether a profit was expected at *any* time, irrespective of the critical date. The inventor in that case, merely five days prior to the pertinent critical date, had offered to supply his invention to the Navy at some indeterminate point in the future.¹⁷⁷ At the time this offer was made, the invention had not yet been reduced to practice. Furthermore, the proposed sale to the Navy never materialized. There was no actual sale, no passage of title ever occurred, and no money ever changed hands. Yet, the court found the offer to be commercial activity in contravention of the policies underlying section 102(b). This begs the question: Should a mere proposal to supply an invention to another party at an unspecified date in the future which never materializes into a completed transaction and from which no profit is ever realized be considered "commercial activity," thus offending the underlying policies of the on sale bar resulting in the inventor's complete and irretrievable loss of the right to a patent? This defies one's basic intuition and sense of equity.¹⁷⁸

174. See cases cited *supra* note 99 and accompanying text.

175. See *supra* note 154.

176. 816 F.2d 647 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1025 (1988).

177. *Id.* at 650.

178. In fact, under generally accepted accounting principles (GAAP), revenue from a sale of goods should not be "booked" until there has been an actual market transaction. That is to say, regardless of an outstanding offer to purchase, the seller cannot book revenue from a sale until passage of title to the goods has taken place. GAAP requires that any such transaction be sufficiently firm before it is entered on the income statement. It is apparent in *UMC Electronics* that this was not the case, as the sale, in reality, never materialized. Thus, at no time could the inventor indicate any revenue from the proposed sale on his books. Given this, it defies reason to categorize the inventor's proposal as the form of commercial activity which section 102(b) was designed to prohibit. There was never any extension of the inventor's monopoly here.

Likewise, in *Kinzenbaw*,¹⁷⁹ the Federal Circuit, in holding the inventor's patent invalid pursuant to the public use bar of section 102(b), upheld the following jury instruction given in the district court:

[I]f you find that the type of experimentation being done was primarily for commercializing the apparatus or process or toward gaining a competitive advantage or realizing a commercial gain, then such work, if it took place more than one year before the filing of applications on such alleged inventions, makes invalid any patent issuing on such applications.¹⁸⁰

The inherent problem with such a charge is that most inventors seeking a patent ultimately aspire to commercialize their inventions, gain competitive advantage, and realize commercial profit. Therefore, any experimentation conducted to perfect the invention is necessarily a means to that end. This is precisely the essence of the patent system. Limited monopolies, in the form of patents, are granted to inventors to encourage innovation. The ability to commercialize and profit from an invention is one of the inventor's rewards for stimulating scientific and technological advancement.

Both *Kinzenbaw* and *UMC Electronics* demonstrate the Federal Circuit's propensity for excessively broad time framing with respect to inventors' commercial motivations. Instead of focusing its analysis on the period of experimentation involved and then making a determination as to whether the inventor was profiting *at that time*, the court chooses to broaden the relevant time period for determining profit motive. It appears to ask whether the inventor made any effort to secure a profit at any time in the future while still attempting to perfect his device. If the court answers this question in the affirmative, the inventor will usually be found to have a predominantly commercial objective and will thus be barred, pursuant to section 102(b), from receiving a patent. As discussed above, this analysis runs counter to the underlying policies and goals of the patent system and, accordingly, creates a fundamental and indecipherable tension for inventors, particularly those of EDIs, who are attempting to perfect their inventions in order to obtain a patent.

Also closely related to the commercialization time framing issue, the court, as noted by Judge Smith in *UMC Electronics*,¹⁸¹ occasionally tends to divorce itself from the realities of the marketplace when applying the experimental use doctrine. Rather than considering the business practices necessary in research and development today under its "totality of the circumstances" approach, the court, in *UMC Electronics*, chose

179. 741 F.2d 383 (Fed. Cir. 1984), *cert. denied*, 470 U.S. 1004 (1985).

180. *Id.* at 390.

181. *See supra* text accompanying notes 148-150.

instead to mechanistically apply "rules" of law to reach an inequitable result.¹⁸² In general, the court deems irrelevant an inventor's need to secure a customer prior to devoting significant time and resources to the technological development of an invention (i.e., prior to the critical date). This practice, however, is quite significant in today's highly competitive marketplace particularly in fields such as military defense contracting, where there is an extremely limited market for the invention.

Another reason for the Federal Circuit's less than satisfactory application of the experimental use doctrine is that the court generally fails to perform an adequate policy-based analysis in each individual case. Instead, the court appears to presume that the policies underlying section 102(b) have been violated if it perceives that public use or on sale activity has occurred prior to the critical date.¹⁸³

Finally and most importantly, section 102(b) is itself the ultimate source of the court's inability to consistently and justly apply the on sale and public use bars. The court, in essence, is compelled to apply mechanical, bright-line rules because the statute, by its own terms, requires no less. The one-year grace period of section 102(b) is a bright-line rule. Regardless of the court's attempt to circumvent this bright-line mandate via the experimental use doctrine or policy based arguments, lines will be drawn and mechanical rules applied. This is an unfortunate consequence of a statute lacking in clarity and design.

IV. THE UTILITY REQUIREMENT OF § 101 AND THE ON SALE AND PUBLIC USE BARS OF § 102(b): A STATUTORY DICHOTOMY FOR INVENTORS OF ENVIRONMENTALLY DEPENDENT INVENTIONS

When viewed together, sections 101 and 102(b) present a considerable dilemma for the inventor of EDIs. On the one hand, the inventor must adequately test his invention to ensure that it is sufficiently useful to satisfy the utility requirement of section 101. Depending upon the

182. *UMC Elec. v. United States*, 816 F.2d 647 (Fed. Cir. 1987). For instance, the Federal Circuit readily accepted the fact that a mere offer to sell an invention prior to the critical date is on sale activity within the meaning of section 102(b). *See, e.g.*, cases cited *supra* notes 56-57 and accompanying text. The court's rationale for this rule goes something like this: (1) An offer to sell an invention constitutes commercial activity; (2) Commercial activity prior to the critical date violates the policies underlying the on sale bar of section 102(b); (3) If the underlying policies are offended, the bar is thus implicated; (4) Accordingly, an offer to sell the invention prior to the critical date implicates the on sale bar (i.e., will be on sale activity within the meaning of section 102(b)). This is the rule. The problem with this analysis is that each step in the reasoning process is subject to error (particularly step one) and will thus offset the legitimacy of the rule as applied to any given set of facts. As such, unquestioning application of the rule, without further scrutiny, will lead to illogical (and sometimes inequitable) results such as that reached in *UMC Electronics*.

183. *See infra* notes 191-192 and accompanying text.

nature of the invention and the environment(s) in which it is to be used, this may require substantial testing, both in terms of time and breadth.

On the other hand, the inventor cannot place his invention on sale or in public use more than one year prior to his filing if he wishes to avoid the possibility of subsequent denial or invalidation of his patent.¹⁸⁴ If, however, the inventor must test the invention for more than one year in an environment other than a confidential laboratory setting to reasonably satisfy to himself that the device is sufficiently useful—he is constrained to optimistically rely upon a later and wholly uncertain finding of experimental use by either the Patent Office or the court. If such use or sale of the invention is subsequently found not to have been experimental, regardless of whether the inventor honestly and reasonably believed it to be, his time and effort will have been in vain as his patent will be invalidated pursuant to section 102(b).

Indeed, this situates the inventor between the proverbial rock and a hard place. He is forced to choose between applying preliminarily for a patent, that is, before he is convinced that the device is useful, either to his subjective standards or those of the Patent Office and applying late for a patent (i.e., more than one year after public testing began), knowing that the invention will function properly for its intended purpose. Either way, his invention may be subject to a later attack of invalidity by a contesting party in a patent infringement suit or interference proceeding.¹⁸⁵ If the inventor files too early, he risks rejection by the examiner in the Patent Office for insufficient utility under section 101. Even if the patent is granted on an insufficient showing of practical utility, its validity may be challenged, and hence the patent invalidated, in a later infringement action or interference. If, conversely, the inventor files his application too late, he risks rejection of his application for violating the section 102(b) bars. Again, even if the patent is granted, it may be challenged in a later infringement action on the basis that the invention was on sale or in public use prior to the critical date.

These concepts are elucidated by the following hypothetical illustration. Assume that an inventor has developed an orally administrable pharmaceutical composition which he believes will be effective in

184. The fundamental problem is that both on sale and public use activities are determined retrospectively by the Patent and Trademark Office or the court. Thus, at the time of experimentation, the inventor has no way of knowing whether his activities will be deemed to violate section 102(b) at either the time of application for patent or in a later infringement action.

185. See, e.g., *Sinskey v. Pharmacia Ophthalmics*, 982 F.2d 494 (Fed. Cir. 1992) (holding the inventor's patent invalid under section 102(b), in a patent infringement action, on the infringing party's motion for summary judgment), *cert. denied*, 113 S. Ct. 2346 (1993); *Cross v. Iizuka*, 753 F.2d 1040 (Fed. Cir. 1985) (upholding the validity of the inventor's foreign priority application in an interference proceeding where the challenging party had asserted that the invention lacked "practical utility" under section 101).

preventing the recurrence of a certain form of malignant cancer that is known to exist only in human beings. The composition has already been tested on a group of test animals and has been proven reasonably safe for use in humans. The cancer has a proven recurrence rate of seventy-five percent during the period eighteen to fifty months following remission, and a recurrence rate of less than five percent prior to eighteen months. The inventor is a chemist, not a doctor, and therefore must enlist the assistance of an oncologist to perform the tests properly. Additionally, because the inventor is not a large pharmaceutical corporation, he has limited resources and cannot afford to merely give the expensive composition away. The oncologist, recognizing the remarkable medical potential of the drug, has offered to pay the inventor at cost (i.e., the inventor makes absolutely no profit) for the test supply. The composition is administered daily to a test group of thirty-two patients who are all in remission from the cancer following extended chemotherapy. After thirty-six months of continuous treatment, only two patients have redeveloped the cancer when, without the drug and under the same conditions, fourteen patients would likely have suffered a recurrence. At this point, both the inventor and the oncologist are convinced that the composition is effective and thus useful within the meaning of section 101.

The essential question is: When should the inventor file an application for patent? Under current Federal Circuit precedent, if the inventor were to wait for thirty-six months (the point at which he is certain that the invention is useful) to file his patent application, it would likely be rejected under both the on sale and public use bars of section 102(b) (with the use on patients being considered public and the transfer of the composition, at cost, to the oncologist being deemed on sale activity). If, however, he were to attempt to file for a patent prior to the eighteen month period in which the rate of recurrence was only five percent, there would be no objective basis whatsoever to conclude that the composition does or does not possess utility. Therefore, it is quite unlikely that a patent would issue under these circumstances. Even if the patent were to issue at that time, it would be subject to invalidation pursuant to section 101 in a subsequent challenge by an infringing party.

The determination of when to file a patent application for the composition is difficult given the significant time and resources at stake. It is unlikely that the inventor would pursue such societally beneficial research unless he felt confident that he would receive the protection of a patent for his invention. This quandary, however, is one with which inventors of EDIs are often and unjustifiably faced under the current implementation of section 102(b).

One of the primary problems with this statutory Catch-22 is that the inventor has everything to lose while the challenging party, who may well be a willful infringer, has everything to gain. In other words, the inventor who honestly believed that he was working to perfect his invention may have his patent invalidated following a challenge, under either section 101 or 102(b), by the defendant in an infringement action. Certainly, a statutory scheme which tends to benefit infringers over rightful inventors cannot be the basis of an equitable system of patent rights.

V. A PROPOSAL FOR LEGISLATIVE REFORMATION OF SECTION 102(b)

Statutory reformation of section 102(b) is presently necessary, as the Federal Circuit's application of the experimental use doctrine has proven unsatisfactory in practice. Neither inventors nor patent attorneys can reliably predict which activities the court will deem to place an invention on sale or in public use and which it will consider to be primarily experimental. As a result, inventors wary of having their patents subsequently invalidated are unnecessarily constrained in the scope of their testing and may feel compelled to file patent applications prematurely, before their inventions have been fully perfected. Because society has a legitimate interest in receiving those inventions which have already been perfected,¹⁸⁶ it is essential that the statute itself be modified to afford inventors a greater period of time (i.e., beyond the current one-year period) where necessary to perfect their inventions.

A. *The Policies Underlying Section 102(b)*

The Federal Circuit has consistently recognized four fundamental policies which underlie both the on sale and public use bars of section 102(b).¹⁸⁷ These policies include:

- (1) discouraging removal of inventions from the public domain that the public reasonably has come to believe are freely available;
- (2) favoring the prompt and widespread disclosure of inventions;
- (3) prohibiting the inventor from commercially exploiting his invention beyond the statutorily prescribed time; and
- (4) allowing the inventor a reasonable amount of time following sales activity to determine the potential economic value of a

186. *Elizabeth v. Pavement Co.*, 97 U.S. 126, 137 (1877) ("[I]t is in the interest of the public, as well as [the inventor] himself, that the invention should be perfect and properly tested, before a patent is granted for it.").

187. Although the Federal Circuit has expressly recognized the given policies as underlying the on sale bar, it has implicitly recognized the same four policies as supporting the public use bar. See, e.g., *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549-50 (Fed. Cir. 1990); *TP Labs., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 968 (Fed. Cir), *cert. denied*, 469 U.S. 826 (1984).

patent.¹⁸⁸

Although these policies focus on legitimate public concerns and are genuinely well-intentioned, the on sale and public use bars of section 102(b), as applied to inventors of EDIs, are not efficient or just means of achieving the desired policy ends. It is apparent that section 102(b), when employed to effectuate policies one through three above, is overinclusive in its operative scope. That is to say, application of section 102(b) will accomplish the desired policy objectives, but at the continued expense of inventors of EDIs generally.

For example, the aim of policy number one is to discourage the removal of inventions from the public domain upon which the public has already come to rely. Section 102(b), however, will operate to invalidate or prevent patents from issuing for inventions in which actual public reliance is not even possible—inventions such as those which are impossible to duplicate through reverse engineering methods or those which are so deeply embedded within another device that actual awareness of the invention would be virtually impossible.¹⁸⁹ Public reliance, even for these types of inventions, is generally presumed once the device has entered the public domain.

Section 102(b) is also overinclusive with respect to policy number two which favors the prompt and widespread disclosure of those inventions which have proven to be useful and societally beneficial. Specifically, the on sale and public use bars may be used to invalidate the patent of an invention which had not yet been shown to possess a specific utility as of the date one year following its entry into the public domain. The statute, therefore, assumes that all inventions necessarily possess some demonstrable and specific utility after the invention has been in the public domain for a period of one year. This assumption, however, is not necessarily true.

188. *Envirotech Corp. v. Westech Eng'g, Inc.*, 904 F.2d 1571, 1574 (Fed. Cir. 1990); *UMC Elec. Co. v. United States*, 816 F.2d 647, 652 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1025 (1988); *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 860 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1016 (1986); *In re Caveney*, 761 F.2d 671, 676 (Fed. Cir. 1985); *Manville Sales*, 917 F.2d at 550; *TP Labs.*, 724 F.2d at 968. For a more in-depth discussion of these policies and their evolution and application, see generally Note, *New Guidelines for Applying the On Sale Bar to Patentability*, 24 STAN. L. REV. 730 (1972); William C. Rooklidge, *The On Sale and Public Use Bars to Patentability: The Policies Reexamined*, 1 FED. CIR. B.J. 7 (1991).

189. See, e.g., *Hall v. MacNeale*, 107 U.S. 90 (1883) (public use found where the invention was embodied within the construction of a burglar-proof safe even though the safe would have to be destroyed in order to bring the invention into view); see also *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881) ("[S]ome inventions are by their very character only capable of being used where they cannot be seen . . . by the public eye. . . . Nevertheless, if its inventor . . . allows it to be used without restriction of any kind, the use is a public one."); *Koehring Co. v. Nat'l Automatic Tool Co.*, 362 F.2d 100, 104 (7th Cir. 1966) ("the fact that an invention is buried within a machine is irrelevant to a determination of public use").

Furthermore, considering the Federal Circuit's tendency to apply a broad time frame analysis to inventors' commercial motivations, the statute is also overinclusive with regard to the third enumerated policy. The statute has been used to invalidate patents on the basis of the inventor's commercial ambitions existing prior to the critical date, even though the inventor had not received any payment for the invention at that time and thus cannot be said to have extended the effective length of his patent term.

Finally, with respect to the fourth policy, which is intended to counterbalance policies one through three, section 102(b) is decidedly underinclusive, particularly when applied to the testing and perfection of EDIs. A one-year grace period, irrespective of invention type or other surrounding considerations, is not necessarily a "reasonable amount of time . . . to determine the economic value of a patent."¹⁹⁰ Nor is it necessarily a reasonable period to test and perfect the device to ensure its utility prior to seeking a patent. Problems often arise in this regard, as noted previously, when the testing procedures for EDIs simulate on sale or public use activity.

Beyond the seemingly over and underinclusive nature of the statute itself, the Federal Circuit has done little to tighten the loose fit between the statute and its purported policy objectives. The court, in practice, tends to recite the stated policies and then determine, in a rather conclusory fashion, that the policies have been violated by a given sale or use without providing further policy-based analyses.¹⁹¹ This appears to stem from the presupposition that the mere application of the statute, without more, upholds the underlying policies.¹⁹² The difficulty here

190. *Envirotech*, 904 F.2 at 1574.

191. See, e.g., *id.* at 1574-75; *UMC Elec.*, 816 F.2d at 652-53; *In re Caveney*, 761 F.2d at 676; *TP Labs.*, 724 F.2d at 968. But cf. *Manville Sales*, 917 F.2d at 550-51 (The court analyzed each of the underlying policy considerations in succession with respect to the pertinent facts of the case, holding the on sale and public use bars inapplicable and upholding the patent at issue).

192. The court implicitly applies an inaccurate syllogism in reaching this conclusion. This is best illustrated through use of the transitive property of elementary mathematics, that is: if A=B (step one) and B=C (step two), then A=C (step three). More specifically, if there is a sale or public use before the critical date, the statute has been violated (step one). Violations of the statute are necessarily contrary to the policies underlying the on sale and public use bars of section 102(b) (step two). Thus, any sale or public use before the critical date is contrary to the underlying policies (step three). The problem with this approach is that both steps one and two are flawed. This will lead to a cumulatively defective step three, the conclusion. The problem with step one is that the court typically finds most pre-critical date transfers of an invention between an inventor and another party, regardless of genuine purpose, to constitute on sale or public use activity. The court's application is, thus, usually too strict. Step two, as discussed above, is flawed in that it does not efficiently effectuate the underlying policies of section 102(b), because the statute is both over and underinclusive. Thus, the court's conclusion that a use which it deems to be a sale or public use is contrary to the policies underlying section 102(b) should not readily be accepted on its face.

lies in the fact that the court, with no real congressional guidance, must attempt to remedy the deficiencies inherent in the statute.¹⁹³ Because section 102(b) is ill-suited to properly effectuate the enumerated policy objectives, the court's continued use of the present on sale and public use bars, with its concurrent mitigating application of the experimental use doctrine, will perpetuate the inconsistencies in the court's precedent and, moreover, will go beyond achieving the desired policy ends to cause seemingly inequitable results.

In sum, if the above policies truly reflect Congressional intent, which continues to be the position taken by the Federal Circuit, then section 102(b) is an inefficient means by which to achieve those policies. Statutory change is needed both to better serve the desired policy ends and to promote fairness among inventors who legitimately require longer periods of time to perfect their EDIs. In the end, fairness is a necessary prerequisite in a system designed to stimulate innovation in the sciences and the useful arts.

B. *A Suggested Statutory Amendment*

Section 102(b), when examined in light of the Federal Circuit's application thereof and the inherent conflict existing between it and section 101, fails to adequately and equitably effectuate its underlying policies. The following is a recommended modification of section 102(b) aimed at ensuring all inventors a sufficient period of time to perfect their inventions, while remaining faithful to the other policies which underlie the statute.

First, in addition to the currently existing on sale and public use bars, a pre-patent application process should be implemented whereby an inventor could request experimental status for his invention. The inventor would send to the PTO his preliminary inventive concept (i.e., before any particular utility had been demonstrated) on a standard form, and the PTO would then return notice that the form had been received. The PTO would not immediately scrutinize the contents of the form, but would merely date it and file it away. Once the inventor received notification, he would then be permitted to test the invention in public without implicating either the on sale or public use bars. The invention, while being tested, would be marked with an encircled E (for "experimental use"), which would be prominently located on the invention's exterior surface.¹⁹⁴ The E would indicate to the public that the inventor had initi-

193. Congress has never defined, for purposes of section 102(b), what precisely is meant by the terms on sale and public use. As a result, the court has been forced to define these terms on its own. This, in itself, leads to great uncertainty in the application of the bars.

194. One commentator has proposed a similar marking notice system (i.e., "patent to be

ated this preliminary stage of the patent process, so that others would not come to reasonably believe that the invention was freely available. This procedure would satisfy the first of the statute's underlying policies.

The second stage of this process would entail a subsequent mandatory filing procedure within one year of the inventor's experimental status filing. The inventor would, at this stage, file a complete application for patent. If the invention is determined to possess sufficient utility for patentability on the basis of the application, a patent would issue regardless of the inventor's subjective belief that the invention is not yet complete. If the application is determined to lack sufficient utility for patentability and the inventor can demonstrate due diligence (before the PTO) in attempting to perfect his invention, then the inventor shall be granted an extension on his invention's experimental status. If, on the other hand, the inventor fails to make such a showing of due diligence, he should then lose the right to continued experimental status. More importantly, the inventor should be denied, retroactively, the experimental status granted under stage one of this proposal.

If the extension is granted, it could have either a set time period of say, one year, or could be awarded on the basis of invention class and/or surrounding circumstances. At the end of this extended period, it would be incumbent upon the inventor to file another patent application in order to determine whether a particular utility had been established for his invention. Thus, the process repeats itself until either the invention is found to possess sufficient utility for patentability or until the inventor has failed to establish due diligence in perfecting his invention. Once the invention's utility has been evidenced and a patent consequently issues, the inventor's seventeen-year patent term would accordingly commence from that date.

Thus, the second stage of the proposal would encourage both the policy of favoring the prompt and widespread disclosure of *useful* inventions as well as the policy of prohibiting an inventor from commercially exploiting his invention beyond the statutorily prescribed seventeen-year patent term. An inventor choosing this option would be compelled to diligently pursue his experimentation for fear of losing his invention's experimental status retroactively and being subjected to the already existing on sale and public use bars. It would thus be difficult for inventors to take advantage of this more forgiving proposal in order to extend the effective length of their patent monopolies. Accordingly, inventors who genuinely require additional time to perfect their inventions, beyond that currently afforded by section 102(b), would be permitted to

applied for") to avoid detrimental public reliance on pre-patent inventions placed into the public domain for experimental purposes. See Schainholz, *supra* note 102, at 394.

diligently continue their experimentation until a specific utility can be demonstrated before the PTO. On the other hand, those who attempt to take advantage of this statutory experimental status would be subjected to and unprotected against the currently existing statutory bars.

The following is an encapsulation, in statutory form, of the foregoing proposal:

§ 102. A person shall be entitled to a patent unless—

* * *

(b)(1) except as otherwise provided in paragraph (b)(2) of this section, the invention was . . . 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.¹⁹⁵

(2) If, prior to placing the invention in public use or on sale in this country, such person has applied for and received experimental status for the invention from the Patent and Trademark Office, paragraph (b)(1) of this section shall not apply, provided—

(A) such person, upon placing the invention into the public domain, gives proper notice to the public of the invention's experimental status,¹⁹⁶ and

(B) such person files an application for patent, as prescribed by section 111¹⁹⁷ of this Title, within one year of the application for experimental status and the conditions of paragraph (b)(3) or (b)(4) of this section are subsequently complied with.

(3) If, pursuant to section 101¹⁹⁸ of this Title, the invention is found not to be useful at the time of filing of the application for patent required by paragraph (2)(B) of this section and—

(A) the person demonstrates due diligence in attempting to establish the invention's usefulness, such person shall receive an extension of his invention's experimental status for a period to be established by the Commissioner. Within the prescribed period, such person shall file an additional application for patent. This procedure shall continue until either the invention's usefulness has been estab-

195. 35 U.S.C. § 102(b) (1988). Although the phrase "was patented or described in a printed publication in this or a foreign country" is not shown here as part of the proposed section 102(b), it is nonetheless intended to remain. *See id.* It was omitted here solely for the purpose of narrowing the reader's attention to the matter at hand; that is, to the proposed revisions to the on sale and public use bars of section 102(b).

196. The form of notice contemplated here is similar to that provided for in 35 U.S.C. § 287(a) (1988), which states: "Patentees, and persons making or selling any patented article for or under them, may give notice to the public that the same is patented, either by fixing thereon the word 'patent' or the abbreviation 'pat.'" The only difference being that in the case of notice of experimental status, the required marking should be in the form of an encircled E (similar to the encircled R used for registered trademarks).

197. 35 U.S.C. § 111 (1988) (setting forth the specific requirements for the inventor's application for patent).

198. 35 U.S.C. § 101 (1988). *See discussion supra* part II.

lished for purposes of section 101 of this Title or the person fails to demonstrate due diligence in attempting to establish the invention's usefulness; or

(B) the person fails to demonstrate due diligence in attempting to establish the invention's usefulness, such person shall be deemed not to have satisfied the requirements of subparagraph (b)(2)(B). Accordingly, the limitations of paragraph (b)(1) shall apply, irrespective of any other actions taken by such person under paragraph (b)(2).

(4) If, on the basis of such application for patent as required by subparagraph (2)(B) of this section, the conditions for patentability set forth in this Chapter are otherwise met, a patent shall issue for the invention upon compliance with section 151¹⁹⁹ of this Title.

The principal improvement embraced by this revision of section 102(b) is that experimental use is provided for within the statute itself instead of operating solely as a judicially created exception to section 102(b). The essential difference being that, under this statutory formulation, a more objective basis exists for tracking the inventor's experimental use of his invention, as the determination of experimental use is made simultaneously with the invention's period(s) of testing, as opposed to several years later in an infringement action. This eliminates the retrospective approach currently employed by the Federal Circuit in its application of the experimental use doctrine. Instead the responsibility of ascertaining whether an inventor is genuinely testing his invention is placed upon the PTO, an entity better suited to making such a determination.

Permitting inventors to demonstrate legitimate experimental purposes until they are able to establish a specific utility for their inventions while they are *in the process of testing*, would significantly benefit inventors of EDIs. In sum, implementation of the above statutory proposal would greatly enhance objectivity and certainty with respect to the experimental use of EDIs and would thus serve to eliminate the dichotomy which currently exists between sections 102(b) and 101.

The greatest drawback of this statutory proposal is the administrative burden which it could conceivably place on the PTO. If all inventors were to file for experimental status as contemplated by the statute, and then subsequently proceed to file for extensions thereof, the increased workload on the patent examiners at the PTO would create a significant burden. The proposed experimental status filing is entirely optional, however, and it is quite unlikely that more than a small minor-

199. 35 U.S.C. § 151 (1988) (specifying the notice of payment and payment requirements for issuance of a patent following a determination by the PTO that the applicant is otherwise entitled to a patent under law).

ity of inventors would choose this route because of the risks involved. For example, if the inventor places his invention on sale or in public use before filing for experimental status and thereafter fails to make an adequate showing of due diligence in attempting to perfect his invention on the date one year after the filing for experimental status, he will be retroactively subject to the on sale and public use bars and thus could lose his right to a patent for his invention. Accordingly, the inventor must make an honest and reasonable attempt to perfect his invention during this period.

This system operates as an incentive for the inventor to file a sufficient and complete patent application, thereby discouraging fraudulent attempts at extension of the invention's experimental status for commercial purposes. Those inventors who do not actually require additional time to publicly test their inventions beyond the one-year grace period already provided by section 102(b) will be unlikely to risk losing their right to a patent altogether. Thus, only those inventors who genuinely require an extended period of time to publicly test, in order to perfect, their inventions (i.e., inventors of EDIs), would be willing to undertake such a calculated risk. As such, the proposed section 102(b) is unlikely, in practice, to be as administratively impracticable as it may appear.

VI. CONCLUSION

The fundamental objective underlying the patent laws, as set forth in the United States Constitution, is the promotion of science and the useful arts.²⁰⁰ Any act of Congress enacted pursuant to this directive, in order to withstand Constitutional scrutiny, must be an appropriate and plainly adapted means to this enumerated end.²⁰¹ Accordingly, it follows that the policies underlying any individual patent statute must necessarily be subordinate to the fundamental goal of promoting scientific and technological innovation. A statute which, in practice, tends to hinder or otherwise undermine this scheme should be modified in part or repealed altogether.

Section 102(b), to the extent that its application by the Federal Circuit frustrates this basic Constitutional design (particularly as it is applied to EDIs), must be modified to better effectuate the goal of promoting scientific innovation. The reasons for the statute's seeming failure are several. First and most importantly, the statute, in its present form, affords a fixed one-year grace period irrespective of an inventor's genuine need to adequately test his device in the public domain. The court has attempted to remedy this statutory shortcoming through appli-

200. U.S. CONST. art. I, § 8, cl. 8.

201. See *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316 (1819).

cation of the judicially created experimental use doctrine. It is apparent, however, that the doctrine has fallen short of its intended purpose as inventors are rarely given its benefit by the court, even in those instances where it may be reasonably necessary for the inventor to perfect his invention. Accordingly, the statute has operated as a hindrance, and hence a deterrent, to inventors wishing to satisfactorily test their EDIs.

Additionally, in its present form and application by the court, section 102(b)—whether viewed by itself or in conjunction with the utility requirement of section 101—is a source of great uncertainty for inventors. Inventors and patent counsel alike, under current Federal Circuit precedent, cannot with confidence know where to draw the line between raw idea and proven invention. In many instances, this uncertainty leads to the situation where an inventor, by necessity, extends the period of experimentation beyond the one-year grace period of section 102(b) in an honest attempt to perfect the device, only to have a patent subsequently denied or invalidated by the Patent Office or the courts because his use, in retrospect, did not appear experimental. Nothing serves as a greater deterrent to innovation than denying the well-intentioned inventor, following substantial expenditures of both time and money, the fruits of his labor. The disconcerted inventor will doubtless be once bitten, twice shy.

Finally, the Federal Circuit, in its interpretation of section 102(b), unduly emphasizes an inventor's profit *motive*, as opposed to actual profit received, in determining whether the statute has been transgressed. This analysis ignores the reality that most inventors who seek patent protection for their inventions ultimately aspire to profit from the resulting monopoly. Indeed, this expectation is fundamental to the quid pro quo contemplated by the patent system. To deny inventors patents, in order to penalize them for possessing commercial ambitions prior to the perfection of their inventions, is to undermine the basic incentive scheme necessary for the stimulation of technological innovation. Thus, the court invariably places the policy of preventing an inventor from commercially exploiting his invention beyond the one-year grace period specified in section 102(b) *above* the Constitutional directive of promoting the sciences and useful arts. Undoubtedly, this constitutes a deleterious reorganization of the Constitutional hierarchy which can be rectified only through a statutory reformation of section 102(b).

In summation, doctrinal solutions to the inherent imperfections of section 102(b) have proven unsatisfactory in practice both prior to and following the inception of the Federal Circuit. The appropriate remedy is not to be found doctrinally, but rather in fundamental statutory change of section 102(b). This Comment proposes legislative modification in

the hope that the ultimate Constitutional objective of promoting the progress of science and the useful arts can be maintained while remaining faithful to the policies underlying section 102(b).

JAMES A. JORGENSEN