

AN ANALYSIS OF THE ON SALE BAR AND ITS IMPACT ON THE STRUCTURE AND NEGOTIATION OF DEVELOPMENT AGREEMENTS

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I. INTRODUCTION

Development agreements are commonly used to define the relationship between contracting parties regarding the development of new product technologies. Frequently, development agreements provide that one party, usually the inventor-supplier of the new product technology, deliver prototypes for evaluation by the prospective buyer. In many cases, testing and evaluation of the prototypes make up a feasibility stage that is prefatory to a second supply phase under which the inventor-supplier will manufacture and supply the buyer's requirements for the new product. The stage of development of the invention at the time these agreements are executed can vary widely. The invention may be no more than a naked concept, or it may have been actually reduced to practice. In relation to the stage of development of the invention, the purpose of the development agreement can also vary. The agreement may be designed to evaluate market potential, or the agreement may be designed to show that the invention can indeed function as it was intended. The purpose of many pharmaceutical development agreements is to do the testing required to register the drug with the Food and Drug Administration.

As a consequence of the U.S. Supreme Court's decision in *Pfaff v. Wells Electronics, Inc.*,¹ inventor-suppliers who offer development agreements must negotiate and structure their agreements carefully based on the purpose and the stage of development of the invention; otherwise valuable intellectual property rights can be lost inadvertently. In *Pfaff*, the court established a two-prong test for determining the applicability of the on sale bar.² The first prong requires a "commercial offer for sale" of the

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¹ 525 U.S. 55 (1998).

² See *infra* pt. II (defining the on sale bar).

invention; the second requires that the invention has evolved to the point that it is “ready for patenting.”³ When these two conditions are met, the on sale bar is triggered and one year later the invention can no longer be patented.⁴

In contrast to pre-*Pfaff* standards, under the “ready for patenting” standard, development contracts that provide for the transfer of prototypes or include terms and conditions for the sale of the invention implicate the on sale bar. Once the invention is “ready for patenting,” unless the sale qualifies as an experimental use of the invention, the statutory one year period begins to run.

If the invention does not exist or is not ready for patenting at the time of an offer for sale, the offer is an inchoate bar that begins to run when the invention is ready for patenting.⁵ The bar is considered inchoate because the invention has not been developed to the point that the first prong of the *Pfaff* test is satisfied.⁶ Once both prongs of the *Pfaff* test are satisfied, the one-year statutory period begins to run regardless of whether the invention is first offered for sale or is first ready for patenting.⁷ Thus, an invention that is conceived and brought to a point that it is ready for patenting under a development agreement that includes an offer for sale, may trigger the on sale bar as of one year from the date the invention becomes ready for patenting. This requires that the inventor and his or her counsel be vigilant. As soon as the invention matures to the point that it is ready for patenting, the one-year clock starts to run.

This paper will start by reviewing the history and policies underlying the on sale bar and the experimental use exception, then it will examine approaches to development agreements that will minimize exposure to the on sale bar.

II. SUMMARY OF THE ON SALE BAR

A. *Brief History*

The on sale bar is codified by 35 U.S.C. § 102(b), which states: “[a] person shall be entitled to a patent unless -- (b) the invention was patented or described in a printed publication in this or a foreign country or in public

³ *Id.* at 67-68.

⁴ *Id.* at 67.

⁵ *Robotic Vision Sys., Inc. v. View Engr.*, 249 F.3d 1307, 1313 (Fed. Cir. 2001); *IGT v. Global Gaming Tech.*, 1999 U.S. App. Lexis 13336 (Fed. Cir. June 17, 1999).

⁶ *Robotic*, 249 F.3d at 1313.

⁷ *Id.*

use or on sale in this country, more than one year prior to the date of the application for patent in the United States.”⁸ The on sale bar was first enacted by Congress in the Patent Act of 1836, which prescribed an absolute bar to a patent if the inventor had given permission for his invention to be on sale before the patent application was filed.⁹ In the Patent Act of 1839, Congress enacted a grace period that permitted an invention to be on sale up to two years prior to filing the patent application.¹⁰ In 1939, that grace period was reduced to one year as it stands today.¹¹

B. *Underlying Policies*

The policy considerations underlying the on sale bar have shaped its development.¹² Four important policies underlying § 102(b) were outlined by the Court of Claims, a predecessor of the Court of Appeals for the Federal Circuit, in *General Electric Company v. United States*.¹³ They are: (1) a policy against removal of inventions from the public that the public has come to believe are freely available to all as a consequence of prolonged sales activity; (2) a policy in favor of prompt and widespread disclosure of new inventions to the public; (3) a policy against allowing inventors to commercially exploit the exclusivity afforded by the patent beyond the statutorily prescribed period; and (4) a policy in favor of affording an inventor a reasonable amount of time following sales activity to determine whether filing for patent is a worthwhile investment.¹⁴ The Federal Circuit has held that these policies are not just background rules but, in effect, define the on sale bar.¹⁵ As a result, courts have weighed these policies in determining the applicability of the on sale bar.

C. *Degree of Completion /Availability of the Invention*

The principal issue that the court resolved (at least to its thinking) in *Pfaff* was one with which the courts had struggled for years; namely, at what stage of development of an invention does the on sale bar become applicable when the invention has been the subject of an offer for sale. Over the last 40 years, different bright line rules and tests were proposed to address this issue. One problem inherent to establishing any standard for

⁸ 35 U.S.C. § 102(b) (2004).

⁹ Patent Act of 1836, ch. 357, § 6, 5 Stat. 117, 119 (1836).

¹⁰ Patent Act of 1839, ch. 88, § 7, 5 Stat. 353 (1839).

¹¹ Patent Act of 1939, ch. 450, § 1, 53 Stat. 1212 (1939).

¹² *J.A. LaPorte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577 (Fed. Cir. 1986).

¹³ 654 F.2d 55, 61 (Ct. Cl. 1981).

¹⁴ *Id.*

¹⁵ *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1062 (Fed. Cir. 1989).

determining when the on sale bar arises is that the inventions that are protectable under the patent statute and therefore subject to the on sale bar are quite diverse in terms of their subject matter, complexity, and the amount of testing required before the inventor knows that he or she “has” an invention. For example, they may range from genetically engineered medicines to simple mechanical devices to methods for doing business. The suitability or functionality of some inventions is self-evident at the moment of their conception; for other inventions, substantial testing under real world conditions is required. Some inventions can be reduced to practice at the moment that they are conceived, whereas, according to the Federal Circuit, others are not conceived until they have actually been reduced to practice.¹⁶

At one time court decisions used the “on hand” rule in applying the on sale bar.¹⁷ The on hand rule required that the invention be manufactured and on hand for delivery before the on sale bar could be triggered.¹⁸ As the court stated in *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*,¹⁹ this standard required that “a device incorporating the invention must have existed in its ordinary or contemplated usable form, and must have been on hand and ready for delivery more than one year prior to the patent application filing date.”²⁰ Thus, the invention not only needed to be reduced to practice but also needed to be commercially available for delivery to invoke the on sale bar. The rationale behind this standard was that an invention was not capable of being sold unless it was available for delivery to a customer. However, this allowed inventors to circumvent the application of the on sale bar by controlling production and delivery times of their inventions, and as a result, courts found a need to adopt a tighter standard.²¹

In *Timely Products Corporation v. Arron*,²² the court rejected the on hand doctrine in favor of the “reduction to practice” standard.²³ The court outlined a three-part test for the on sale bar: (1) the complete invention claimed must have been embodied in or obvious in view of the thing offered for sale; (2) the invention must have been tested sufficiently to verify that it is operable and commercially marketable; and (3) the sale

¹⁶ See *Mycogen Plant Science, Inc. v. Monsanto Co.*, 243 F.3d 1316 (Fed. Cir. 2001).

¹⁷ See e.g. *Burke Elec. Co. v. Indep. Pneumatic Tool Co.*, 232 F. 145 (2d Cir. 1916); *McCreery Engr. Co. v. Mass. Fan Co.*, 195 F. 498 (1st Cir. 1912).

¹⁸ *Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.*, 731 F.2d 831, 836 (Fed. Cir. 1984).

¹⁹ *Id.*

²⁰ *Id.*

²¹ See *Timely Prod. Corp. v. Arron*, 523 F.2d 288, 301-02 (2d Cir. 1975).

²² *Id.*

²³ *Id.*

must have been primarily for profit rather than for experimental purposes.²⁴ The third requirement reflected the experimental use doctrine. The second requirement, however, distinguished the analysis as it essentially required that the invention be “reduced to practice,” that is, the invention must have been constructed and demonstrated to work for its intended purpose in order to invoke the on sale bar.²⁵

Although the “reduction to practice” standard had the advantage of being readily ascertainable, it was the subject of criticism because inventors could commercially exploit their inventions more than a year prior to filing if the invention was not actually reduced to practice.²⁶ This again allowed the inventor to circumvent the on sale bar while reaping the commercial benefits beyond the prescribed one-year statutory period.²⁷

D. *“Totality of the Circumstances” Test*

In *UMC Electronics Company v. United States*,²⁸ the Federal Circuit took yet another approach to the on sale bar. Noting that “reduction to practice of the claimed invention has not been and should not be made an absolute requirement of the [on sale] bar,”²⁹ the court instead established a “totality of the circumstances” analysis stating that consideration should be given to “[a]ll of the circumstances surrounding the sale or offer to sell, including the stage of development of the invention and the nature of the invention weighed against the policies underlying section 102(b).”³⁰ The totality of circumstances test was, however, inherently vague. It was incapable of providing a fixed standard by which inventors could determine whether an offer for sale would trigger the on sale bar based on the extent of development of their inventions. This caused even more confusion for the courts, and the inconsistency in the Federal Circuit’s subsequent decisions regarding the on sale bar reflected this confusion.

*Micro Chemical Inc. v. Great Plains Chemical Co., Inc.*³¹ is one of a series of cases in which the Federal Circuit elaborated upon the totality of the circumstances analysis. The court had construed *UMC* to require that “a sale or definite offer to sell a substantially completed invention, with reason to expect that it would work for its intended purpose upon

²⁴ *Id.* at 302.

²⁵ *Id.*

²⁶ See *UMC Elec. Co. v. U.S.*, 816 F.2d 647 (Fed. Cir. 1987).

²⁷ *Barmag*, 731 F.2d at 837.

²⁸ 816 F.2d 647.

²⁹ *Id.* at 656.

³⁰ *Id.*

³¹ 103 F.3d 1538 (Fed. Cir. 1997).

completion, suffices to generate a statutory bar."³² In *Micro*, the patentee had not built a working prototype before offering the invention for sale, and after the offer, when the prototype was finally built, it did not work satisfactorily. These facts spawned yet another standard: an invention must be "substantially complete" to trigger the on sale bar. But once again, the standard was indefinite.³³

In *Seal-Flex, Inc. v. Athletic Track and Court Construction*,³⁴ a case that involved the sale of an all-weather athletic running track, the court held that "the general rule is that the on-sale bar starts to accrue when a completed invention is offered for sale."³⁵ According to the court, this gives the inventor more guidance as to when an invention is subject to the on sale bar.³⁶

E. *Pfaff v. Wells - "Ready for Patenting" Standard*

The different standards that the courts used in addressing the on sale bar prior to *Pfaff* set the stage for the Supreme Court to step in and attempt to establish a bright line rule.

1. Factual Background

In November 1980, Pfaff was contacted by Texas Instruments ("TI") to develop a socket for TI's leadless chip carriers.³⁷ The sockets were relatively simple mechanical devices.³⁸ Indeed, Pfaff created drawings of the concept during a meeting with TI,³⁹ and according to footnote three of the court's opinion, the inventor routinely went directly from the drawing board to hard tooling. On April 8, 1981, a TI representative issued a purchase order to Pfaff's company for 30,100 of the sockets.⁴⁰ After he tested the sockets, Pfaff shipped the sockets to TI.⁴¹ Pfaff filed a patent application for the socket on April 19, 1982, making the critical § 102(b) date for filing April 19, 1981.⁴²

Pfaff sued Wells Electronics, Inc. for infringement of the patent and

³² *Id.* at 1545.

³³ *Id.*

³⁴ 98 F.3d 1318 (Fed. Cir. 1996).

³⁵ *Id.* at 1324.

³⁶ *Id.* at 1323.

³⁷ *Pfaff*, 525 U.S. at 55.

³⁸ See U.S. Patent No. 4,491,377 (issued Jan. 1, 1985).

³⁹ *Pfaff*, 525 U.S. at 58.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

Wells claimed that Pfaff's invention was invalid under the on sale bar.⁴³ The district court held that the invention was not on sale under § 102(b) because there was no physical embodiment at the time of sale.⁴⁴ On appeal, the Federal Circuit used the "substantially complete" standard and ruled that although there was no physical embodiment of the invention at the time of the offer for sale, it was "substantially complete" because there was "reason to expect that it would work for its intended purpose upon completion."⁴⁵

2. Ready for Patenting

The Supreme Court affirmed the Federal Circuit's decision of the invalidity of Pfaff's invention.⁴⁶ However, the court outlined a different standard for determining whether an invention has reached a stage of development at which it can be considered on sale if it is the subject of a commercial offer.⁴⁷ The court framed the issue as "whether the commercial marketing of a newly invented product may mark the beginning of the 1-year period even though the invention has not yet been reduced to practice."⁴⁸ The Supreme Court's analysis began with its conclusion that the word "invention in the Patent Act . . . refers to the inventor's conception rather than to a physical embodiment of that idea."⁴⁹ The court concluded that the statute does not require an invention to be "reduced to practice before it can be patented" and said that Pfaff could have obtained a patent on his invention when he accepted the purchase order before there was a physical embodiment of the invention.⁵⁰ The court cited *The Telephone Cases*.⁵¹ In those cases, Bell's patent was upheld "even though he had filed his application before constructing a working telephone."⁵² Bell did not have a physical embodiment of the telephone, but he did have detailed drawings, which allowed a "good mechanic of proper skill in matters of the kind . . . [to] construct an apparatus."⁵³ Using parallel reasoning, the court concluded that Pfaff's drawings had "sufficient clearness and precision to enable those skilled in the matter' to produce the [chip carriers]."⁵⁴

⁴³ *Id.*

⁴⁴ *Pfaff v. Wells Elecs., Inc.*, 5 F.3d 514, 516 (Fed. Cir. 1993).

⁴⁵ *Pfaff v. Wells Elecs., Inc.*, 124 F.3d 1429, 1434 (Fed. Cir. 1997).

⁴⁶ *Pfaff*, 525 U.S. 55.

⁴⁷ *Id.* at 57.

⁴⁸ *Id.*

⁴⁹ *Id.* at 60.

⁵⁰ *Id.*

⁵¹ *Id.* at 61-62.

⁵² *Id.* at 61 (citing *The Telephone Cases*, 126 U.S. 1 (1888)).

⁵³ *Id.* at 62 (citing *The Telephone Cases*, 126 U.S. 1 (1888)).

⁵⁴ *Id.* at 63.

3. Analysis of the Standard

In *Pfaff*, the court took a very pragmatic approach to the on sale bar. *Pfaff* was barred because he could have filed a patent application by the critical date.⁵⁵ Once the invention is ready for patenting, the policies of encouraging prompt filing and allowing the inventor time to determine whether the invention is commercially viable without unjustifiably extending the patent monopoly appear to be mutually accommodated. Until the invention is ready for patenting, the inventor is not in a position to file, and logically, under the ready for patenting standard, the inventor is not penalized for delaying to file until the invention is ready.

In footnote fourteen of the *Pfaff* decision, the court rejected a theory advanced by the Solicitor General that any invention that is the subject of an offer for sale should be barred from patent protection a year later without regard to the stage of development of the invention at the time of the offer.⁵⁶ The court explained in the footnote that the theory underlying the Solicitor General's standard fails because it does not consider whether aspects of the invention were developed after the critical date.⁵⁷

According to the court, "ready for patenting" can be proved in at least two ways: "by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention."⁵⁸ Based on *The Telephone Cases*, the court noted that an invention can be "complete and ready for patenting" before it has actually been reduced to practice. The court then interpreted statements in its earlier decisions to the effect that an invention is complete when it is reduced to practice as meaning that "reduction to practice demonstrates that an invention is no longer in an experimental phase."⁵⁹ Reduction to practice is thus a trailing indicator that an invention is ready for patenting.

"Ready for patenting" appears to merge two concepts: (1) the

⁵⁵ The term "critical date" is used in this article as it is used in many of the reported cases to refer to the date one year before the application filing date.

⁵⁶ *Pfaff*, 525 U.S. at 68 n. 14.

⁵⁷ This suggests that proof that subsequent developments were required to provide an enabling disclosure will indicate that an invention is not ready for patenting. There is an important patent drafting lesson here. To avoid prematurely qualifying as ready for patenting, post-critical date developments should be disclosed and emphasized in the application.

⁵⁸ *Pfaff*, 525 U.S. at 67-68.

⁵⁹ *Id.* at 66.

concept of complete conception of the invention, and (2) the concept of an enabling disclosure. In addressing the standard applied by the Federal Circuit, the court noted: “[t]he word 'invention' must refer to a concept that is complete rather than merely one that is 'substantially complete.’”⁶⁰ But, “ready for patenting” is not synonymous with complete conception. If it were, presumably the court would have used the latter term. “Ready for patenting” requires something more than conception but something less than reduction to practice. That “something extra” appears at least to be an enabling disclosure or the ability to provide an enabling disclosure.

4. Conviction of Success v. Mere Hope

Pfaff dealt with a predictable art. The *Pfaff* Court did not address the result under the ready for patenting analysis when an inventor is able to prepare an enabling *but untested* disclosure in less predictable arts. Unfortunately, the *Pfaff* Court did not comment on a key point underlying the Federal Circuit's decision, that *Pfaff* had “reason to expect that the invention would work for its intended purpose.”⁶¹ An inventor can write a disclosure that later turns out to be enabling, yet not know (with varying degrees of uncertainty) that it will work. In *Space Systems/Loral, Inc. v. Lockheed Martin Corp.*,⁶² the Federal Circuit acknowledged that in the case of a complex invention, “development and verification” (and not just description) may be needed in order to prepare a patent application:

[If] the inventor himself was uncertain whether it could be made to work, a bare conception that has not been enabled is not a completed invention ready for patenting. Although conception can occur before the inventor has verified that his idea will work, [citation omitted] when development and verification are needed in order to prepare a patent application that complies with § 112, the invention is not yet ready for patenting.⁶³

The ultimate question of whether an invention has been placed on sale in violation 35 U.S.C. § 102(b) is a question of law which will be reviewed *de novo*.⁶⁴ To establish an on sale bar, it must be shown that the device sold or offered for sale fully anticipated the claimed invention or would have rendered the claimed invention obvious in view of the prior

⁶⁰ *Id.*

⁶¹ *Pfaff v. Wells Elecs., Inc.*, 124 F.3d at 1434, (quoting *Micro*, 103 F.2d at 1545).

⁶² 271 F.3d 1076 (Fed. Cir. 2001).

⁶³ *Id.* at 1080.

⁶⁴ *Tec Air, Inc. v. Denso Mfg. Mich., Inc.*, 192 F.3d 1353, 1358 (Fed. Cir. 1990).

art.⁶⁵ One problem with the “ready for patenting” standard is that it is a backward looking infringer’s defense as opposed to a forward looking inventor’s standard. In litigation, the patent is presumed valid under 35 U.S.C. § 282 and the defendant-infringer bears the burden of proving by clear and convincing evidence that the invention was ready for patenting by the critical date.⁶⁶ The defendant-infringer may be able to carry this burden by showing (1) a disclosure prior to the critical date; and (2) that the invention later worked in the manner in which it was disclosed. The inventor’s brilliance may work against him. Pfaff himself may have been a victim. He proudly testified:

Q: You are satisfied, obviously, when you come up with some drawings that it is going to go – “it works”?

A: I know what I’m doing, yes, most of the time.⁶⁷

In *Robotic Vision Systems, Inc. v. View Engineering, Inc.*,⁶⁸ the Federal Circuit dismissed the inventor’s professed uncertainty regarding the operability of his invention.⁶⁹ An inventor’s *belief* that his invention will work is not, as a matter of the patent law that has been developed in making priority determinations in interferences, an element of the act of conception, but it should be an element of “ready for patenting.”⁷⁰ An inventor cannot realistically be expected to file for patent protection until he or she has some conviction, or at least some reasonable expectation or confidence, that the invention is capable of providing the desired function or result.

The *Robotic* decision may be distinguished as one involving readily predictable subject matter in which the inventor’s doubts regarding the functionality of his invention simply appeared unrealistic or disingenuous to the court.⁷¹ Where the invention is untested and the art is less predictable, “ready for patenting” should arguably provide an opportunity to test the invention. If not to the point of a full-fledged reduction-to-practice, it should be tested at least to the point at which the inventor can determine that no further developmental work is required to enable one skilled in the art to practice his or her invention, or require that the invention has enough rudimentary functionality to justify filing. Therefore, in less predictable arts, the ready for patenting analysis will include not

⁶⁵ *Id.*

⁶⁶ *Cordis Corp. v. Medtronic Ave, Inc.*, 339 F.3d 1352, 1364 (Fed. Cir. 2003).

⁶⁷ *Pfaff*, 525 U.S. at 58.

⁶⁸ 249 F.3d 1307.

⁶⁹ *Id.* at 1312-13.

⁷⁰ *See Space Systems*, 271 F.3d 1076.

⁷¹ *See Robotic*, 249 F.3d 1307.

only an enabling disclosure, but also a reasonable expectation of success. Indeed, early Supreme Court cases state that the on sale bar does not attach to a naked idea.⁷²

Time will tell, but the logic that underlies Federal Circuit decisions, such as *Burroughs Wellcome Company v. Barr Laboratories, Inc.*,⁷³ holding that for some inventions, conception does not occur until reduction to practice, may shift the ready for patenting analysis toward reduction to practice in less predictable arts.⁷⁴ In *Burroughs*, the Federal Circuit explained the need for a complete conception this way:

The conception analysis necessarily turns on the inventor's ability to describe the invention with particularity. Until he can do so, he can not prove possession of the complete mental picture of the invention. These rules ensure that patent rights attach only when an idea is so far developed that the inventor can point to a definite particular invention.⁷⁵

The same "rules" the *Burroughs* Court referenced are arguably also useful to insure that the on sale bar attaches "only when an idea is so far developed that the inventor can point to a definite particular invention."⁷⁶ In *Hitzeman v. Rutter*,⁷⁷ the court denied Hitzeman the benefit of his naked conception, noting, "[n]othing in the record suggests that Hitzeman had a reasonable expectation that using yeast as a host cell, rather than bacteria, would yield successful assembly of particles."⁷⁸ The court characterized Hitzeman's conception as a "mere hope."⁷⁹ Clearly, if "mere hope" is insufficient to constitute conception, it should likewise fail in the ready for patenting analysis.

On the other hand, the Federal Circuit has already exhibited a willingness to jettison interference principals underlying "conception" in performing the ready for patenting analysis.⁸⁰ In *Scaltech, Inc. v. Retec/Tetra, L.L.C.*,⁸¹ in a decision authored by Judge Dyk, the court held a

⁷² See *Space Systems*, 271 F.3d at 1080.

⁷³ 40 F.3d 1223 (Fed. Cir. 1994).

⁷⁴ *Id.* at 1228.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ 243 F.3d 1345 (Fed. Cir. 2001).

⁷⁸ *Id.* at 1357.

⁷⁹ *Id.*

⁸⁰ *Scaltech, Inc. v. Retec/Tetra, L.L.C.*, 269 F.3d 1321 (Fed. Cir. 2001).

⁸¹ *Id.*

process patent invalid based on an offer to carry out the process for value.⁸² The process was for producing petroleum coke from a petroleum waste and the broadest claim in the patent recited a suspension having a defined particle size.⁸³ The patentee lost even though the importance of the particle size was not recognized until after the critical date.⁸⁴ The court cited *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.* for the proposition that the limitation does not have to be appreciated to reduce an invention to practice and hence to make it ready for patenting.⁸⁵ If this is the case, it raises the question and possibility that there may be situations in which, to be equitable, ready for patenting should not be held to occur until after reduction to practice.

F. *The Offer*

The other part of the Supreme Court's two-part test requires a commercial "offer for sale."⁸⁶ Prior to *Pfaff*, the on sale bar could be met by commercial activity which did not rise to the level of a formal "offer" under contract law principles.⁸⁷ Activities such as preliminary negotiations, price quotations, and advertisements were sufficient to constitute an "offer for sale."⁸⁸ Following the *Pfaff* decision, the Federal Circuit addressed the question of what legally constitutes "on-sale." In *Group One, Ltd. v. Hallmark Cards, Inc.*,⁸⁹ the Federal Circuit determined that the "commercial offer for sale" prong of the *Pfaff* on sale analysis requires a formal offer under contract law. According to the court, "only an offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance (assuming consideration), constitutes an offer for sale under § 102(b)."⁹⁰ The Federal Circuit also held that the question of whether a commercial activity qualifies as an offer is a question of Federal Circuit law as distinguished from the law of any particular state. At the same time, the court acknowledged that the Uniform Commercial Code was a "useful, though not authoritative, source" for determining the meaning of the terms used by the parties.⁹¹ Recently, the objective clarity in the *Group One* standard may

⁸² *Id.* at 1330-31.

⁸³ *Id.* at 1321-1325.

⁸⁴ *Id.* at 1325-1326.

⁸⁵ *Id.* at 1331 (citing *Abbott Labs. v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1318-1319 (Fed. Cir. 1999)).

⁸⁶ *Pfaff*, 525 U.S. at 67.

⁸⁷ *RCA*, 887 F.2d at 1062.

⁸⁸ See e.g. *State Indus. Inc. v. Mor-Flo Indus. Inc.*, 639 F.Supp. 937 (E.D. Tenn. 1986); *Reactive Metals and Alloys Corp. v. ESM, Inc.*, 769 F.2d 1578 (Fed. Cir. 1985).

⁸⁹ 254 F.3d 1041 (Fed. Cir. 2001).

⁹⁰ *Id.* at 1048. In that case, the offer consisted of the written inquiry: "We could provide the machine and/or the technology and work on a license/royalty basis." *Id.* at 1044.

⁹¹ *Id.* at 1047.

have been threatened by the court's decision in *Lacks Industries, Inc. v. McKechnie Vehicle Components USA, Inc.*⁹² In that case, the court reversed a holding of invalidity because the lower court failed to consider evidence of industry practices in determining whether the promotional activities of the patentee constituted an offer for sale. The court, in an opinion authored by Judge Michel, instructed:

On remand the district court (or Special Master) should resolve whether or not it needs to take additional evidence on sales practice in the automotive industry to determine if the sales promotion activities by Lacks rise to a contractual offer for sale (and, of course, take such evidence if necessary).⁹³

Judge Newman dissented, reasoning:

Determination of whether there has been an offer of sale in terms of § 102(b) requires objective application of uniform contract law, not indulgence based on disputed local custom in the automobile tire wheel cladding business. . . . In developing uniform national law it is as important that the law be consistent across [sic] industry boundaries as it is across state boundaries. Such consistency is undermined by the majority's new accommodation to assertions of idiosyncratic industry patterns of dealing. While principles of federalism counsel against imposing a possibly alien legal standard upon transactions that are primarily matters of state law, such as the law of sales, the panel majority is not here invoking the guidance of state law, but of practices ostensibly peculiar to a segment of the automotive industry -- practices unencumbered by state law, indeed unknown, uncodified, and variable.⁹⁴

The Federal Circuit has consistently distinguished the offer for sale of a product from the offer of a license. While the former bars a patent, the latter does not.⁹⁵ An offer to enter into a license under a patent for the future sale of the invention is not an offer for sale.⁹⁶ Similarly, providing potential customers with samples of a product, without providing any other

⁹² 322 F.3d 1335 (Fed. Cir. 2003).

⁹³ *Id.* at 1351.

⁹⁴ *Id.* at 1352.

⁹⁵ *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1217 (Fed. Cir. 1998).

⁹⁶ *In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002).

terms, has been held not to constitute a commercial offer for sale because the recipient could not act in such a way that would create a contract.⁹⁷ However, even a commercial offer to sell the invention *to the patentee* initiated by the buyer can lead to a bar in the same way that an offer to sell the invention to a third party can lead to a bar.⁹⁸

III. EXPERIMENTAL USE -- NEGATION OF THE ON SALE BAR

In *Pfaff*, the Supreme Court made it clear that the experimental use exception lives on. The court distinguished the sale in *Pfaff* as “commercial rather than experimental in character.”⁹⁹ The court also referenced *City of Elizabeth v. American Nicholson Pavement Company*¹⁰⁰ and thereby indicated that within the context of *Pfaff*’s two-pronged analysis, the exception of activities that are genuinely experimental has not changed.

The experimental use exception is more accurately described as the experimental use negation because the experimental nature of the activity negates the on sale bar. The strict statutory limitation of the on sale bar prevents inventors from putting their inventions on sale or in public use prior to one year before filing. In *City of Elizabeth* and its progeny, the courts have recognized that in some cases it is necessary to test an invention in the public view for extended periods of time in order to determine whether the invention will work for its intended purpose.¹⁰¹ The experimental use exception recognizes that there may be uses or sales of the invention by or on behalf of the inventor that are primarily for the purpose of experimentation which may occur prior to the prescribed one-year statutory period.¹⁰² Accordingly, the experimental use exception “negates” the application of the on sale bar in instances where the sale is principally motivated by a need to experiment to bring the invention to perfection or to determine whether it will work for its intended purpose.¹⁰³ However, this exception is limited by the inventor’s intention to commercially exploit the invention.¹⁰⁴ Thus, courts assess whether a sale was primarily for the purpose of experimentation or for the purpose of commercially exploiting the invention.¹⁰⁵ As with the on sale doctrine, courts rely on the policies

⁹⁷ *Minn. Mfg. & Mining Co. v. Chemque, Inc.*, 303 F.3d 1294, 1308 (Fed. Cir. 2002).

⁹⁸ *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 182 F.3d 888, 890 (Fed. Cir. 1999).

⁹⁹ *Pfaff*, 525 U.S. at 67.

¹⁰⁰ *City of Elizabeth v. Nicholson Pavement Co.*, 97 U.S. 126 (1887).

¹⁰¹ *Id.*; see also *EZ Dock, Inc. v. Schafer Sys., Inc.*, 276 F.3d 1347 (Fed. Cir. 2002).

¹⁰² *City of Elizabeth*, 97 U.S. at 135.

¹⁰³ *Id.* at 134-37.

¹⁰⁴ See e.g. *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 256 (1887); *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1187 (Fed. Cir. 1993); *Labounty Mfg., Inc. v. U.S. Intl. Trade Commn.*, 958 F.2d 1066, 1071 (Fed. Cir. 1992).

¹⁰⁵ *Id.*

that underlie the experimental use exception in determining the applicability of experimental use in cases involving the on sale bar.¹⁰⁶

A. *History of the Experimental Use Exception*

The experimental use exception was firmly established by the Supreme Court in the landmark case *City of Elizabeth*,¹⁰⁷ which involved a public use. In that case, an inventor had patented a pavement that he had used on a section of a private toll road for six years before he applied for the patent.¹⁰⁸ The *City of Elizabeth* Court claimed that the patent was invalid because the pavement had been in public use for more than the prescribed statutory period.¹⁰⁹ The inventor claimed that his activities were experimental, namely, for the purpose of testing the durability of the pavement.¹¹⁰ In order to be useful on roadways the pavement had to be permanent and durable.¹¹¹ The inventor had monitored the results almost daily for six years and upon becoming convinced that his pavement worked as a useful and durable road, he applied for a patent on it.¹¹² The court held that the public testing did not constitute public use as "it is the interest of the public, as well as [the inventor], that the invention should be perfect and properly tested, before a patent is granted for it."¹¹³ The court further stated that "[t]he use of an invention . . . by way of experiment, and in order to bring the invention to perfection, has never been regarded as such a [public] use."¹¹⁴

Courts have relied on the policies surrounding the on sale bar and experimental use in defining the exception and, in turn, defining the on sale bar itself.¹¹⁵ The Federal Circuit has outlined a number of critical factors that it takes into consideration as part of the analysis in determining whether the experimental use exception applies to inventions that have been on sale or subject to an offer for sale prior to the critical date.¹¹⁶

B. *Policies Underlying Experimental Use*

The experimental use doctrine is essentially a balance of two

¹⁰⁶ Donald Chisum, *Chisum on Patents* § 6.02[7][b](LEXIS 2004).

¹⁰⁷ *City of Elizabeth*, 97 U.S. 126.

¹⁰⁸ *Id.* at 127.

¹⁰⁹ *Id.* at 136.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.* at 137.

¹¹⁴ *Id.* at 134.

¹¹⁵ *RCA, supra*. See also *Lough v. Brunswick*, 86 F.3d 1113 (Fed. Cir. 1996).

¹¹⁶ *Lough*, at 1119.

policies.¹¹⁷ It weighs the policy which favors the inventor in allowing time to test and perfect the invention and to assess its utility against the policy which prevents inventors from extending the statutory period of monopoly by delaying filing while commercially exploiting the invention.¹¹⁸ The Supreme Court explained the experimental use doctrine in *Pfaff* this way:

[A]n inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention – even if such testing occurs in the public eye. The law has long recognized the distinction between inventions put to experimental use and products sold commercially.¹¹⁹

The Court then relied upon *City of Elizabeth* to explain the rationale of experimental use:

It is sometimes said that an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law; but this cannot be said with justice when the delay is occasioned by a bona fide effort to bring his invention to perfection, or to ascertain whether it will answer the purpose intended. His monopoly only continues for the allotted period, in any event; and it is the interest of the public, as well as himself, that the invention should be perfect and properly tested, before a patent is granted for it. Any attempt to use it for a profit, and not by way of experiment, for a longer period than [two years] before the application, would deprive the inventor of his right to a patent.¹²⁰

Thus, one of the rationales of the experimental use doctrine is to further the public interest by allowing inventors to “perfect” their inventions before applying for a patent. In that regard, the public will be able to enjoy inventions that are “complete” and work for their intended purpose. Furthermore, the experimental use doctrine allows inventors to experiment with their inventions to “completion,” rather than having to expeditiously file an application for a patent on a half-baked invention subsequent to a

¹¹⁷ Chisum, *supra* n. 106, at § 6.02[7][b].

¹¹⁸ *Id.*

¹¹⁹ *Pfaff*, 525 U.S. at 64.

¹²⁰ *Id.* at 64-65 (citing *City of Elizabeth*, 97 U.S. at 137).

public use or sale. Nonetheless, the sale must be primarily for experimental purposes; any sale or offer for sale rendered otherwise would invalidate the patent if the transaction occurred before the critical date.

C. *Factors Considered in Determining Experimental Use*

The Federal Circuit, in a series of cases involving the experimental use doctrine, has outlined the significant factors that it uses to determine whether a sale or use is for experimental purposes.¹²¹ Factors such as the inventor's intent to commercially exploit the invention, the amount of control over the invention exercised by the inventor following the sale, and the extent of commercial exploitation in relation to the purpose of experimentation, along with other factors, were assessed in a "totality of the circumstances" approach in determining whether the experimental use exception should apply in negating the application of the on sale bar.¹²²

1. Commercial Intent

Courts have looked at the inventor's purpose in commercially exploiting his invention as one factor in determining whether or not the sale/commercialization qualifies for the experimental use exception.¹²³ If the use is primarily commercial rather than experimental, then the on sale bar will apply.¹²⁴ The inventor's subjective intent is of little relevance.¹²⁵ Instead, courts look at the objective evidence to assess the purpose of the sale.¹²⁶ For example, an inventor may claim at trial that his intentions were primarily for the purpose of experimentation, but if the objective evidence is otherwise, the experimental use exception may not apply.

In addition, the inventor's profit on the sale is not a controlling factor in the application of the experimental use doctrine.¹²⁷ For instance, if an inventor makes no profit or loses money in a sale but his objective is commercial rather than experimental, the on sale bar may still apply. On the other hand, if the inventor benefits commercially from the sale, but the primary purpose of the sale is experimental, the experimental use exception

¹²¹ See *Lough*, *supra* n. 115.

¹²² *EZ Dock, Inc.*, at 1352, 1354.

¹²³ *TP Labs., Inc. v. Prof. Positioners, Inc.*, 724 F.2d 965, 971 (Fed. Cir. 1984). The infringer bears the burden of proving a commercial offer for sale. *Id.* The burden of persuasion does not shift at any time to the patentee. *Id.* Experimental use and offer for sale are not separate issues. *Id.* The court is faced with a single issue -- was the invention on sale under § 102(b). *Id.*

¹²⁴ See *Labounty Mfg., Inc.*, 958 F.2d at 1071-72.

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ *Barmag*, 731 F. 2d at 840.

may apply.¹²⁸ The Federal Circuit looks at an inventor's profit motive rather than actual profit received in determining whether the on sale bar has been revoked.¹²⁹ Receipt of payment is usually indicative of commercial intent. In addition, the amount of the payment for the invention is a factor which courts look at in determining experimental use.¹³⁰ A sale for full price may be viewed as a bar rather than as an experimental use.¹³¹ However, mere reimbursement to the inventor for the cost of the invention does not necessarily constitute experimental use.¹³² The courts look at the "totality of the circumstances" involved with the sale.¹³³ In essence, the commercial exploitation must be incidental to the primary purpose of experimentation for the experimental use exception to apply.¹³⁴

2. Inventor's Control Over the Invention Following Sale

Another important factor that courts have used frequently to assess whether a use is experimental or commercial is the amount of control that the inventor exercised over his invention.¹³⁵ Courts reason that an inventor's lack of control over his experiment after a sale or public use shows that the motivation behind the sale or use is not experimental.¹³⁶ In *Lough v. Brunswick*,¹³⁷ the Federal Circuit reasoned that "control is critically important, because, if the inventor has no control over the alleged experiments, he is not experimenting. If he does not inquire about the testing or receive reports concerning the results, similarly, he is not experimenting."¹³⁸ Evidence of control may include that the inventor kept progress records of the invention.¹³⁹ On the other hand, a lack of progress reports by the inventor may indicate the lack of experimental purpose and result in an on sale bar.¹⁴⁰

3. Other Factors

In addition to the inventor's commercial purpose and control over

¹²⁸ *Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1564 (Fed. Cir. 1987).

¹²⁹ *Labounty Mfg., Inc.*, 958 F.2d at 1071-72.

¹³⁰ *Grain Processing Corp. v. American Maize-Prods. Co.*, 840 F.2d 902, 906 (Fed. Cir. 1988); *Baker Oil Tools, Inc.*, 828 F.2d at 1564; see also *EZ Dock, Inc. v. Schafer Sys., Inc.*, 276 F.3d 1347 (Fed. Cir. 2002).

¹³¹ *In re Theis*, 610 F.2d 786, 793 (C.C.P.A. 1979).

¹³² *U.S. Envtl. Prods., Inc. v. Westall*, 911 F.2d 713, 717 (Fed. Cir. 1990).

¹³³ *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549 (Fed. Cir. 1990).

¹³⁴ *Ushakoff v. United States*, 327 F.2d 669, 672 (Ct. Cl. 1964).

¹³⁵ *In re Hamilton*, 882 F.2d 1576 (Fed. Cir. 1989).

¹³⁶ *Id.*

¹³⁷ 86 F.3d 1113 (Fed. Cir. 1996).

¹³⁸ *Id.* at 1120.

¹³⁹ *Labounty Mfg. Inc.*, 958 F.2d at 1071.

¹⁴⁰ *U.S. Envtl. Prods., Inc.*, 911 F.2d at 717.

his invention, there are a number of other factors which courts have considered in assessing whether a sale was for the primary purpose of experimentation. The length of the test period and its relation to the nature of the invention is also important in determining experimental use.¹⁴¹ The test period should be reasonable in relation to the time period necessary to test whether the invention will work for its intended purpose.¹⁴² For example, an invention such as a pavement for which durability is material to the invention may require more time for experimentation.¹⁴³

Other factors that courts have considered relate to the transaction between the inventor and purchaser. A confidentiality agreement may show that the sale was for experimental purposes.¹⁴⁴ However, the existence of a confidentiality agreement is not controlling.¹⁴⁵ In addition, one case holds that the purchaser must be aware of the experimentation at the time of the use or sale.¹⁴⁶ An explicit clause in the agreement that the transaction is for experimental purposes may help show experimental use, but is certainly not dispositive of experimental use.¹⁴⁷

One form of testing which courts have scrutinized under the experimental use exception is market testing.¹⁴⁸ Testing to see how the market will accept the product does not fall within the experimental use doctrine. The rationale is that this type of testing is primarily for commercializing the invention and not for testing function or performance, and thus results in the on sale bar.¹⁴⁹ Additionally, experimental use only negates a statutory bar when the testing addresses the claimed features of the invention or properties or performance considerations that are inherent to them.¹⁵⁰

4. Effect of Reduction to Practice

According to *City of Elizabeth*, the rationale behind the experimental use doctrine is to further public interest by allowing inventors to perfect their inventions before applying for a patent. But, what does it

¹⁴¹ *Baker Oil Tools, Inc.*, 828 F.2d at 1564.

¹⁴² *City of Elizabeth*, 97 U.S. at 135.

¹⁴³ *Id.*

¹⁴⁴ *Labounty Mfg., Inc.*, 958 F.2d at 1071.

¹⁴⁵ *See In re Caveney*, 761 F.2d 671, 674 (Fed. Cir. 1985).

¹⁴⁶ *Labounty Mfg., Inc.*, 958 F.2d at 1072.

¹⁴⁷ *Id.*

¹⁴⁸ *See e.g. Smith & Davis Mfg. Co. v. Mellon*, 58 F. 705, 707 (8th Cir. 1893); *Cataphote Corp. v. De Soto Chem. Coatings, Inc.*, 356 F.2d 24 (9th Cir. 1966).

¹⁴⁹ *Id.*

¹⁵⁰ *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306 (Fed. Cir. 2004) (citing *LaBounty Mfg., Inc.*, 958 F.2d at 1074; *In re Brigance*, 792 F.2d 1103, 1109 (Fed. Cir. 1986)).

mean to “perfect” an invention and at what point under the *Pfaff* ready for patenting analysis does this right to conduct experimentation end? In *Piher, S.A. v. CTS Corporation*,¹⁵¹ the court held “reduction to practice is *not* synonymous with mechanical perfection; all that is required [for reduction to practice] is a demonstration of practical efficacy and utility.”¹⁵² The plain language of the *City of Elizabeth* decision suggests that permissible experimentation might extend beyond the reduction to practice of an invention. However, the Federal Circuit appears to construe the concept of “perfecting the invention” synonymously with reduction to practice; a reduction to practice occurs when an invention is “perfected” and an invention is “perfected” when it works for its intended purpose.¹⁵³

During the period when the courts relied upon the “on hand” standard and subsequently the “reduction to practice” standard in assessing the stage of development of an invention, the experimental use doctrine was applied with respect to activities that occurred after the invention had been reduced to practice.¹⁵⁴ Logically, this made sense because under these standards the on sale bar could be invoked only after a reduction to practice. Therefore, application of the experimental use exception to negate the effect of the offer or sale would occur only after reduction to practice. After the Federal Circuit changed the standard and held that an invention may be subject to the on sale bar before it is reduced to practice,¹⁵⁵ a split developed between cases that held that experimental use can apply after an invention is reduced to practice and those that held otherwise.¹⁵⁶ More recently, the Federal Circuit has consistently held that once an invention is reduced to practice, the experimental use defense is no longer available.¹⁵⁷ In *Aerovox Corporation v. Polymert Manufacturing Corporation*,¹⁵⁸ *General Motors Corporation v. Bendix Aviation Corporation*,¹⁵⁹ and *Atlas v. Eastern AirLines, Inc.*,¹⁶⁰ the inventions all were held to have been reduced to practice and subsequent testing qualified as experimental. But in these cases the courts equated reduction to practice with simply the

¹⁵¹ 664 F.2d 122 (7th Cir. 1981).

¹⁵² *Id.* at 127 (emphasis added).

¹⁵³ *RCA*, 887 F.2d at 1061. Once reduced to practice, the invention cannot be the subject of an experiment that negates an on sale bar. *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 5 F.3d 1477, 1480 (Fed. Cir. 1993).

¹⁵⁴ See e.g. *General Motors Corp. v. Bendix Aviation Corp.*, 123 F. Supp. 506, 520 (N.D. Ind. 1954); *Atlas v. E. Air Lines, Inc.*, 311 F.2d 156, 162 (1st Cir. 1962).

¹⁵⁵ *UMC*, 816 F.2d at 647.

¹⁵⁶ *Baker Oil Tools, Inc.*, 828 F.2d at 1558 (holding that experimental use may still apply after reduction to practice).

¹⁵⁷ See e.g. *RCA*, 887 F.2d at 1056; *Atlantic Thermoplastics*, 5 F.3d at 1480; *Contl. Plastic Containers v. Owens Brockway Plastic Prods., Inc.*, 141 F.3d 1073, 1079 (Fed. Cir. 1998).

¹⁵⁸ 67 F.2d 860, 862 (2d Cir. 1933).

¹⁵⁹ 123 F. Supp. at 520.

¹⁶⁰ 311 F.2d at 162.

availability of a working model of the invention and excepted, as permissible experimentation, testing to confirm that the invention was suitable for its intended purpose. Nevertheless, consistent with the conventional understanding of “bring[ing] the invention to perfection” in *City of Elizabeth*,¹⁶¹ the courts have generally held that testing to confirm commercial suitability does not invoke the on sale bar.

*Manville Sales Corporation v. Paramount Systems, Inc.*¹⁶² involved an invention for an iris arm luminaire pole.¹⁶³ The invention was tested in a lab but was further tested in public at a rest stop to determine its durability to different winter conditions.¹⁶⁴ The court held that “when durability in an outdoor environment is inherent to the purpose of an invention, then further testing to determine the invention's ability to serve that purpose will not subject the invention to a §102(b) bar.”¹⁶⁵ Here, the inventor had a working model but needed to ascertain that it would work for its intended purpose, namely, to endure the winter conditions of Wyoming. In *Baker Oil Tools, Inc. v. Geo Vann, Inc.*,¹⁶⁶ the court dismissed the district court's reasoning that an admission by the inventor during interference hearings that the invention was reduced to practice excluded the application of the experimental use defense.¹⁶⁷ The Federal Circuit, in *RCA Corp v. Data Gen. Corp.*,¹⁶⁸ held that “experimental use, which means perfecting or completing an invention to the point of determining that it will work for its intended purpose, ends with an actual reduction to practice.”¹⁶⁹

Can there be “experimental” sales or uses after an invention is reduced to practice? Although the Supreme Court does not address the issue directly, the court states in dicta, “It is true that reduction to practice *ordinarily* provides the best evidence that an invention is complete.”¹⁷⁰ Additionally, in footnote 12, the court notes: “Several of this Court's early decisions stating that an invention is not complete until it has been reduced to practice are best understood as indicating that the invention's reduction to practice demonstrated that the concept was no longer in an experimental phase.”¹⁷¹ It appears from footnote 12 that the court perceives that once an invention is reduced to practice, it is no longer in the experimental phase

¹⁶¹ 97 U.S. at 134.

¹⁶² 917 F.2d 544.

¹⁶³ *Id.*

¹⁶⁴ *Id.* at 547-48.

¹⁶⁵ *Id.* at 551.

¹⁶⁶ 828 F.2d 1558.

¹⁶⁷ *Id.* at 1565.

¹⁶⁸ 887 F.2d 1056.

¹⁶⁹ *Id.* at 1061; see also *Zacharin v. U.S.*, 213 F.3d 1366 (Fed. Cir. 2000).

¹⁷⁰ *Pfaff*, 525 U.S. at 66 (emphasis added).

¹⁷¹ *Id.* at 66 n. 12.

and further experimentation would not be excepted under the experimental use exception. It also appears from footnote 12 that the court believes that the stage of development of the invention is a critical factor to consider in determining whether the offer for sale is primarily commercial or experimental in nature.¹⁷² But, if the offer for sale is affiliated with an inventor's bona fide objective to "perfect" the invention, will the offer for sale bar the invention regardless of whether the invention is in fact reduced to practice? It does not appear so. Footnote 12 suggests that reduction to practice represents the outer limit for any public experimental activity that the inventor might expect would not otherwise trigger the on sale bar.¹⁷³

IV. APPROACHES TO DEVELOPMENT AGREEMENTS

A. Overview

Development agreements frequently include provisions for the development and transfer of prototypes. These events often are used as milestones that trigger payments or further performance under the agreements. In some cases, as part of a co-development agreement, one party may supply the other with a prototype or product for use in testing and further development of the invention as in the *Elan* case discussed below. While in many cases the parties are likely to view the development agreement as a contract for services in which one party uses its technical expertise to design and develop or assist in the design and/or development of a product for the other, provisions in the agreement for supplying prototypes or for supplying the product on a commercial basis can effect an offer or sale that will trigger the statutory bar unless the offer or sale qualifies as an experimental use of the invention. This may be true regardless of whether the agreement actually ties the delivery of the prototypes to the receipt of a specific amount of monetary consideration.

In *Zacharin v. United States*,¹⁷⁴ Zacharin, an engineer working for the U.S. Army, developed a ram air decelerator or "RAD."¹⁷⁵ The Army entered into a four-phase development program with the Breed Corporation to develop the RAD as part of a submunition system.¹⁷⁶ The first contract covered two phases of the program, and the second contract covered the third phase and provided for the construction and delivery of six thousand RAD units.¹⁷⁷ The second contract was executed more than a year before

¹⁷² See *id.*

¹⁷³ *Id.*

¹⁷⁴ 213 F.3d 1366.

¹⁷⁵ *Id.* at 1367.

¹⁷⁶ *Id.* at 1368.

¹⁷⁷ *Id.*

Zacharin's patent application was filed.¹⁷⁸ Zacharin stipulated that the invention had been reduced to practice prior to entering the second contract and he did not challenge the sale under the experimental use exception.¹⁷⁹ The second contract included supply provisions based on a cost plus incentive fee.¹⁸⁰ Zacharin argued that "the [second] contract did not constitute a commercial offer to sell the invention, because [it] was not a supply contract with fixed unit prices and a definite delivery schedule."¹⁸¹ The court disagreed.¹⁸² Quoting from its 1985 decision in *In re Caveney*, the court stated: "[A] sale is 'a contract between parties to give and pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold.'"¹⁸³ Importantly, the court distinguished Zacharin's supply agreement from a contract for development services noting: "This case is not one in which the inventor took his design to a fabricator 'and paid the fabricator for its services in fabricating a few sample products.'" ¹⁸⁴ The court also noted that under its precedent, the patent was barred regardless of the fact that the contract was made by a third party and the products were supplied at the buyer's direction as opposed to the seller's direction.

In *Netscape Communications Corporation v. Konrad*,¹⁸⁵ the Federal Circuit held that Konrad's offer to create a remote database object system for the Superconducting Super Collider Laboratory, in exchange for four months full-time employment, constituted an offer for sale of the invention and invalidated his patents under § 102(b).¹⁸⁶ Konrad had developed the system while working under a Department of Energy ("DOE") contract at the Lawrence Berkeley Laboratory and contended that because his work at the laboratories was commonly funded by the DOE, at all times, the invention remained under the control of the DOE and no sale had occurred.¹⁸⁷ The offer was embodied in a memorandum purchase order that Konrad contended was merely an accounting convenience for tracking the transfer of research funds between two DOE laboratories, and therefore did not involve the sale of a commercial embodiment of the invention.¹⁸⁸ In a decision authored by Judge Mayer,¹⁸⁹ the Federal Circuit disagreed.¹⁹⁰

¹⁷⁸ *Id.*

¹⁷⁹ *Id.* at 1369.

¹⁸⁰ *Id.* at 1370.

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.* (quoting *In re Caveney*, 761 F.2d at 676).

¹⁸⁴ *Zacharin*, 213 F.3d at 1370 (quoting *Brasseler*, 182 F.3d at 891).

¹⁸⁵ 295 F.3d 1315 (Fed. Cir. 2002).

¹⁸⁶ *Id.* at 1324-25.

¹⁸⁷ *Id.* at 1322.

¹⁸⁸ *Id.* at 1324.

¹⁸⁹ Judges Prost and Newman were also on the panel. *Id.* at 1315.

According to the court, the DOE did not exercise such control over the two laboratories so as to render them the same legal entity, and a sale had occurred from one laboratory to the other.¹⁹¹

In *Elan Corporation, PLC v. Andrx Pharmaceuticals, Inc.*,¹⁹² the Federal Circuit reversed a district court's holding of patent invalidity under the on sale bar.¹⁹³ Elan had sent Lederle and several other large pharmaceutical companies letters offering to partner with one of them in the development and FDA registration of an extended release tablet form of the drug naproxen.¹⁹⁴ In the letter, Elan set forth licensing fees and proposed a relationship under which Elan would supply the tablets to the partnering drug company and the partner would package and resell the product with a margin of at least 70%.¹⁹⁵ The district court held that these activities barred the patent on the extended release tablet.¹⁹⁶ Elan's letter proposed three different transactions that could have created an on sale bar: first, the license offer itself (admittedly, as discussed earlier, the Federal Circuit has consistently indicated that licensing does not qualify as a bar); second, the offer to supply the tablets at a price that would permit a 70% margin after packaging and resale; and third, the inherent commitment by Elan to make tablets available for clinical studies in conjunction with the FDA approval process. The Federal Circuit, in a decision authored by Judge Lourie,¹⁹⁷ did not find that any of these activities barred the invention.¹⁹⁸ The court noted:

The letter to Lederle is clear on its face that Elan was not offering to sell naproxen tablets to Lederle, but rather granting a license under the patent and offering Lederle the opportunity to become its partner in the clinical testing and eventual marketing of such tablets at some indefinite point in the future.¹⁹⁹

The court also sent the patent bar a warning against misusing the licensing exception and further noted:

Of course, if Elan had simply disguised a sales price as a licensing fee it would not avoid triggering the on-sale bar.

¹⁹⁰ *Id.* at 1324.

¹⁹¹ *Id.*

¹⁹² 366 F.3d 1336 (Fed. Cir. 2004).

¹⁹³ *Id.* at 1337.

¹⁹⁴ *Id.* at 1337-38.

¹⁹⁵ *Id.* at 1338.

¹⁹⁶ *Id.* at 1339.

¹⁹⁷ Judges Michel and Dyk were also on the panel. *Id.* at 1336.

¹⁹⁸ *Id.* at 1340, 1342.

¹⁹⁹ *Id.* at 1341.

Nonetheless, that is not what Elan did here. If Lederle had accepted Elan's offer, it would have owed Elan \$500,000 at contract signing and additional amounts at various milestones in the collaboration. *There is no statement in the letter of how many tablets Elan would supply in exchange for those funds, and there is no suggestion that the number of tablets supplied would depend in any way on those payments (although the payments were to be keyed to the number of patients enrolled in clinical trials per the fifth paragraph of the letter).*²⁰⁰

The *Elan* court might have gone a step further in justifying its decision and observed that the Lederle letter did not clearly indicate that the parties intended to effect a transfer of title to the tablets to Lederle. For example, Lederle could have been expected to test the tablets on behalf of Elan.

These cases demonstrate that the on sale bar raises very important considerations for both negotiating and drafting development agreements that provide for or involve the delivery of prototypes and/or products. When the delivery of prototypes is part of a potential agreement, the supplier-prospective patent applicant must be careful because he or she can create the basis for the on sale bar prior to actually delivering the product and, depending on how carefully the negotiations are conducted, prior to executing the agreement. Even if the agreement is not signed, the bar can arise if offers that could be accepted to form a binding agreement are made in the course of the negotiations. Under *Group One*, if a party puts an offer on the table that the other party can accept, the on sale bar arises. The offer is a bar even if it is rejected. In order to avoid this result, a patent application should be filed within the critical year. Otherwise, development agreements should be negotiated and drafted such that they do not include a commercial offer to sell the invention, whether it is in the form of a commitment to manufacture and deliver a prototype, or it is in the form of a commercial supply agreement. If this is not practical, then an effort should be made to structure the agreements so that the testing and evaluation of the prototypes qualify as an experimental use.

Offers to transfer or sell products that have been reduced to practice, but not disclosed in a patent application, should be avoided because they can have serious and undesirable ramifications for the inventor. They place the inventor in a position of having to guess when the

²⁰⁰ *Id.* (emphasis added).

invention is “ready for patenting,” and the statutory year begins to run.²⁰¹

B. *Avoiding the Offer for Sale*

One approach to avoiding the on sale bar is to make it clear in the development agreement that title to the product or prototypes is not being transferred. This can be done by following the dicta in *Zacharin* and drafting the agreement as a development services agreement and by expressly stating that the prototypes are and shall continue to remain the property of the inventor-supplier. For example, the agreement might be structured such that the parts or raw materials from which the prototypes are made are purchased by or on behalf of the party who will ultimately receive the prototype, and the party supplying the product is simply paid a construction fee.

Another approach to avoiding the on sale bar is to structure the agreement such that the transfer may qualify as an experimental use. Merely providing a prototype for testing, however, will not be sufficient to constitute experimental use; the invention cannot have been reduced to practice.²⁰² To give the agreement the best opportunity to qualify as an experimental use, the agreement preferably should provide that the results of the evaluation of the prototypes will be shared with the inventor and used to improve or perfect the invention. Depending on the nature of the invention and the required testing, the prototypes should be returned to the inventor at the completion of the evaluation. The prototypes also should be provided with restrictions on their use and confidentiality. If the prototype is being tested by the non-inventor party because the inventor does not have the facilities or because the non-inventor is in a better position to test and evaluate the ability of the prototypes to satisfy their intended use, the agreement could reflect these facts. In any case, it is important that the results of the testing are shared with the inventor. If the inventor is not involved in the evaluation of the results, the purpose of the transfer may not be considered experimental.²⁰³ Delivery of the prototype without further inventor involvement is indicative of a commercial sale. The agreement might also be structured to provide specifically for post-test services and collaboration to provide further evidence that the testing was performed to improve the invention. Again, the language of an agreement will not trump reality. Under current authority, if the invention has been reduced to

²⁰¹ A contract to supply the invention in commercial quantities can bar the invention regardless of whether the invention is being tested or whether some pre-production testing is contemplated when the commercial extent of the offer exceeds any experimental purpose. *Zacharin*, 213 F.3d at 1369.

²⁰² *See id.*; *see also* *RCA*, 887 F.2d at 1061.

²⁰³ *See supra* pt. III(C)(2) (discussing *Lough*).

practice it is not eligible for the experimental use exception.²⁰⁴

C. *Supply Commitments*

Another area in which an offer for sale can arise in the context of a development agreement is in provisions relating to the commercial supply of the product. In many instances, the inventor-technology supplier may not be willing to enter into a development agreement unless he or she has the right to manufacture and supply the product. For example, many manufacturers take the position that they are not “in the research business,” meaning that they are not willing to commit their engineering capabilities to a project unless they are guaranteed that they will at least be considered for a manufacturing and supply agreement when the invention is commercialized. In these instances, development agreements often include manufacturing and supply provisions.

For example, the agreements may include provisions for delivery, price, price adjustments, second source, and product liability indemnification. These provisions may constitute a commercial offer to sell the invention such that one year after the offer or one year after the invention is ready for patenting, whichever is later, patent protection will be barred if an application disclosing the invention has not been filed. In order to avoid this result, the practitioner can consider several strategies. Of course, the supply commitments could be left to a subsequent agreement that the parties negotiate in good faith, although this may not provide much comfort to the inventor-supplier. Another approach to avoiding a potentially barring offer is to have the purchaser give the supplier a right of first offer or a right of first refusal to supply the product. Alternatively, the development agreement may be structured such that commitments regarding the sale or offer to sell the product are clearly contingent upon some future event, such as successful testing of the product.

For instance, the agreement might read: Contingent upon successful development and testing of the invention, the inventor-supplier agrees to offer to sell and the purchaser agrees to buy its entire requirements for the invention on the terms set forth in the agreement itself or an appended supply agreement. Another approach that may also avoid the bar is to state that contingent upon successful testing, the inventor-supplier and the buyer agree to execute a supply agreement that is attached as a separate document and has all the terms of the sale, including price, delivery, indemnification, etc. set forth therein. For reasons discussed

²⁰⁴ *Zacharin*, 213 F.3d at 1369 ; *see also RCA*, 887 F.2d at 1061.

below, arguably this agreement to contract to supply does not constitute an offer because it cannot be converted to a contract for sale by simple acceptance.

In summary, when addressing supply provisions in a development agreement for an invention that has not been disclosed in a patent application, the agreement should very clearly indicate that the offer does not occur unless a condition precedent, such as successful testing, has been satisfied. An approach in which the inventor-supplier and the prospective licensee-purchaser evaluate test results, and in which their future dealings are contingent upon successfully completing the testing, has the dual advantage of evincing an experimental objective and postponing the occurrence of any contractually binding offer for sale.

Under *Group One*, as currently construed by the Federal Circuit, strategies such as those outlined here should be successful in avoiding the on sale bar. In *Group One*, the court noted that one advantage of requiring an offer that is sufficient is that it can be accepted and made into a binding contract: “Applying established concepts of contract law, rather than some amorphous test, implements the broad goal of *Pfaff* . . . to bring greater certainty to the analysis of the [on sale] bar.”²⁰⁵ In *Pfaff*, the Supreme Court justified its on sale approach stating: “An inventor can both understand and control the timing of the first commercial marketing of his invention.”²⁰⁶

In summary, as currently construed by the Federal Circuit, *Pfaff* and *Group One* appear to give inventors more control over the ramifications of their commercial activities. Inventors that find themselves parties to a development agreement, and that have satisfied the commercial offer for sale prong of the *Pfaff* test by contracting for the sale and delivery of prototypes, may elect to apply for a patent within a year of the date of the offer. Under *Group One*, the inventor-supplier’s exposure to the on sale bar can be controlled by constructing development agreements to avoid or postpone the offer for sale, and if the invention has not been reduced to practice, by controlling the use of any prototypes so that the activities under the agreement may qualify as an experimental use.

²⁰⁵ *Group One*, 254 F.3d at 1047.

²⁰⁶ *Pfaff*, 525 U.S. at 67.