SCALTECH INC. V. RETEC/TETRA L.L.C. & ABBOTT LABORATORIES V. GENEVA PHARMACEUTICALS, INC.

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The complexities of modern inventions demand continued evolution of intellectual property law. While the constitutional goal of patent law remains to "promote the Progress of Science and useful Arts,"[1] the tests that effectively promote this policy are shaped by the technologies to which they apply. Advancements in technologies require refinements in the rules that analyze their development and determine their legal status.

A fundamental tenet of American patent law involves a "carefully crafted bargain" which grants limited exclusivity to a new, useful and nonobvious development in exchange for its disclosure and eventual dissemination.[2] A provision in the law specifically designed to enforce this statutorily defined exclusivity period is the "on-sale" bar to patentability, codified in section 102(b) of the Patent Act.[3] The bar prevents an inventor from obtaining a patent on an otherwise eligible invention if it was commercially marketed in the U.S. more than a year before its patent application.[4]

The history of section 102(b) reveals a continuing judicial controversy surrounding the interpretation of the term "invention." The issue concerns the extent to which an invention must be developed before its commercialization will trigger the on-sale bar.[5] The recent Supreme Court deci-

1. U.S. CONST. art. I, § 8, cl. 8.
2. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150-51 (1989).
3. 35 U.S.C. § 102(b) provides: "A person shall be entitled to a patent unless . . . the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States. . . ." 35 U.S.C. § 102(b) (1994). *See generally* William G. Phelps, *When Does On-Sale Bar of 35 U.S.C.A. § 102(b), Which Denies Patentability to Invention That Has Been On Sale for More Than One Year Prior to Date of Patent Application, Prevent Issuance of Valid Patent*, 155 A.L.R. FED. 1 (1999).
4. *See* 35 U.S.C. § 102(b) (1994). When asserted as an affirmative defense against infringement, § 102(b) can invalidate a patent if a showing of clear and convincing proof that the patent should not have been granted overcomes its presumptive validity. *See* Abbott Lab. v. Geneva Pharm., 182 F.3d 1315, 1318 (Fed. Cir. 1999); 35 U.S.C. § 282 (1994) (providing that a patent is presumed valid and that the burden of establishing invalidity shall lie with the party asserting it).
5. *See* Pfaff v. Wells Elec., Inc., 119 S. Ct. 304, 308 (1998).

sion in *Pfaff v. Wells Electronics, Inc.* provides a new test in which the commercialization of an invention triggers the bar if the invention is "ready for patenting."[6] Readiness for patenting, in turn, can be shown by the invention's "reduction to practice."[7] Two recent Federal Circuit cases, *Scaltech Inc. v. Retec/Tetra L.L.C.*[8] and *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*,[9] however, both involved sales of inventions allegedly reduced to practice at a time before the inventors were cognizant of all of their patentable features. This situation arose partly because of the complex technologies involved in the patents at issue, namely, petroleum refining in *Scaltech*[10] and pharmaceutical chemistry in *Abbott.*[11] *Scaltech* and *Abbott* thus reveal an inconsistency within the *Pfaff* test: inventions reduced to practice may not literally satisfy the "ready for patenting" prong of the test.

This Note will first consider the history and policies of the on-sale bar, including other aspects of patent law that impinge upon its interpretation, and how these interpretations have shaped 102(b) analyses. It will next summarize the holding of *Pfaff* and the decisions that followed in *Scaltech* and *Abbott*. The Note will then discuss how these two cases reveal a structural inconsistency within the test and analyze how courts apply the inherency doctrine so as to resolve this inconsistency in accordance with principle. Finally, the Note will suggest an amended *Pfaff* test that may more directly and reliably effectuate its underlying purpose.

I. BACKGROUND

A. History and Policy of the "On-Sale" Bar

Originally, any sale or public disclosure of an invention abrogated an inventor's right to a patent.[12] Congress later ameliorated this rule to allow inventors a two year grace period in which to file.[13] One hundred years

6. *Id.* at 312.
7. *Id.*
8. Scaltech Inc. v. Retec/Tetra, L.L.C., 178 F.3d 1378 (Fed. Cir. 1999).
9. Abbott Lab. v. Geneva Pharm., Inc., 182 F.3d 1315 (Fed. Cir. 1999).
10. *See Scaltech*, 178 F.3d at 1380.
11. *See Abbott Lab.*, 182 F.3d at 1316.
12. *See* Pennock v. Dialogue, 27 U.S. (2 Pet.) 1, 14-15 (1829) (precluding patentability of an improved means of making hose where the hose had been made and sold for a number of years before its patenting under the rule that "if an inventor makes his discovery public, . . . he abandons the inchoate right to the exclusive use of the invention, to which a patent would have entitled him had it been applied for before such use").
13. *See* Patent Act of 1839, ch. 88, § 7, 5 Stat. 353, 354 (1839).

later, Congress reduced this period to one year.[14] The "on-sale" bar, and the closely related "public use" bar, are presently codified in section 102(b), which provides that an inventor cannot obtain a patent on an invention that has been patented or published anywhere or that has been "in pubic use or on sale" in the U.S. for more than one year before the date of applying for a U.S. patent.[15]

The application of section 102(b) has involved a search for a bright line test that can be uniformly applied while upholding the policies underlying the law. The policy considerations served by the on-sale bar include: (1) preventing the removal of inventions from the public that have been available through prolonged sales activity; (2) favoring prompt disclosure of new inventions; (3) avoiding effective extension of the statutorily defined exclusivity period; and (4) allowing the inventor a reasonable time for evaluating whether the invention is worth patenting.[16] Indeed, courts aim to apply section 102(b) in light of these principles,[17] and the law seeks to provide inventors with clear standards as to the type of activity that may trigger the bar.[18] The question remains as to whether the *Pfaff* test succeeds in furthering this goal.

B. Relation to Other Aspects of Patent Law

A basic discussion of certain other areas of patent law enables a better understanding of how courts interpret the on-sale bar. As statutory terms are presumed to have the same meaning throughout the Patent Act, a consideration of how the terms "invention" and "reduced to practice" are used in other sections of the Act enhances a 102(b) analysis. Further, the concepts of "inherency" and "experimental use" both concern features of an invention that are as yet undiscovered or unconfirmed—concepts at issue in applying the on-sale bar. Moreover, as section 102(b) aims to further the general policies of patent law, any particularized interpretation must reflect the law's broader philosophies.

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14. *See* Patent Act of 1939, ch. 450, § 1, 53 Stat. 1212, 1212 (1939).

15. 35 U.S.C. § 102 provides that "A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, ..." 35 U.S.C. § 102(b) (1994).

16. *See* Abbott Lab. v. Geneva Pharm., Inc., 51 U.S.P.Q.2d (BNA) 1301, 1305 (N.D. Ill. 1998), *aff'd*, 182 F.3d 1315 (Fed. Cir. 1999).

17. *See generally* David W. Carstens & Craig Allen Nard, *Conception and the "On Sale" Bar*, 34 WM. & MARY L. REW. 393, 395 (1993).

18. *See* Pfaff v. Wells Elec., Inc., 119 S. Ct. 304, 311 (1998) (noting that "these provisions identify an interest in providing inventors with a definite standard for determining when a patent application must be filed").

1. *The meaning of invention: sections 100–103*

Section 100 defines the term invention as meaning "invention or discovery,"[19] whereas section 101 recites three general conditions for patentability of an invention—novelty, utility and permissible subject matter.[20]

The requirement of novelty, defined in section 102, is closely related to the statutory bars, for it prevents the removal of previously available information from the public.[21] Nonobviousness, codified in section 103, provides that a patentable invention must represent a non-trivial extension of what is generally known by "a person having ordinary skill in the art."[22]

2. *The definition of reduction to practice: section 102(g)*

Reduction to practice may be a clear indicator of when an invention is complete.[23] An invention is reduced to practice when it is physically created in a functional form or successfully carried out.[24] The only section in Title 35 that expressly uses this term, however, is section 102(g), which provides the standard in resolving priority issues in interference proceed-

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19. 35 U.S.C. § 100(a) (1994) ("The term 'invention' means invention or discovery. . . .").

20. 35 U.S.C. § 101, "Inventions patentable," provides, "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. . . ." 35 U.S.C. § 101 (1994). This provision has been broadly interpreted. *See* Diamond v. Chakrabarty, 447 U.S. 303, 315 (1980) (holding that "[t]he subject matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting 'the Progress of Science and the [sic] useful Arts'").

21. 35 U.S.C. § 102(a) provides that an invention is not patentable if it was "known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent. . . ." 35 U.S.C. § 102(e) precludes patentablility of an invention "described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent. . . ." 35 U.S.C. § 102 (1994).

22. 35 U.S.C. § 103(a) provides that an invention may not be patented "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a) (1994).

23. *See* Pfaff v. Wells Elec., Inc., 119 S. Ct. 304, 311 ("It is true that reduction to practice ordinarily provides the best evidence that an invention is complete.").

24. *See* Corona Cord Tire Co. v. Dovan Chem. Corp., 276 U.S. 358, 383 (1928) ("A process is reduced to practice when it is successfully performed. A machine is reduced to practice when it is assembled, adjusted and used. . . . A composition is reduced to practice when it is completely composed.").

ings.[25] There, a claimant is considered the first to invent if she was the first to conceive of the invention and also was continually diligent in attempting to reduce it to practice, even if not the first to actually do so.[26]

3. *The concepts of inherency and experimental use*

Two concepts that arise in the context of inventions in the process of development are the inherency doctrine and the exception for experimental use. These concepts directly relate to section 102(b).

A property is inherent to an invention if it is "necessarily present" in the invention or is the "natural result" of its use.[27] The inherency doctrine provides that where an invention is inherently, though inadvertently, created prior to its purposeful production, it is still considered novel.[28] That is, the doctrine can serve as an exception to anticipation. Conversely, the inherency doctrine acts to negate the novelty of undisclosed features in prior art references.[29] That is, discovering or defining a feature inherent to

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25. Interference proceedings "resolve the question of priority of invention when more than one applicant seeks a patent on substantially the same invention." DONALD S. CHISUM, CHISUM ON PATENTS § 10.09[1](a) (1998). *See also* 35 U.S.C. § 135 (1994).

26. 35 U.S.C. § 102(g) (1994) provides that in priority determinations "there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other." 35 U.S.C. § 102(g) (1994).

27. *See* Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268-69 (Fed. Cir. 1991).

28. *See* Tilghman v. Proctor, 102 U.S. 707, 711-12 (1880) (holding that the accidental production of fatty acids in a lubricant used in steam engines did not negate the novelty of a later process that similarly, though intentionally, separated fatty acids); *see also* Eibel Process Co. v. Minnesota & Ont. Paper Co., 261 U.S. 45, 66 (1923) (holding that accidental and unappreciated results obtained by tilting paper-making machines did not anticipate a later patent teaching that specific tilts enable the machines to run at higher speeds). *See generally* ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 173-74 (1997).

29. *See, e.g., Continental Can*, 948 F.2d at 1268-69 (discussing whether a patent for a bottle design with hollow ribs was anticipated by a prior one that may have inherently contained such ribs without actually describing them as "hollow"); *In re* Spada, 911 F.2d 705, 708-09 (Fed. Cir. 1990) (holding that an inventor could not patent polymers already in the prior art, although he had discovered a new, nonobvious property that they possessed); Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 630-33 (Fed. Cir. 1987) (holding that a patent on a process for manufacturing fertilizer based on using a heat-sink was anticipated by a prior pending patent that described the same process without acknowledging the heat-sink); *In re* King, 801 F.2d 1324, 1325-28 (Fed. Cir. 1986) (holding that an article of manufacture in a prior patent anticipates method claims for controlling constructive interference of light incident on the article, although the earlier patent did not disclose the scientific means of defining the effects); Titanium Metals Corp. v.

existing prior art does not make it new, even though it was hitherto unrecognized.[30]

Experimental use can also serve as an exemption to the statutory bars.[31] Namely, the public use or sale of an invention primarily to determine whether it will meet its intended purpose does not trigger the grace period.[32]

C. Development of Terms within the Context of Section 102(b) Analyses

Evolving interpretations of the terms "invention," "on-sale," and "experimental use" have shaped section 102(b) analyses. Indeed, application of the on-sale bar depends upon how these fundamental terms are defined.

1. Interpretation of "the invention"

Since the implementation of the on-sale bar, courts have applied various tests in determining when an invention triggers the bar.[33] The three major tests have been the "on hand" standard,[34] the "reduction to practice" rule,[35] and the "totality of circumstances" test.[36] According to the "on hand" doctrine, "a device incorporating the invention must have existed in

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Banner, 778 F.2d 775, 781-82 (Fed. Cir. 1985) (holding that inventor's titanium alloys were anticipated by a prior article disclosing alloys of identical composition, although the article did not mention their corrosion-resistant properties).

30. *See In re* Spada, 911 F.2d at 708 ("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition.").

31. *See* City of Elizabeth v. American Nicholson Pavement Co., 97 U.S. 126, 135-36 (1877) (holding that the public use of the inventor's pavement to test its durability did not trigger the statutory bar).

32. *See id.*; *see also* Seal-Flex, Inc. v. Athletic Track & Court Constr., 98 F.3d 1318, 1324 (Fed. Cir. 1996) (precluding summary judgment on the issue of patentability under the on-sale bar where an all-weather athletic tract was offered for sale before the critical date because "[w]hen an evaluation period is reasonably needed to determine if the invention will serve its intended purpose, the § 102(b) bar does not start to accrue while such determination is being made.").

33. *See generally* Vincent J. Allen, *The On Sale Bar: When Will Inventors Receive Some Guidance?*, 51 BAYLOR L. REV. 125, 131-40 (1999); Daniel J. Whitman, The "On-Sale" Bar to Patentability: Actual Reduction to Practice Not Required in Pfaff v. Wells Electronics, Inc., 32 AKRON L. REV. 397, 400-05 (1999).

34. *See* Galland-Henning Mfg. Co. v. Dempster Bros., 315 F. Supp. 68, 80 (E.D. Tenn. 1970) ("If patented articles are on hand ready to be delivered . . . they are on sale. . . .").

35. *See* Timely Prod. Corp. v. Arron, 523 F.2d 288, 302 (2d Cir. 1975) ("[A]n invention cannot be offered for sale until . . . its reduction to practice.").

36. *See* UMC Elec. Co. v. United States, 816 F.2d 647, 656 (Fed. Cir. 1987) ("All of the circumstances surrounding the sale or offer to sell . . . must be considered. . . .").

its ordinary or contemplated usable form and must have been on hand ready for delivery more than a year prior to the patent application date."[37] Courts later replaced this standard with a three-part "reduction to practice" test which required that the invention be (1) anticipated or made obvious by the subject matter of the sale; (2) operable and commercially marketable; and (3) sold or offered for sale "primarily for profit rather than for experimental purposes."[38] Later still, the Federal Circuit held that reduction to practice should serve only as a tool in determining if the invention was on sale.[39] Rather, all the circumstances surrounding the sale should be weighed in light of the policies underlying section 102(b).[40] The application of this balancing test, however, has been uneven, with courts requiring the invention be "completed,"[41] "substantially completed,"[42] or capable of operation.[43]

2. *Interpretation of "on-sale"*

Interpretation of the meaning of "on-sale" has proved more straightforward. A bright-line test provides that even a single sale or offer triggers the bar.[44] An offer for sale must be definite and objectively manifested, though it need not comport with formal contract law definitions.[45] Further, courts continue to recognize that the sale must be primarily for profit rather than for experimental purposes.[46]

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37. *Galland-Henning*, 315 F. Supp. at 80.

38. *See Timely Prod.*, 523 F.2d at 302.

39. *See UMC Elec.*, 816 F.2d at 656.

40. *See id.*

41. *See* Seal-Flex, Inc. v. Athletic Track & Court Constr., 98 F.3d 1318, 1324 (Fed. Cir. 1996) (stating that "[t]he general rule is that the on-sale bar starts to accrue when a completed invention is offered for sale.").

42. *See* Micro Chem., Inc. v. Great Plains Chem. Co., 103 F.3d 1538, 1545 (Fed. Cir. 1997) (interpreting *UMC* as standing for the proposition that "a sale or a definite offer to sell a substantially completed invention, with reason to expect that it would work for its intended purpose upon completion, suffices to generate a statutory bar").

43. *See* Robotic Vision Sys., Inc. v. View Eng'g, Inc., 112 F.3d 1163, 1167 (Fed. Cir. 1997) (holding that incomplete development of software, necessary for the operation of the invention, precluded application of the on-sale bar).

44. *See* Intel Corp. v. U.S. Int'l Trade Comm'n, 946 F.2d 821, 830 (Fed. Cir. 1991).

45. *See* RCA Corp. v. Data Gen. Corp., 887 F.2d 1056, 1062 (Fed. Cir. 1989).

46. *See* Kolmes v. World Fibers Corp., 107 F.3d 1534, 1540 (Fed. Cir. 1997).

3. *Interpretation of the "experimental use" exemption*

Overlaying an analysis of section 102(b) is the interpretation of experimental use that serves as a defense to invalidity.[47] A sale or offer for sale of an invention primarily for experimental purposes does not trigger the bar.[48] The Federal Circuit, however, has held that experimental use "ends with an actual reduction to practice,"[49] so that continued monitoring of the invention will not continue to toll the bar.[50]

II. SUMMARY OF THE CASES

A. Pfaff v .Wells Electronics, Inc.

In deciding that a new computer chip socket was barred from patentability, the Supreme Court promulgated the most recent test for applying the "on-sale" bar.[51] The test provides two conditions that must be met to trigger the one year grace period.[52] First, the invention must be "the subject of a commercial offer for sale."[53] Second, the invention must be "ready for patenting."[54] The second prong, in turn, can be satisfied in one of at least two ways.[55] The invention must be either "reduced to practice" or described with sufficient specificity to enable one skilled in the art to practice the invention.[56] This test emphasized the Court's interpretation that the term "invention" refers to a fully conceived innovation, while its physical embodiment serves merely as definitive proof of such.[57] In applying the test, the Court found that a purchase order for 30,100 of Pfaff's chips satisfied the first prong, and that detailed engineering drawings of the chip satisfied the other.[58] As both conditions were met one year and 11

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47. *See* City of Elizabeth v. American Nicholson Pavement Co., 97 U.S. 126, 135 (1877) ("So long as [the invention] is not on sale for general use, [an inventor] does not lose his title to a patent.").

48. *See* U.S. Envtl. Prod. v. Westall, 911 F.2d 713, 716 (Fed. Cir. 1990).

49. *RCA Corp.*, 887 F.2d at 1061.

50. *See* Seal-Flex, Inc. v. Athletic Track & Court Constr., 98 F.3d 1318, 1323 (Fed. Cir. 1996).

51. *See* Pfaff v. Wells Elec., Inc., 119 S. Ct. 304, 311-12 (1998).

52. *See id.* at 311.

53. *Id.*

54. *Id.* at 312.

55. *See id.*

56. *See id.*

57. *See id.* at 311-12.

58. *See id.* at 307, 312.

days before Pfaff had applied for his patent, the patent was rendered invalid.[59]

B. Scaltech Inc. v. Retec/Tetra L.L.C.

Following *Pfaff*, the Federal Circuit reheard *Scaltech* specifically to take the new test into account.[60] Applying *Pfaff*, the Court held that as long as the process offered for sale fell within the scope of the later claims, the invention was "reduced to practice," irrespective of whether the seller had yet recognized its patentable features.[61]

The Scaltech patent involved a more efficient way of producing fuel coke from the waste products of petroleum.[62] The process involved injecting unrefined hydrocarbons into heated drums called coker units.[63] Scaltech had the idea of improving this procedure by reducing the oil content of the injected mixture.[64] To acquire access to coker units and further test its idea, Scaltech offered to process petroleum waste for a number of refineries.[65] Scaltech stipulated that the technique being used was experimental in all but the last two of these proposals, which were made on March 30 and November 15, 1988.[66] Later, in 1992, Scaltech discovered that small particle size in the injection mixture increased the efficiency of the process.[67] These particles were produced inadvertently in the de-oiling procedure.[68] Scaltech subsequently applied for a patent on the improved process, describing the necessary conditions of small particle size and high solid concentration.[69]

When Scaltech sought to enforce its patent against Retec, the alleged infringer raised the defense of patent invalidity under section 102(b).[70] The district court invalidated the patent on summary judgement,[71] construing the final two offers made by Scaltech in March and November of

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59. *See id.*

60. *See* Scaltech Inc. v. Retec/Tetra, L.L.C., 178 F.3d 1378, 1380 (Fed. Cir. 1999).

61. *See id.* at 1383-84.

62. *See id.* at 1380-81.

63. *See id.* at 1382.

64. *See id.* Injection rates exceeding two pounds of solids per ton of coke resulted in non-homogeneous coke formation and noxious fumes. *See id.*

65. *See id.* at 1382.

66. *See id.*

67. *See id.* at 1382-83.

68. *See id.* at 1383.

69. *See id.* The Scaltech patent specifies a "coker quench stream having a particle size distribution such that greater than about 70% of the total solids volume comprises solids having a particle size of less than about 15 microns. . . ." *See id.* at 1381.

70. *See id.*

71. *See id.*

1988 as commercial rather than experimental.[72] As these transactions did occur more than a year before Scaltech applied for its patent, the statutory bar applied.[73]

The Federal Circuit originally vacated the district court's ruling one month before the *Pfaff* decision.[74] To determine if the bar applied under the "totality of circumstances" test,[75] the court remanded the case for a consideration of whether the process offered for sale constituted an embodiment, or at least a "substantially completed" embodiment, of the claimed invention, that would be expected to work for its intended purpose.[76] Notably, the Federal Circuit expressed the opinion that the invention was not "conceived" until Scaltech had the opportunity, in 1991, to characterize the new process' features of small particle size and high solid concentration.[77] The court added that while an inventor is still working towards the development of a conception, there is "not yet an 'invention' that [can be] offered on sale."[78]

Rehearing the case after *Pfaff*, the Federal Circuit once again remanded after analysis under the new test.[79] The court maintained that a section 102(b) inquiry begins with a determination of whether the subject matter satisfying the applicable test was in fact the subject matter of the later patent.[80] Discarding the rejected "substantially complete" part of the test, however, the Federal Circuit held that to embody the claimed invention, the innovation that was on sale must have met each of the claim limitations of the patent.[81] Further, the Federal Circuit deemed it irrelevant whether the proposals expressly identified these limitations or whether Scaltech was aware of their significance at the time.[82] Rather, the court

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72. *See id.* at 1382.

73. *See id.* at 1382-83.

74. *See* Scaltech Inc. v. Retec/Tetra, L.L.C., 156 F.3d 1193, 1194 (Fed. Cir. 1998), *amended by* 178 F.3d 1378 (Fed. Cir. 1999).

75. *See* UMC Elec. Co. v. United States, 816 F.2d 647, 656 (Fed. Cir. 1987) ("All of the circumstances surrounding the sale or offer to sell . . . must be considered and weighed against the policies underlying section 102(b)."); *see also* Micro Chem., Inc. v. Great Plains Chem. Co., 103 F.3d 1538, 1545 (Fed. Cir. 1997) (interpreting *UMC* as standing for the proposition that "a sale or a definite offer to sell a substantially completed invention, with reason to expect that it would work for its intended purpose upon completion, suffices to generate a statutory bar.").

76. *See Scaltech,* 156 F.3d at 1197.

77. *See id.* at 1198.

78. *Id.*

79. *See Scaltech,* 178 F.3d at 1380.

80. *See id.* at 1383.

81. *See id.*

82. *See id.*

held that if the process offered for sale in 1988 inherently contained the claim limitations of the patented process, it would trigger the on-sale bar.[83] That is, inherently meeting the claims necessarily constituted a reduction to practice of the invention so as to meet the "ready for patenting" prong of the new test.[84] The Federal Circuit consequently remanded the case for consideration of these questions.[85]

C. Abbott Laboratories v. Geneva Pharmaceuticals

The Federal Circuit in *Abbott* applied the *Pfaff* test to determine whether third party sales triggered the on-sale bar, even if the parties were unaware of the identity of the compound being sold.[86] Relying on its reasoning in *Scaltech*, the court rejected the patentee's contention that there can be no sale of an invention until its "conception."[87]

The Abbott patent claimed Form IV anhydrate, one of the forms of terazosin hydrochloride used in treating hypertension and benign prostatic hyperplasia.[88] When other companies sought to market a generic version of the drug, Abbott brought a suit for patent infringement.[89] Raising a 102(b) defense, the defendants asserted that a company not party to the action had sold Form IV terazosin hydrochloride anhydrate in the U.S. during the period of 1989-92.[90] Although these sales occurred more than a year before the 1994 filing date of Abbott's patent, it was not until 1995 that Abbott determined the exact chemical identity of the imported drug.[91]

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83. *See id.* at 1383-84.

84. *See id.* at 1383 (pointing out that "[o]ne way to satisfy the second condition is by proof of reduction to practice before the critical date" before discussing that the process offered for sale had to fall within the scope of the claim).

85. *See id.* at 1384.

86. *See* Abbott Lab. v. Geneva Pharm., Inc., 182 F.3d 1315, 1318 (Fed. Cir. 1999).

87. *See id.* at 1318-19.

88. *See id.* at 1316. The compound exists in four anhydrous crystalline forms and as dihydrate crystals. *See id* at 1316-17. Form IV anhydrate constituted the subject matter of claim 4 of Abbott's U.S. Patent No. 5,504,207. *See id.*

89. *See id.* at 1317. 35 U.S.C. § 271(e)(2)(A) makes the filing of an Abbreviated New Drug Application with the FDA an act of patent infringement. Such an application seeks to rely on safety and efficacy studies of the patent holder's drug in order to more cheaply market a generic version. 35 U.S.C. § 271(e)(2)(A) (1994).

90. *See Abbott Lab.*, 182 F.3d at 1317. Two of these sales were made to the defendant Geneva Pharmaceuticals by the nonparty company, Byron Chemical Company, Inc. *See id.*

91. *See id.* at 1317 n.2. The compound's chemical structure is determined by principle peaks that occur at characteristic values in an x-ray diffraction pattern. *See id.* An anhydrous terazosin hydrochloride exhibiting a powder x-ray diffraction pattern with the same principle peaks as those defined in claim 4 of the Abbott patent falls within its

One month prior to the *Pfaff* decision the district court granted summary judgment on the issue of invalidity under section 102(b), from which Abbott appealed.[92]

Applying the criteria set forth in *Pfaff*, and building on its reasoning in *Scaltech*, the Federal Circuit held that it was irrelevant whether or not the parties involved in the sales knew the identity of the particular compound being sold.[93] Instead the court concluded that the sale of the material as a useful product was a reduction to practice that clearly satisfied the "ready for patenting" prong.[94] The court asserted that while proof of conception was necessary for priority determinations, it was not necessary for on-sale bar analyses where the invention has been reduced to practice and sold.[95] The court noted that this result furthered the 102(b) policy of not removing inventions from the public domain.[96] Thus, holding that the invention met *Pfaff's* conditions, the Federal Circuit affirmed the district court's summary judgment invalidating the Form IV anhydrate claim under the on-sale bar.[97]

III. LITERAL INCONSISTENCY WITHIN THE *PFAFF* TEST

A. Exposé of the Inconsistency

The literal inconsistency within the *Pfaff* test involves the observation that an "invention" may be "reduced to practice" before it is fully "ready for patenting." That is, an invention may come into existence before all of its patent-worthy features have been determined. In deriving the *Pfaff* test, the Supreme Court emphasized the importance of conception in determining an earlier triggering point for the on-sale bar.[98] The Court held that "[t]he primary meaning of the word 'invention' in the Patent Act *unquestionably refers to the inventor's conception* rather than to a physical em-

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scope. *See* Abbott Lab. v. Geneva Pharm., 51 U.S.P.Q.2d (BNA) 1301, 1302 (N.D. Ill. 1998), *aff'd*, 182 F.3d 1315 (Fed. Cir. 1999).

92. *See Abbott Lab.*, 182 F.3d at 1316.

93. *See id.* at 1318-19. The court also pointed out that it was irrelevant whether the sale was made by a company other than Abbott. *See id.* at 1318.

94. *See id.* at 1318-19.

95. *See id.*

96. *See id.* at 1319.

97. *See id.*

98. *See* Pfaff v. Wells Elec., Inc., 119 S. Ct. 304, 308-09 (1998) (analogizing extensively, for example, to *The Telephone Cases*, 126 U.S. 1 (1888), where Alexander Graham Bell's conception of how his invention would work entitled him to a patent although he had not yet constructed a working prototype).

bodiment of that idea."[99] On the other hand, reduction to practice does not require prior conception of the invention.[100] It is possible, for example, to reduce an invention to practice without being aware of exactly what has been created. Thus there is a structural inconsistency in the *Pfaff* test in having "proof of reduction to practice" as one of the ways "ready for patenting" can be shown. Indeed, an invention inadvertently created is reduced to practice although no one has as yet determined its patent-worthy features.

The difficulty in finding a bright line test promoting the policies of section 102(b) lies partly in the fact that the policies themselves conflict with the way modern inventions are brought into existence. The more complex an innovation, the more research that is needed to ascertain its inherent characteristics in determining why it works. Hence the greater are the potential delays between obtaining workable, as opposed to comprehensible, results. In the course of developing a new process or product, for example, an inventor may not have identified all of the patentable features of her invention even upon successfully creating it or carrying it out. Thus, an "invention" may be ready for public availability before its inventor can describe how it works. Similarly, the inventor may be able to begin market testing before being able to begin the process of securing a patent. Literal application of the *Pfaff* test to cases involving complex technologies reflect these difficulties and reveal the structural incongruity in the test itself.

The recent Federal Circuit opinions in *Scaltech* and *Abbott* involved, respectively, a complex refinery process[101] and a complex pharmaceutical product.[102] The Scaltech process of producing fuel coke required access to large coker units, large amounts of petroleum waste and highly technical monitoring.[103] Thus, the "inventors" did not know which features of the new process were responsible for improving efficiency even when they had initially succeeded in making it work.[104] Further, they did not have the

99. *Id.* at 308 (emphasis added).

100. *See* Abbott Lab. v. Geneva Pharm., Inc., 182 F.3d 1315, 1318 (Fed. Cir. 1999); Scaltech Inc. v. Retec/Tetra, L.L.C., 178 F.3d 1378, 1383-84 (Fed. Cir. 1999); Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 633 (Fed. Cir. 1987); *In re* King, 801 F.2d 1324, 1326 (Fed. Cir. 1986); Titanium Metals Corp. v. Banner, 778 F.2d 775, 781-82 (Fed. Cir. 1985).

101. *See Scaltech,* 178 F.3d at 1380.

102. *See Abbott Lab.*, 182 F.3d at 1316-17.

103. *See Scaltech,* 178 F.3d at 1382.

104. *See id.* at 1382-83 (describing Scaltech's later surprise at finding that the particles of the waste slurry were of very small size).

opportunity to continue their investigation until years later.[105] Similarly, the pharmaceutical at issue in *Abbott* existed in several closely related forms that required differentiation and characterization by complex analyses.[106] Hence, a pharmaceutical company could prepare the compound and appreciate its clinical indications without knowing the exact form present in any particular batch.[107] In both cases, then, the product or process was available to the public before the parties could completely disclose the invention. Similarly, in both cases, the parties could begin evaluating the commercial potential of their inventions before having enough information to apply for their respective patents.

The divergent policies of section 102(b), reflected in the *Pfaff* test's structural discrepancy, enabled the patentees in both cases to argue that the bar should not apply, while the alleged infringers could argue with almost equal force that it should. Scaltech contended that its new process was in an experimental stage,[108] and hence not "ready for patenting" at the time of the invalidating sales.[109] Likewise, Abbott argued that the on-sale bar cannot be triggered before an "invention" is conceived,[110] echoing the Supreme Court's reasoning in formulating the *Pfaff* test.[111] In contrast, op-

105. *See id.* at 1382. Scaltech was working for Chevron when it first implemented the de-oiling process. *See id.* After its contract with Chevron ended, it was not until 1992 that it received permission from another refinery to resume its research. *See id.*

106. *See* Abbott Lab. v. Geneva Pharm., Inc., 182 F.3d 1315, 1316-17 (Fed. Cir. 1999). These analyses involve obtaining x-ray diffraction patterns of the different forms, each characterized by principle peaks at distinct values. *See* Abbott Lab. v. Geneva Pharm., Inc., 51 U.S.P.Q.2d (BNA) 1301, 1302 n.1 (N.D. Ill. 1998), *aff'd*, 182 F.3d 1315 (Fed. Cir. 1999).

107. Abbott and Geneva performed x-ray diffraction analyses only in 1995 and 1996, respectively, on samples of the batches sold before 1993. *See Abbott Lab.*, 182 F.3d at 1317 n.2. At the district court level, Abbott had contended that the compound manufactured for the early sales may actually have been an unstable crystalline form of terazosin hydrochloride that subsequently transformed over time into Form IV. *See Abbott Lab.*, 51 U.S.P.Q.2d at 1304. The court, however, found this argument unsupported by the evidence. *See id.*

108. *See* Scaltech Inc. v. Retec/Tetra, L.L.C., 178 F.3d 1378, 1384 n.1 (Fed. Cir. 1999).

109. Indeed, the Federal Circuit maintained that *Scaltech* was surprised to discover in 1992 that the small particle size was a feature of the improved process. *See id.* at 1382-83. This feature, however, was later included in the patent claims that define a coker quench stream having over 70% of its solid volume comprised of particles smaller than 15 microns. *See id.* at 1381. Hence, *Scaltech* was not ready to draft such a claim until after its 1992 discovery.

110. *See Abbott Lab.*, 182 F.3d at 1318-19. Specifically, Abbott argued that "parties must 'conceive,' or know precisely, the nature of the subject matter with which they are dealing." *Id.* at 1318.

111. *See* Pfaff v. Wells Elec., Inc., 119 S. Ct. 304, 308-09 (1998).

posing arguments in both cases asserted that proof of reduction to practice at the time of the sale is all that the new 102(b) test requires to render the transactions invalidating.[112]

In both cases, the Federal Circuit rigidly applied the new test, following a literal interpretation of "reduction to practice." In *Scaltech*, the court held that as long as the process offered for sale met each of the claim limitations of the patent, it was an embodiment of the invention that would satisfy the second prong of the *Pfaff* test.[113] Likewise, the court in *Abbott* held that the sale of a product known to have utility constituted a reduction to practice, regardless of whether its structure had yet been conceived.[114]

B. Role of the Inherency Doctrine in the *Pfaff*-Test Inconsistency

At the heart of the discrepancy between an invention that is "ready for patenting" and one that is "reduced to practice" lie different applications of the doctrine of inherency. As noted earlier, when the doctrine is applied to determining whether prior art anticipates an inventor's work, all characteristics inherent to the subject matter of the prior reference negate claims of novelty.[115] It is irrelevant whether the prior art specifically mentions those features or, if the prior reference is a patent, whether the patentee was even cognizant of those characteristics at the time of filing.[116] In contrast, an invention that was created inadvertently and whose features initially go unrecognized is not unpatentable for lack of novelty.[117] From these two lines of precedent, it appears that how the inherency doctrine is applied depends on how much of the invention is unknown. On one hand, unrecognized features of an invention do not change what constitutes its

112. *See Scaltech*, 178 F.3d at 1383 (asserting that one way to satisfy the second condition of the *Pfaff* test is by proof of reduction to practice, and that the process offered for sale must be something within the scope of the patent claim, whether or not Scaltech recognized the significance of the claimed features at the time of the offer). *See also Abbott Lab.*, 182 F.3d at 1318 (agreeing with defendants' arguments that under the *Pfaff* test it is irrelevant that parties to the sales did not know that they were dealing with the form later claimed, and that "[a]n invention may be shown to be 'ready for patenting' . . . by 'proof of reduction to practice before the critical date'").

113. *See Scaltech*, 178 F.3d at 1383-84. The Federal Circuit directed that "[t]he district court must determine if the process offered for sale, . . . inherently satisfies each claim limitation. If so, then the offer creates a § 102(b) bar." *Id.* at 1384.

114. *See Abbott Lab.*,182 F.3d at 1318 ("The fact that the claimed material was sold under circumstances in which no question existed that it was useful means that it was reduced to practice.").

115. *See supra* Part I.B.3.

116. *See id.*

117. *See id.*

"embodiment" in that its inherent features are not deemed to be "new."[118] On the other hand, an entirely unrecognized invention is treated as though it never actually existed for patent purposes in that it can later be deemed "novel."[119]

In applying the inherency doctrine to the 102(b) analyses in *Scaltech* and *Abbott*, the Federal Circuit rejected the "still novel" interpretation in favor of the "not new" one.[120] Specifically, the holdings in both cases interpret the term "invention" to refer to what is inherently embodied within even an accidental or uncharacterized reduction of that invention to practice. The *Scaltech* court held that as long as the uncharacterized process on sale met each of the limitations of the claims in the later patent, the invention was reduced to practice.[121] The *Abbott* court held that once an imported batch contained the same crystalline form of the pharmaceutical as that later claimed, it constituted a barring reduction to practice.[122] Similarly, in both cases, the court held that such reductions to practice obviated the need to consider whether anyone had actually conceived of the inventions at the time of the contentious sales.[123]

Using this interpretation of the inherency doctrine, the Federal Circuit was able to apply the new *Pfaff* test to complex inventions while avoiding its structural inconsistency. Indeed, had a different interpretation of the inherency doctrine been applied, the court might have reached a conclusion irreconcilable with the new test. For instance, the court might have been required to hold that because the parties were unaware, at the time of the sales, of important inherent characteristics of their inventions, the inventions should be treated as though they never existed for patent purposes. Thus, there would have been no "invention" within the meaning of the statute, and consequently there could have been no invalidating sales. Indeed, the court may have then buttressed its argument by pointing out that these inventions were not "ready for patenting" at the time of the

118. *See supra* note 29 and accompanying text.

119. *See supra* note 28 and accompanying text.

120. *See* Scaltech Inc. v. Retec/Tetra, L.L.C., 178 F.3d 1378, 1383-84 (Fed. Cir. 1999) (expressly citing *Titanium Metals*, *Verdegaal Bros*, *In re King*, and *Continental Can* to support the assertion that unrecognized features can still bar patentability). *See also* Abbott Lab. v. Geneva Pharm., Inc., 182 F.3d 1315, 1319 (Fed. Cir. 1999) (explicitly declining to follow the *Tilghman/Eibel Process* line of precedent advanced by Abbott in its attempt to avoid the on-sale bar).

121. *See Scaltech*, 178 F.3d at 1383-84.

122. *See Abbott Lab.*, 182 F.3d at 1318.

123. *See Scaltech*, 178 F.3d at 1383. ("Nor is there a requirement that Scaltech must have recognized the significance of these limitations at the time of the offer."); *see also Abbott Lab.*, 182 F.3d at 1318 ("[w]e disagree that proof of conception was required.").

transactions in question. Specifically, Scaltech could not have applied for a patent claiming the exact characteristics of the process that increased efficiency before discovering what those characteristics were.[124] Abbott's competitors could not have applied for a patent claiming a specific structure not yet identified.[125] However, as the inventions had been reduced to practice, at least in a literal sense, such analyses would have resulted in the inventions simultaneously meeting and not meeting the second prong of the *Pfaff* test.

It appears that, while aiming to provide a clearer standard for determining the point between conception and reduction to practice that triggers the on-sale bar, the *Pfaff* test overlooked cases of inadvertent reduction to practice occurring before conception.[126] Presented with this dilemma in *Scaltech* and *Abbott*, the Federal Circuit applied the test literally, relying on formal definitions of "reduction to practice."[127] This circumvented the need to address the questions of whether the inventions were conceived at the time of the invalidating sales.[128]

Nevertheless, if the application of the inherency doctrine depends on the extent to which the invention is unknown, its application to 102(b) analyses should focus on how much was known about the "invention" at the time of the sale. At the time of the alleged sales in *Scaltech*, the inventor was still determining whether or not increasing the solid concentration of the injection mixture improved efficiency.[129] He had not yet real-

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124. *See Scaltech*, 178 F.3d at 1381-83 (relating how the Scaltech patent claimed the requirement of small particle size although at the time of the allegedly invalidating sales Scaltech had not recognized that small particles were formed in the process).

125. *See Abbott Lab.*, 182 F.3d at 1317 (noting that "at the time of the sales, the parties to the United States transactions did not know the identity of the particular crystalline form with which they were dealing."). However, Abbott's patent on Form IV terazosin hydrochloride, which was filed in 1994, specifically identifies the compound by reference to its x-ray powder diffraction pattern. *See* Abbott Lab. v. Geneva Pharm., Inc., 51 U.S.P.Q.2d (BNA) 1301, 1302-03 (N.D. Ill. 1998), *aff'd*, 182 F.3d 1315 (Fed. Cir. 1999).

126. The Court noted that reduction to practice "ordinarily provides the best evidence that an invention is complete," and then summarily includes it as one of the ways of showing an invention is ready for patenting. *See* Pfaff v. Wells Elec., Inc., 119 S. Ct. 304, 311-12 (1998).

127. *See supra* Part III.A.

128. *See id.* For example, the Federal Circuit in *Abbott* stated with no explanation other than a cite to the *Pfaff* test, "[i]t is . . . clear that the invention was 'ready for patenting' because at least two foreign manufacturers had already reduced it to practice." Abbott Lab. v. Geneva Pharm., Inc., 182 F.3d 1315, 1318 (Fed. Cir. 1999).

129. *See* Scaltech Inc. v. Retec/Tetra, L.L.C., 178 F.3d 1378, 1382-83 (Fed. Cir. 1999).

ized the related importance of reducing particle size.[130] Thus, he had not conceived of one of the main features of the invention and was uncertain as to the relevance of the other at the time of the contentious sales. At the time of the invalidating sales in *Abbott*, the tetrazosin hydrochloride compounds that were sold had a known use but information was lacking as to their precise structures.[131] Indeed such structural information comprised the essence of the later product claim.[132] Here, too, no one in the U.S. had "conceived" of the invention in the way it was eventually claimed.[133] If invention begins with conception, one can argue that both *Abbott* and *Scaltech* involved entirely unrecognized inventions at the time of their sales. Hence, the "still novel" interpretation of the inherency doctrine should apply.[134] Such an interpretation would require treating the inventions that were not yet conceived as not yet existing for patent purposes; hence their sales would not trigger the bar. What, then, might explain the Federal Circuit's opinions?

C. Consistent Promulgation of Policy despite the *Pfaff* Inconsistency

While the test applied in on-sale bar analyses continues to evolve, the policies animating the rule remain constant. *Pfaff* aimed to effectuate these polices by establishing a clear, multi-part test.[135] Interestingly, in both *Scaltech* and *Abbott*, the same result was obtained under both pre- and post-*Pfaff* analyses.[136] Hence, these cases provide an opportunity to analyze whether the results obtained actually effected the policies underlying section 102(b) and whether the *Pfaff* test afforded a more reliable standard for arriving at such results.

The Federal Circuit's original opinion in *Scaltech* called for a determination of whether the process on sale was at a sufficient level of development to trigger the bar under the "totality of circumstances test."[137] This

130. *See id.*

131. *See Abbott Lab.*, 182 F.3d at 1317.

132. *See id.* at 1316-17 (describing that the Abbott patent specifically claims the Form IV anhydrate, defined by its x-ray diffraction pattern).

133. *See id.* at 1317. A letter from the Japanese manufacturer, who had made the early sales, claimed to have identified the structure as Form IV terazosin hydrochloride anhydrate in 1990, but the district court found this piece of evidence deficient and did not include it in its analysis. *See* Abbott Lab. v. Geneva Pharm., Inc., 51 U.S.P.Q.2d (BNA) 1301, 1304-05 (N.D. Ill. 1998), *aff'd*, 182 F.3d 1315 (Fed. Cir. 1999).

134. *See supra* note 120 and accompanying text.

135. *See* Whitman, *supra* note 33, at 417-19.

136. *See* Scaltech Inc. v. Retec/Tetra, L.L.C., 156 F.3d 1193, 1194 (Fed. Cir. 1998), *amended by* 178 F.3d 1378, 1380 (Fed. Cir. 1999); *Abbott Lab.*, 51 U.S.P.Q.2d at 1302, *aff'd*, 182 F.3d at 1316.

137. *See Scaltech*, 156 F.3d at 1197.

test involved balancing a number of different factors, including whether the process offered for sale was at least a "substantially completed embodiment of the claimed invention"[138] that was highly likely to work for its intended purpose.[139] Importantly, however, the court noted that, at the time of the sales, the invention had not yet been conceived, and that even the offer for sale of "the mere concept" of an invention does not trigger the bar.[140] While noting that this furthered the policy of prompt disclosure of a comprehended invention, the opinion neglected to address the other policies underlying section 102(b).[141]

On rehearing after *Pfaff*, the *Scaltech* court maintained its prior ruling but remanded the case with different and clearer instructions.[142] The *Pfaff* test obviated the need for a complicated determination of whether the invention was "substantially complete" and highly likely to perform.[143] The lower court was directed simply to determine whether the invention was "reduced to practice" by having met each of the claim elements of the later patent.[144] This result depended, in turn, on the court's interpretation of the inherency doctrine, which established that the process could be a reduction to practice, irrespective of whether Scaltech was aware of all of its inherent features at the time.[145] Hence, the "reduction to practice" part of the second prong, coupled with the court's application of the inherency doctrine, obviated the need to determine complex issues of conception. As conception precedes the ability to apply for a patent, this analysis also obviated a determination of whether the invention was "ready for patenting" at the time of the sales, contrary to the *Pfaff* test itself. But as noted above, particular policies of the on-sale bar indicate that such commercial sales should trigger the grace period.[146] Thus, in spite of its inconsistency, the

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138. *Id.* at 1197.

139. *See id.* at 1198.

140. *See id.* at 1198. The court commented that "the invention was not conceived until Scaltech . . . had the opportunity to develop the claimed invention and discover the particle size and solids concentration limitations beginning in February 1992." *Id.* These comments were deleted from the court's analysis following *Pfaff*.

141. *See id.* at 1198.

142. *See Scaltech*, 178 F.3d at 1384.

143. *See* Pfaff v. Wells Elec., Inc., 119 S. Ct. 304, 311-12 (1998).

144. *See Scaltech*, 178 F.3d at 1384.

145. *See id.*

146. Specifically, this result effectuates the policy of preventing removal of inventions from the public that have been available through prolonged sales activities and the policy of avoiding effective extensions of the statutorily defined monopoly period. *See* Abbott Lab. v. Geneva Pharm., Inc., 51 U.S.P.Q.2d (BNA) 1301, 1305 (N.D. Ill. 1998) *aff'd*, 182 F.3d 1315 (Fed. Cir. 1999).

new *Pfaff* test enabled a clearer result that more directly furthered section 102(b)'s policies.

In *Abbott*, the district court initially invalidated the claim directed to Form IV terazosin hydrochloride on summary judgment under the "totality of circumstances" test.[147] In doing so, however, the court had to rely on an especially expansive reading of that test, concerning the requirement that the invalidating sale involve "a completed invention . . . known to work for its intended purpose."[148] The court found that Geneva's purpose in buying the uncharacterized batch was to develop generic versions of Abbott's drug, and held that the compound sold was in fact adequate for this intended purpose.[149]

On appeal after *Pfaff*, however, the Federal Circuit was able to affirm the lower court's holding more directly and efficiently. Relying on the basic definition of reduction to practice, the Federal Circuit held that Abbott's product clearly met the second prong of the *Pfaff* test.[150] As in *Scaltech*, the court applied the inherency doctrine to establish that when a product offered for sale intrinsically possesses all of the claim limitations of a later patent, it constitutes a reduction to practice irrespective of the parties knowledge at the time.[151] And again, as in *Scaltech*, this interpretation rendered inquiry into details of conception unnecessary.[152] Further, the literal application of this part of the test better supported the underlying policy that inventions made available to the public should not later be withdrawn.[153] Indeed, it can be appreciated that once an invention has been reduced to practice and sold to the public, it should not later be withdrawn because details of its structure are subsequently determined.

D. Resolution of the Inconsistency within the *Pfaff*-Test

The structure of the *Pfaff* test may be modified so as to resolve internal incongruity and avoid a strained interpretation of the inherency doctrine. Specifically, "reduction to practice" should be considered an alternative to the "ready for patenting" prong, rather than a sub-test for meeting it. Under this modified test, the on-sale bar would apply if, before the critical date, an invention is both the "subject of a commercial offer for sale" and

147. *See id.* at 1306-07.

148. *Id.* at 1306 (quoting Seal-Flex, Inc. v. Athletic Track & Court Constr., 98 F.3d 1318, 1324 (Fed. Cir. 1996)) (emphasis omitted).

149. *See id.* at 1306-07.

150. *See* Abbott Lab. v. Geneva Pharm., Inc., 182 F.3d 1315, 1318 (Fed. Cir. 1999).

151. *See id.* at 1318-1319.

152. *See id.*

153. *See id.* at 1319.

either "ready for patenting" *or* "reduced to practice." As before, "ready for patenting" could be shown by enabling descriptions of the invention.[154] And, as in recent applications of the test, "reduction to practice" could be shown irrespective of conception of the invention.[155] The alternative prongs capture the central idea that commercialization of that which inherently embodies or depicts the invention should trigger the bar.

The proposed modification preserves the traditional test of the on-sale bar while incorporating recent decisions involving modern technologies. By restoring "reduction to practice" as a separate prong, the modified test preserves express recognition of what has traditionally been considered the "best evidence that an invention is complete."[156] Further, as reduction to practice does not require conception,[157] having this prong stand alone helps clarify that the inherency doctrine should be applied in 102(b) analyses just as it would be applied in cases where recognition of intrinsic features is unnecessary. Just as an existing reference abrogates novelty of undisclosed but inherently contained features,[158] so, too, a commercialized invention should eventually bar patentability of what it inherently embodies. This would motivate the inventor who happens upon a useful product or process to seek to discover why it works, and to apply for a patent that discloses and explains the advance. The proposed framework, then, would better comport with the realities of how complex inventions are made while more clearly effectuating the principles underlying the on-sale bar.

Applying the proposed test to each of *Pfaff*, *Scaltech* and *Abbott* readily reveals how its modified structure enables more direct realization of the policies of section 102(b). Analysis of *Pfaff* under the proposed test remains the same, as here enabling descriptions satisfied the "ready for patenting" requirement.[159] At the time of the sale, detailed engineering drawings showed that Pfaff's socket was ready for patenting.[160] In addition to realistically addressing the realities of how some inventions are

154. *See* Pfaff v. Wells Elec., Inc., 119 S. Ct. 304, 312 (1998) (holding that ready for patenting could be met by proof of "drawings or other descriptions of the invention . . . sufficiently specific to enable a person skilled in the art to practice the invention.").

155. *See* Scaltech Inc. v. Retec/Tetra, L.L.C., 178 F.3d 1378, 1383-84 (Fed. Cir. 1999); *Abbott Lab.*, 182 F.3d at 1318-19.

156. *Pfaff*, 119 S. Ct. at 311.

157. *See supra* Part III.A.

158. *See supra* Part III.B.

159. *See Pfaff*, 119 S. Ct. at 312 ("In this case the second condition of the on-sale bar is satisfied because the drawings Pfaff sent to the manufacturer before the critical date fully disclosed the invention.").

160. *See id.*

commercialized,[161] the test directly comports with the policy of limiting Pfaff's effective monopoly on his chip socket while allowing time for its market evaluation.

In *Scaltech*, the independent "reduction to practice" prong of the proposed test might have more readily directed attention to the issue of whether the process on sale inherently embodied the invention later claimed.[162] This may have helped the lower court avoid the error of failing to address that question before granting summary judgment under section 102(b).[163] Further, the ensuing analysis would not have needed to address whether the process was ready for patenting. This would have enabled an analysis that more clearly reflects the principles of limiting removal of inventions from the public, limiting the time allowed for an invention's evaluation, and limiting the effective exclusivity period.

Likewise, in *Abbott*, the proposed test would have rendered arguments pertaining to conception moot, as a compound that inherently embodied the invention had already been made available to the public.[164] Again, such analysis would have more directly promulgated this 102(b) policy.

Finally, it should be noted that consideration of what "inherently embodies" the invention is a similar approach to one proposed by Judge Bryson in a prior Federal Circuit case.[165] Bryson's test provided that "if the sale or offer in question embodies the invention for which a patent is later sought, a sale or offer to sell that is primarily for commercial purposes" should trigger the bar.[166] In *Pfaff*, the Supreme Court rejected this test in a footnote.[167] In doing so, however, the Court noted that evidence satisfying this test might trigger the grace period if "it is clear that *no aspect of the invention was developed* after the critical date."[168] The Court's use of the word "developed" here, rather than "conceived," is important and instruc-

161. For example, it was Pfaff's custom to begin marketing his inventions before making a prototype. *See id.* at 307.

162. *See* Scaltech Inc. v. Retec/Tetra, L.L.C., 156 F.3d 1193, 1197 (Fed. Cir. 1998) (stating that the district court erred in failing to address, as a threshold question, whether the process on sale was actually an embodiment, or a substantially completed form, of the claimed invention), *amended by* 178 F.3d 1378 (Fed. Cir. 1999).

163. *See id.*

164. *See* Abbott Lab. v. Geneva Pharm., Inc., 182 F.3d 1315, 137-19 (Fed. Cir. 1999).

165. *See* Seal-Flex, Inc. v. Athletic Track & Court Constr., 98 F.3d 1318, 1325 (Fed. Cir. 1996) (Bryson, J., concurring in part and concurring in the result).

166. *Id.*

167. *See* Pfaff v. Wells Elec., Inc., 119 S. Ct. 304, 312 n.14 (1998) (stating that, although this test was advanced by the Solicitor General, the Court declines to adopt it).

168. *Id* (emphasis added).

tive. The Court's proviso can be read as requiring a determination that all features of the later patented invention were actually present in the product or process on sale before the critical date. In other words, all aspects of the later patented invention must have been inherent, and not later developed, in the commercialized product or process. Applying this same reasoning to *Abbott* and *Scaltech*, one would not be able to say a crystal's structure is "developed" when it is first determined, nor that a requirement of small particle size is "developed" when its significance is first recognized. Hence, these cases are examples in which "it is clear that no aspect of the invention was developed after the critical date."[169] By more clearly importing the doctrine of inherency into 102(b) analyses, the proposed *Pfaff* test may thus also help reconcile recent decisions under *Pfaff* with *Pfaff's* final footnote.

IV. CONCLUSION

Fundamental tenets of patent law animate the tests that apply the on-sale bar. With ever-advancing technologies, these tests do not always embrace the realities of the inventive process. Such a tension is reflected in the recent *Pfaff* test when applied to complex industries. *Scaltech* and *Abbott* raise the question of whether *Pfaff* provides a clearer test in section 102(b) analyses, or if the more elusive policy considerations must still control. A proposed modification of the test's structure promises more consistent realization of these policies in the continuing evolution of the on-sale bar.

169. *Id.*