

Chapter 5

Statutory Bars Under Section 102

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§ 5:1 Introduction

This chapter is directed to Title 35 as amended by the America Invents Act (AIA), and as effective for patent applications having, at any time, at least one claim having an effective filing date (EFD) on or after March 16, 2013. For the treatment of patent applications having only claims with an EFD prior to March 16, 2013, legacy chapters 5 and 6 of Appendix A should be consulted. In either case, certain circumstances or situations described in section 102 of the statute can bar a person from securing a patent for an invention, and therefore are known as statutory bars. Statutory bars relating to applications

having a claim with an effective filing date on or after March 16, 2013 are discussed in this chapter. Also discussed are exceptions, under which a patent may still be obtained.

§ 5:2 Step 2 of the Flow Chart for Patentability

The second step for investigating patentability, as demonstrated in the Flow Chart 3-2, Patentability (Validity)—First to File, in chapter 3, is to determine based on dates alone whether the reference cited against the inventor's application or patent is a possible statutory bar under subsection (a) of section 102. Before discussing how section 102(a) relates to the second step in the flow chart, this chapter first examines all the statutory bars set forth in the subsections of section 102(a)(1) and 102(a)(2).

§ 5:3 Statutory Bars Under Sections 102(a)(1) and 102(a)(2)

There are six statutory bars specified in section 102(a)(1) and section 102(a)(2). If any statutory bar is applicable, an inventor is not entitled to a patent, because the claimed invention is "contemplated" by the prior art. In other words, the claimed invention is not "new," and it is not patentable. This is also known as a "complete anticipation," which precludes the issuance of a patent.¹

Sections 102(a) reads:

- (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—
 - (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
 - (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

The statutory bars can be interpreted as whether the claimed invention was:

1. If the prior art is something less than the complete invention, it can still be evaluated under the unobviousness requirement of section 103. See chapter 7.

- (1) Patented by the inventor or anyone else, anywhere in the world, before the EFD of the inventor's patent claim, section 102(a)(1);
- (2) Published by the inventor or anyone else, anywhere in the world, before the EFD of the inventor's patent claim, section 102(a)(1);
- (3) Publicly used by the inventor or anyone else before the EFD of the inventor's patent claim, section 102(a)(1);
- (4) Placed on sale or sold by the inventor or anyone else before the EFD of the inventor's patent claim, section 102(a)(1);
- (5) Otherwise available to the public before the EFD of the patent claim, section 102(a)(1);
- (6) Described in an issued U.S. patent or in a published U.S. patent publication, or deemed to be published, naming another inventor and having an EFD before the EFD of the inventor's patent claim. The phrase "deemed to be published" is a reference to 35 U.S.C. § 374, which provides that the publication under the PCT of an international application designating the United States shall be deemed a publication under 35 U.S.C. § 122(b).

The EFD for an inventor's patent claim specified in sections 102(a)(1) and 102(a)(1) can include the benefit of a provisional application (section 119), a continuation application (section 120), a continuation-in-part application (section 120), a divisional application (section 121), a convention application (section 119), an international application under the Patent Cooperation Treaty (PCT), or a convention application upon which an international application is based.²

The discussion below relating to specific circumstances that qualify as statutory bars is based largely on case law decided before the passage of the America Invents Act (AIA). While it is believed that this body of law will remain largely intact, modifications may be made by the courts as the new act is interpreted and applied to the facts of particular cases.

§ 5:3.1 "Patented" As a Statutory Bar

Under section 102(a)(1), a prior art patent in item (1) in the list above must be a document that gives rise to legal rights and must contemplate the inventor's complete invention, as claimed, in order to

2. See chapter 4 for a detailed discussion of effective filing dates.

be a “complete anticipation.” If the prior art patent describes something less than the complete invention, the patent can still be evaluated under section 103.

§ 5:3.2 “Publication” As a Statutory Bar

As a statutory bar under section 102(a)(1), a publication in item (2) above can be anything that is printed and available to the public in any country without any injunction of secrecy. This can include, for example, material in a public library, a catalog for promoting sales, papers distributed at a meeting of a technical society, or something published on the Internet. The prior art publication must contemplate the inventor’s complete invention, as claimed, in order to be a “complete anticipation.” If the prior art publication describes something less than the complete invention, the publication can still be evaluated under section 103.

§ 5:3.3 “Use” As a Statutory Bar

In order for use to qualify as a bar under section 102(a)(1), the use should be accessible to the public, that is, performed openly. A secret use has not generally been a bar under section 102(a).

Experimental use also has not constituted a bar under section 102(a). Experimental use relates to developing, perfecting, or testing the invention.

The CAFC, in the 2008 *Omeprazole* decision³ concerning a possible “use” bar, extended the two-prong *Pfaff* test for a “sale” bar⁴ as follows:

We may nevertheless affirm the district court’s conclusion that the claims were not invalid under section 102(b) based on the court’s factual determination that the claimed formulation was not ready for patenting until after the clinical studies were completed. . . . (“the ready for patenting component of *Pfaff*’s two-part test [is] another necessary requirement of public use bar.”). The district court found that the claimed formulation was not reduced to practice before the clinical trials were completed, and we uphold that finding.

To be a “complete anticipation” under section 102(a), the prior art use must contemplate the complete invention being claimed by the inventor. If the prior art use is something less than the complete invention, the use can still be considered under section 103.⁵

3. *In re Omeprazole Patent Litig.*, 536 F.3d 1361 (Fed. Cir. 2008).

4. *See* section 5:3.4.

5. *See* chapter 7 for a detailed discussion of unobviousness.

§ 5:3.4 “Sale” As a Statutory Bar

An offer for sale, such as a demonstration, or an actual sale in (4) above can cause a bar under section 102. To qualify as a “complete anticipation,” the prior art sale must contemplate the complete invention being claimed by the inventor. If the prior art sale is something less than the complete invention, the sale can still be considered under section 103. This is illustrated in a 1999 decision,⁶ where the CAFC stated that the subject matter of the offers for sale did not fully anticipate the claimed invention and the alleged infringer did not argue that the offers would have rendered the invention obvious.

The U.S. Supreme Court in the *Pfaff* decision⁷ promulgated a two-prong test for proving a sale bar. First, the product must be the subject of a commercial sale or sales offer. Second, the invention must be “ready for patenting,” which can be established by a reduction to practice or by proof that the inventor has drawings or other descriptions of the invention that are sufficiently specific to enable a person skilled in the art to practice the invention.

In 2000, the CAFC applied the *Pfaff* test to determine whether the subject matter of a patent was on sale to qualify as a bar under section 102(b), which was the relevant section at that time. According to the court, there was sufficient evidence that the invention was ready for patenting, that is, a model of the invention and its subsequent promotion.⁸

Three 2001 decisions clarified the standard for an “offer for sale” to satisfy the first prong of *Pfaff*'s two-prong test for proving a sales bar, that is, that the product must be the subject of a commercial sale or sales offer. The *Group One* court⁹ stated that because of “the importance of having a uniform national rule regarding the on-sale bar, we hold that the question of whether an invention is the subject of a commercial offer for sale is a matter of Federal Circuit law, to be analyzed under the law of contracts as generally understood.” As guidance, the court suggested the Uniform Commercial Code, the *Restatement (Second) of Contracts*, and the vast amount of existing contract law.

The *Scaltech* decision¹⁰ addressed the second subpart of the first prong of the *Pfaff* test, namely, that the sale or sales offer must be for the “patented invention.” According to the court, “the invention that is the subject matter of the offer for sales must satisfy each claim

6. *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353 (Fed. Cir. 1999).

7. *Pfaff v. Wells Elecs., Inc.*, 119 S. Ct. 304 (1998).

8. *STX, LLC v. Brine, Inc.*, 211 F.3d 588 (Fed. Cir. 2000).

9. *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041 (Fed. Cir. 2001).

10. *Scaltech, Inc. v. Recte/Tetra, LLC*, 269 F.3d 1321 (Fed. Cir. 2001).

limitation of the patent, though it may do so inherently.” See also the *Tec Air* decision,¹¹ above, where an offer can render the invention obvious.

In the third decision,¹² the *Linear* court based its definition of an offer for sale on section 24 of the *Restatement (Second) of Contracts*: “the manifestation of willingness to enter into a bargain, so made as to justify another person in understanding that his assent to that bargain is invited and will conclude it.”

The *Pechiney Rhenalu* court¹³ in 2002 promulgated three guidelines for determining whether there is a commercial offer under traditional contract law. First, the transaction must rise to a level where the other party could bind the offeror by an acceptance. Second, the offer is the manifestation of a willingness to enter into a bargain in such a way that the offeree believes an acceptance will create a binding contract. Third, the language used by the offeror should be indicative of a legal offer with certain phrases suggesting such a legal offer.

Mere quotations did not constitute commercial offers for sale under prior section 102(b),¹⁴ since they were deemed to be only suggestions to negotiate. More terms are required in addition to the quotations, such as time and place of delivery, price, and quantity.

Merely sending samples to customers, without any other evidence of entering into a contract, was not an offer that triggers the sale bar.¹⁵ Again, the transaction should include contract terms, such as prices and the like.

In *Minton*, a 2003 decision,¹⁶ the CAFC considered the type of invention (tangible or intangible) and the type of transaction (sale, license, or lease) with regard to the sale bar. Concerning the invention, the court stated that

there are different types of sales of different types of inventions. It is not correct that “nothing in §102(b) compels different treatment between an invention that is a tangible item and an invention that describes a series of steps in a process.” The very nature of the invention may compel a difference. The sale of a tangible item is usually a straightforward event; the item is transferred

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11. *Tec Air, Inc.*, 192 F.3d 1353.
 12. *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040 (Fed. Cir. 2001).
 13. *Pechiney Rhenalu v. Alcoa, Inc.*, 224 F. Supp. 2d 773 (D. Del. 2002).
 14. *MLMC, Ltd. v. Airtouch Commc'ns, Inc.*, 215 F. Supp. 2d 464 (D. Del. 2002); *Poly-America, Inc. v. Serrot Int'l, Inc.*, 2002 WL 1996561 (N.D. Tex. 2002).
 15. *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294 (Fed. Cir. 2002).
 16. *Minton v. Nat'l Ass'n of Sec. Dealers, Inc. & NASDAQ Stock Mkt., Inc.*, 336 F.3d 1373 (Fed. Cir. 2003).

from the seller to the buyer, who normally owns it outright. In contrast, a process is a series of acts, and the concept of sale as applied to those acts is ambiguous.¹⁷

With respect to the transaction, the court noted “the established rule that merely granting a license under potential patent rights is usually not a ‘sale’ of the invention within the meaning of the statute.”¹⁸ In contrast,

a commercial transaction arranged as a “license” or a “lease” of a product or a device . . . may be tantamount to a sale (*e.g.*, a standard computer software license), whereupon the bar of §102(b) would be triggered because the product is . . . just as immediately transferred to the “buyer” as if it were sold.¹⁹

One of the interesting issues in sales is whether a sale to the inventor developing an invention, or to a business entity that intends to exploit an invention, can start the running of the one-year period during which an inventor can still file a patent application. For example, what are the outcomes if an inventor contracts to have his invention built for him by a vendor, or a business contracts with another company to make a product that it intends to sell at a later time?

In July 2016, the CAFC issued an opinion, in an en banc rehearing, in the case of *Medicines Co. v. Hospira, Inc.*^{19.1} The claims of a first patent in suit were directed to pharmaceutical batches of a drug product. A second patent in suit included product-by-process claims reciting the manner of producing the product.

The Medicines Company (MedCo) did not have production facilities of its own, but contracted with a supplier, Ben Venue Laboratories, to supply commercial quantities of the product. After having some trouble developing a pharmaceutical product that would be approved for use by the FDA, MedCo sought expert help in developing a product. This proved to be successful. More than one year before the filing of its patent applications, MedCo paid Ben Venue \$347,500 to manufacture batches of the product. These batches had a value, on the commercial market, of over \$20 million. However, the batches were placed in quarantine with MedCo’s distributor and logistics coordinator, Integrated Commercial Solutions (ISC), until FDA approval was obtained. Also more than one year before the filing

17. *Id.* at 1378.

18. *Id.*

19. *Id.* (some internal quotation marks and citations omitted).

19.1. *Meds. Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016).

of its patent applications, MedCo entered into a distribution agreement, making ICS its exclusive authorized dealer for the products in question. The agreement stated that title and risk of loss of with respect to the batches would remain with MedCo, and pass to ICS following release from quarantine.

Hospira, having been accused of infringement, alleged noninfringement and patent invalidity, based on the on-sale bar having been triggered when MedCo paid Ben Venue to manufacture the product batches. Hospira further alleged that MedCo triggered the on-sale bar by offering to sell the products to ICS.

A three-judge merits panel of the CAFC agreed with Hospira, and reversed the district court's determination that the on-sale bar had not been triggered. However, the CAFC asked that the following question be briefed for the full court:

- (a) Do the circumstances presented here constitute a commercial sale under the on-sale bar of 35 U.S.C. § 102(b)?
 - (i) Was there a sale for the purposes of § 102(b) despite the absence of a transfer of title?
 - (ii) Was the sale commercial in nature for the purposes of § 102(b) or an experimental use?
- (b) Should this court overrule or revise the principle in *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), that there is no "supplier exception" to the on-sale bar of 35 U.S.C. § 102(b)?^{19.2}

In its opinion, the court reiterated the longstanding holding that whether the on-sale bar applies is a question of law. Further, the court noted that while it reviews a district court's findings of fact with deference, the ultimate question of validity is reviewed *de novo*.

The court identified four policies underlying § 102(b):

to promote the early filing of patent applications—i.e., to foster disclosure of patented inventions to the public; to prevent an inventor from profiting from the commercial use of an invention for a prolonged period before filing a patent application claiming that invention; to discourage the removal of inventions from the public domain; and to give inventors a reasonable time to discern the potential value of an invention.^{19.3}

19.2. *Id.* at 1370.

19.3. *Id.* at 1372.

The court noted that for many years it used a “totality of circumstances” standard in applying the on-sale bar. However, the court expressed the opinion that this changed with the two-pronged test of *Pfaff*.^{19.4}

On the merits, the court affirmed the holding of the district court that the claims were not barred under 35 U.S.C. § 102(b). The court stated:

In the discussion that follows, we first clarify that the mere sale of manufacturing services by a contract manufacturer to an inventor to create embodiments of a patented product for the inventor does not constitute a “commercial sale” of the invention. We then address the issue of “stockpiling” by an inventor and clarify that “stockpiling” by the purchaser of manufacturing services is not improper commercialization under § 102(b). We explain that commercial benefit—even to both parties in a transaction—is not enough to trigger the on-sale bar of § 102(b); the transaction must be one in which the product is “on sale” in the sense that it is “commercially marketed.” There are, broadly speaking, three reasons for our judgment in this case: (1) only manufacturing services were sold to the inventor—the invention was not; (2) the inventor maintained control of the invention, as shown by the retention of title to the embodiments and the absence of any authorization to Ben Venue to sell the product to others; and (3) “stockpiling,” standing alone, does not trigger the on-sale bar.^{19.5}

The court also indicated that:

The absence of title transfer further underscores that the sale was only of Ben Venue’s manufacturing services. Because Ben Venue lacked title, it was not free to use or sell the claimed products or to deliver the patented products to anyone other than MedCo, nor did it do so. Section 2-106(1) of the Uniform Commercial Code describes a “sale” as “the passing of title from the seller to the buyer for a price.” U.C.C. § 2-106(1). The passage of title is a helpful indicator of whether a product is “on sale,” as it suggests when the inventor gives up its interest and control over the product. A “sale” under § 102(b) “occurs when the parties . . . give and pass rights of property for consideration.”^{19.6}

19.4. *Id.*

19.5. *Id.* at 1373–74.

19.6. *Id.* at 1375 (quoting *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355 (Fed. Cir. 2001)).

The court treated the confidential nature of the transactions as follows:

Like the absence of title transfer, the confidential nature of the transactions is a factor which weighs against the conclusion that the transactions were commercial in nature. Again, this factor is not disqualifying in all instances—it too is not of talismanic significance. Indeed, we, and our predecessors, have found confidential transactions to be patent invalidating sales under § 102(b). . . . In this case, however, we find that the scope and nature of the confidentiality imposed on Ben Venue supports the view that the sale was not for commercial marketing purposes.^{19.7}

With regard to stockpiling, the court noted:

The statute itself says the invention must be “on sale,” or that there must be an offer for sale of the invention. *Pfaff* made this distinction clear and explained that we are not to look to broad policy rationales in assessing whether the on-sale bar applies; we are to apply a straightforward two-step process—one which permits an inventor to “both understand and control the first commercial marketing of his invention.” 525 U.S. at 67. For this reason, we find that the mere stockpiling of a patented invention by the purchaser of manufacturing services does not constitute a “commercial sale” under § 102(b). Stockpiling—or building inventory—is, when not accompanied by an actual sale or offer for sale of the invention, mere pre-commercial activity in preparation for future sale. This is true regardless of how the stockpiled material is packaged. The on-sale bar is triggered by actual commercial marketing of the invention, not preparation for potential or eventual marketing. Contrary to *Hospira’s* assertions, not every activity that inures some commercial benefit to the inventor can be considered a commercial sale. Instead, stockpiling by an inventor with the assistance of a contract manufacturer is no more improper than is stockpiling by an inventor in-house.^{19.8}

As an important point of clarification with regard to its prior decisions, the court stated:

Lest there be any doubt, however, to the extent language in those cases might be viewed as dictating a different result here, they are overruled with one important caveat. We still do not recognize a blanket “supplier exception” to what would otherwise constitute a commercial sale as we have characterized it today. While the fact that a transaction is between a supplier and inventor is an important indicator that the transaction is not a commercial

19.7. *Id.* at 1376 (citations omitted).

19.8. *Id.* at 1377.

sale, understood as such in the commercial marketplace, it is not alone determinative. Where the supplier has title to the patented product or process, the supplier receives blanket authority to market the product or disclose the process for manufacturing the product to others, or the transaction is a sale of product at full market value, even a transfer of product to the inventor may constitute a commercial sale under § 102(b). The focus must be on the commercial character of the transaction, not solely on the identity of the participants.^{19.9}

In a footnote, the court indicated that its analysis may not apply to post-AIA cases:

The government argues that recent amendments to § 102 in the AIA reflects Congress's view that the public use bar and the on-sale bar both turn on the "public" nature of the activity at issue. We do not address here whether or to what extent § 102(b) may differ post-AIA from the pre-AIA description we now employ.^{19.10}

In view of its decision that the transactions were not commercial in nature, the court refrained from reaching the district court's findings that the transactions between Ben Venue and MedCo were experimental and for the purpose of validating whether its processes would work as claimed and generate a consistently acceptable product.

In *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*,^{19.11} one issue that the Federal Circuit addressed was whether, under the AIA, a sale occurring more than one year before the effective filing date of a patent application must publicly disclose the invention to give rise to a bar under 35 U.S.C. § 102(a)(1). Only one of the four patents in suit was governed by the AIA.

The court held that:

The asserted claims of the patents-in-suit were subject to an invalidating contract for sale prior to the critical date of January 30, 2002, and the AIA did not change the statutory meaning of "on sale" in the circumstances involved here. The asserted claims were also ready for patenting prior to the critical date.^{19.12}

While many of the terms of the agreement by Helsinn Healthcare to sell the pharmaceutical products to MGI Pharma, Inc. were publicly disclosed, two features, the price terms and the unusually low dosages of the key ingredient, were not disclosed.

19.9. *Id.* at 1380.

19.10. *Id.* at 1380 n.3.

19.11. *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017).

19.12. *Id.* at 1360.

The court opined that:

Requiring such disclosure as a condition of the on-sale bar would work a foundational change in the theory of the statutory on-sale bar. Indeed, the seminal Supreme Court decision in *Pennock* addressed exactly such a situation—the public sale of an item but the withholding from “the public the secrets of [the] invention.” *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829). Failing to find such a sale invalidating, said the Court, “would materially retard the progress of science and the useful arts, and give a premium to those who should be least prompt to communicate their discoveries.” *Id.*

So too under our cases, an invention is made available to the public when there is a commercial offer or contract to sell a product embodying the invention and that sale is made public. Our cases explicitly rejected a requirement that the details of the invention be disclosed in the terms of sale. *See RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1060 (Fed. Cir. 1989), *overruled in part on other grounds by Grp. One*, 254 F.3d at 1048 (rejecting the argument “that the bid documents themselves must disclose the invention with respect to all claim elements” since that is “clearly not legally correct” and there can be “a definite offer for sale or a sale of a claimed invention even though no details are disclosed”).

A primary rationale of the on-sale bar is that publicly offering a product for sale that embodies the claimed invention places it in the public domain, regardless of when or whether actual delivery occurs. The patented product need not be on-hand or even delivered prior to the critical date to trigger the on-sale bar. And, as previously noted, we have never required that a sale be consummated or an offer accepted for the invention to be in the public domain and the on-sale bar to apply, nor have we distinguished sales from mere offers for sale. We have also not required that members of the public be aware that the product sold actually embodies the claimed invention. For instance, in *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 182 F.3d 1315 (Fed. Cir. 1999), at the time of the sale, neither party to the transaction knew whether the product sold embodied the claimed invention and had no easy way to determine what the product was. *Id.* at 1317–18.^{19.13}

With respect to a portion of the legislative history, the court stated:

There are no floor statements suggesting that the sale or offer documents must themselves publicly disclose the details of the claimed invention before the critical date. If Congress intended to

19.13. *Id.* at 1369–71 (footnotes omitted).

work such a sweeping change to our on-sale bar jurisprudence and “wished to repeal . . . [these prior] cases legislatively, it would do so by clear language.” *Dir., OWCP v. Perini N. River Assocs.*, 459 U.S. 297, 321 (1983).^{19.14}

The court summarized its view on the issue by stating:

We conclude that, after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale. For the reasons already stated, the Supply and Purchase Agreement between Helsinn and MGI constituted a sale of the claimed invention—the 0.25 mg dose—before the critical date, and therefore both the pre-AIA and AIA on-sale bars apply. We do not find that distribution agreements will always be invalidating under § 102(b). We simply find that this particular Supply and Purchase Agreement is.^{19.15}

Thus, the court indicated that it would not alter the pre-AIA law concerning the on-sale statutory bar. While many practitioners believe that it was the intent of the AIA to disqualify secret prior art, *Helsinn* indicates that changes will not be so dramatic. Further, many commentators and amici in *Helsinn* believe that *Helsinn* was correctly decided based on the pre-AIA policy considerations related to section 102 mentioned above.

On January 16, 2018, the Federal Circuit denied a request for reconsideration en banc. On February 28, 2018, Helsinn filed a petition for a writ of certiorari at the Supreme Court. Ten amicus briefs (one in support of neither party) were filed, with regard to the petition. On June 25, 2018, the Court granted the petition. Twenty amicus briefs on the merits have been filed (six in support of neither party). Oral argument is scheduled for December 4, 2018.

The central specific issue of contention is the meaning of the words “or otherwise available to the public” at the end of 35 U.S.C. § 102(a)(1). One interpretation, outlined below in section 5:3.5, is that this is another category of items that can be considered as prior art, but are not specifically listed in section 102(a)(1). However, it is the position of Helsinn, and some of the amici, that this phrase is instead meant to limit prior art to what is publicly available.

A more general issue is whether it was the intent of the America Invents Act to simplify the consideration of prior art by limiting it to what was publicly available at the time of filing. However, this would mean that the patent forfeiture provisions of commercial sales by

19.14 . *Id.* at 1371.

19.15. *Id.*

the patentee more than one year before applying for a patent would be abandoned, thus abrogating one of the policy considerations for the law as it existed before the implementation of the America Invents Act. To the extent that this is a policy consideration, the Supreme Court is in a good position to make the decision. However, if the result is widely criticized, it may become the task of Congress to decide whether to amend the statutory language.

Associated with these inquiries is the question of whether there can be “experimental sales,” just as there are experimental uses, that do not start the running of the one-year period leading to a statutory bar.

There is a line of cases that clearly hold that there are experimental sales that do not start the running of the one-year period for a statutory bar. In a sense, these cases can be thought of as revolving around the second prong of the *Pfaff* inquiry: whether the invention is ready for patenting. The factors used by the CAFC in determining whether a sale between the patentee and the customer is experimental were summarized in *Continental Can Co. USA, Inc. v. Monsanto Co.*^{19.16} as “whether there was a need for testing by other than the patentee; the amount of control exercised; the stage of development of the invention; whether payments were made and the basis thereof; whether confidentiality was required; and whether technological changes were made.”^{19.17}

The court stated that “All of the circumstances attending the relationship must be considered in light of the public policy underlying § 102(b).”

§ 5:3.5 “Otherwise Available to the Public” As a Statutory Bar

As noted above in section 5:3.4, one interpretation of this phrase is that it is a catchall provision, covering cases where the invention becomes available to the public, but the availability may not fall within items (1) to (4) in the list above (section 5:3). Some examples that have been cited are a poster at a conference, or a posting on the Internet. The invention or knowledge of it in item (5) above should be accessible to the public to qualify as a section 102(a)(1) bar. The prior art availability must contemplate the inventor’s complete invention, as claimed, in order to be a “complete anticipation.” If the prior art availability is something less than the complete invention, the knowledge can still be evaluated under section 103.

19.16. *Cont’l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991).

19.17. *Id.* at 1269.

§ 5:3.6 Disclosure in a U.S. Patent or a U.S. Patent Publication As a Statutory Bar

In the situation described in item (6) above, under section 102(a)(2), a person is barred from securing a patent if the invention has been disclosed in a U.S. patent, or a published U.S. patent application issued to another, and having an EFD before the EFD of the claimed invention. A person is also barred from securing a patent if the invention has been disclosed in a patent application published under the PCT that designates the United States as an elected state, and has an EFD before the EFD of the claimed invention. This is due to the AIA, which amends 35 U.S.C. §§ 102, 363, and 374 to provide simply that the publication under the PCT of an international application designating the United States shall be deemed a publication under 35 U.S.C. § 122(b).

Thus, according to section 102(a)(2), the disclosure of a U.S. patent or patent application, issued to another, or a published PCT application naming another inventor or inventors, can be cited as prior art against an inventor's patent application (or issued patent) when the cited U.S. patent, U.S. patent publication, or published PCT application was filed before the inventor's EFD. If a cited U.S. patent or U.S. patent publication, issued to another, or a PCT application, was issued or published before the inventor's EFD, section 102(a)(1), discussed above, would be applicable.

§ 5:4 Exceptions to Statutory Bars Under Sections 102(a)(1) and 102(a)(2)

Section 102(b) reads:

EXCEPTIONS.—

- (1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—
 - (A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
 - (B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

- (2) DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS.—A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if—
- (A) the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;
 - (B) the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
 - (C) the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

Under section 102(b)(1)(A), if the inventor or joint inventors, or someone who obtained the subject matter directly or indirectly from the inventor or joint inventors, discloses the subject matter, the inventor or inventors still have one year from such disclosure to apply for a U.S. patent.

Under section 102(b)(1)(B), if the inventor or inventors, or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor, publicly disclose the invention claimed, and then someone else discloses the invention before the EFD of the invention, the inventor or joint inventors of the claimed subject matter still have one year from when they first publicly disclosed the invention to apply for a U.S. patent. What this means is that the inventor or joint inventors, by publicly disclosing their invention, in effect reserve their right to file for a period of one year, even as against others who independently developed the invention, and chose to disclose the information.

A question under this provision is the extent of the disclosure that is required to preserve the right of the inventor or joint inventors. If the disclosure is not enabling for what is later claimed, there may be no reservation of rights. Further, it is possible that the nonenabling disclosure may be used as prior art against the inventor or joint inventors. Relying on this provision may require a complete disclosure of the invention. If a document evidencing such disclosure is available, it may be preferable to file at least a provisional patent application, for reasons including certainty in the preservation of U.S. patent rights, and patent rights outside of the United States, as more fully discussed below.

These exceptions under section 102(b)(1) have the effect of preserving, in the new law, the so-called “one-year grace period” under U.S. law in the first-to-invent system applicable to claims having an EFD prior to March 16, 2013. The exceptions provide inventors with an opportunity to undertake certain activities with respect to their inventions prior to filing a patent application, without a loss of potential U.S. patent rights. However, as noted in chapter 6, such a grace period is not available in most other countries, and without the proper precautions or sequence of events, U.S. patent rights may be preserved, while foreign patent rights are lost.

A consequence of the one-year grace period is that the changes in law enacted by the AIA do not change the United States to a pure first-to-file jurisdiction. Instead, the U.S. system is still, to an extent, a hybrid system, with first-to-file provisions and a grace or reservation period for the inventor’s or inventors’ own acts.

Under section 102(b)(2)(A), a disclosure is not prior art to a claimed invention under section 102(a)(2) (in an issued U.S. patent or published U.S. patent application) if the subject matter disclosed was obtained directly or indirectly from the inventor or joint inventor. In addition, under section 102(b)(2)(B), if before the subject matter was filed in a patent application that was published or that issued as a patent, the subject matter was publicly disclosed by the inventor or joint inventors, or someone who obtained the subject matter directly or indirectly from the inventor or joint inventors, it is not considered to be prior art under section 102(a)(2), although it may be prior art under section 102(a)(1). Under section 102(b)(2)(C), if the subject matter disclosed in a published application or an issued patent and the subject matter claimed in an application were, at a time not later than the EFD of the claimed invention, owned by the same person or subject to an obligation of assignment to the same person, the subject matter in the published patent application or issued patent will not be prior art against the claimed invention under section 102(a)(2).

Section 102(c) reads:

COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS.—Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if—

- (1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;

- (2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
- (3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

This provision provides an opportunity for different organizations to enter into research and development agreements under which inventions may be created, without the work of an inventor in one organization being prior art against an inventor in the other organization. Specifically, the inventors in the organizations who are parties to the agreement can work together without the work of a first inventor in a first organization, who is under an obligation to assign any inventions he may make to the first organization, to be considered as prior art against the work of a second inventor who is under an obligation to assign any inventions she may make to a second organization. However, for this provision to be operative, the agreement must have been in effect on or before the EFD of a claimed invention, the claimed invention must have been made as a result of activities within the scope of the agreement, and the patent application must disclose, or be amended to disclose, the names of the parties to the agreement.

§ 5:5 Effective Dates of Patents and Publications As References

Section 102(d) reads:

PATENTS AND PUBLISHED APPLICATIONS EFFECTIVE AS PRIOR ART.—For purposes of determining whether a patent or application for patent is prior art to a claimed invention under subsection (a)(2), such patent or application shall be considered to have been effectively filed, with respect to any subject matter described in the patent or application—

- (1) if paragraph (2) does not apply, as of the actual filing date of the patent or the application for patent; or
- (2) if the patent or application for patent is entitled to claim a right of priority under section 119, 365(a), or 365(b), or to claim the benefit of an earlier filing date under section 120, 121, or 365(c), based upon 1 or more prior filed applications for patent, as of the filing date of the earliest such application that describes the subject matter.

This provision deals with step 2 of Flow Chart 3-2, and determines the effective date of a U.S. patent or a U.S. published patent application as a reference under section 102(a)(2). If the U.S. patent or U.S. published patent application claims no earlier priority date, then under section 102(a)(1), its effective date as a reference is the filing date of the U.S. patent or U.S. published patent application. However, if the U.S. patent or U.S. published patent application claims the benefit any earlier priority date, as set forth in chapter 2, then the U.S. patent or U.S. published patent application will be effective as a reference as of the filing date of the earliest application from which priority is claimed that describes the subject matter that is being used as prior art against claimed subject matter.

The provisions discussed in the previous paragraph represent a significant departure from prior law (see legacy chapter 5, in Appendix A), wherein the reference would only be effective as of the earliest filing date in the United States in which the subject matter being claimed was described. Thus, for claims being examined under the AIA, the effective date of a U.S. patent or U.S. published patent application may include earlier dates from which priority is being claimed, based on the filing dates of applications outside of the United States, that are claimed as priority dates of the U.S. patent or the U.S. published patent application.

§ 5:6 Problem on Statutory Bars Under Sections 102(a)(1) and 102(a)(2)

This problem will assume facts that may occur at a future date. Assume the following facts to be true. *A*'s EFD for a patent application covering the invention is March 30, 2013.

Consider statutory bars under section 102(a)(1) and section 102(a)(2) with regard to each of the following "specific" activities:

- (a) *A* sold the invention in the United States on December 30, 2011.
- (b) *B*'s U.S. patent application disclosing the invention was filed on April 1, 2013.
- (c) *C* published an article describing the invention in Japan on May 3, 2010.
- (d) *D* publicly used the invention in Belgium on February 1, 1995.
- (e) *E* in the United States knew about the invention on March 1, 2013.
- (f) *F* sold the invention in France on January 1, 2013. *A* published an article describing the invention on April 17, 2012.

- (g) *G*'s British patent disclosing the invention was issued on July 5, 2006.
- (h) *A* publicly used the invention in the United States on August 1, 2012.
- (i) *A* published an article describing the invention in the United States on September 1, 2012.
- (j) *B*'s U.S. patent disclosing the invention was issued on August 1, 2005.
- (k) *B* in Holland knew about the invention on January 1, 2005, and told all his friends and relatives, and just about anyone else who would listen to him, within the same year.
- (l) *E*'s U.S. patent, which discloses *A*'s invention, issued on December 2, 2014, based on an application filed on October 1, 2011, and was published on April 4, 2013.
- (m) *M* patented *A*'s invention on March 12, 2013, which was the first publication of *M*'s application. *M* obtained knowledge of the invention from *A*.

**§ 5:7 Answers to Problem on Statutory Bars Under
 Sections 102(a)(1) and 102(a)(2)**

- (a) There is a section 102(a)(1) bar, because *A* sold *A*'s invention more than one year before *A* filed a patent application. Section 102(a)(2) does not apply in the case of a sale.
- (b) Since *B*'s patent application can be issued as a patent only after *A*'s filing date, there is no section 102(a)(1) or 102(a)(2) bar. Since *B*'s patent application can be published only after *A*'s filing date, there is no section 102(a)(2) bar on the basis of publication.
- (c) A section 102(a)(1) bar exists, since *C*'s article was published more than one year before *A*'s filing date. Section 102(a)(2) does not apply in the case of a published article.
- (d) There is a section 102(a)(1) bar, because of *D*'s public use, which is not limited to the United States. This also falls with the "otherwise available to the public" category of section 102(a)(1). Section 102(a)(2) does not apply in the case of a public use.

- (e) *E*'s knowledge in the United States, which was before *A*'s filing date, is not a section 102(a)(1) bar unless that knowledge was public. Knowledge is not an activity mentioned in section 102(a)(1), unless it falls within "otherwise available to the public." Section 102(a)(2) does not apply in the case of knowledge.
- (f) The sale by *F* in France raises the possibility of a section 102(a)(1) bar. However, the publication of the article by *A* before the sale by *F*, at a time less than one year before *A*'s EFD, falls within the exception of section 102(b)(1)(B), so there is no statutory bar under section 102(a)(1). There is no section 102(a)(b) bar because it does not apply.
- (g) There is a section 102(a)(1) bar, because *G*'s patent was issued before *A*'s EFD. There is no section 102(a)(b) bar because it does not apply to a patent issued by a foreign country.
- (h) *A*'s public use is not a section 102(a)(1) bar because of the exception under section 102(b)(1)(B). There is a grace period of one year for *A*'s public use, and the public use was less than one year before *A*'s EFD. There is no section 102(a)(b) bar because it does not apply.
- (i) *A*'s publication is not a section 102(a)(1) bar because of the exception under section 102(b)(1)(B). There is a grace period of one year for *A*'s publication, and the public use was less than one year before *A*'s EFD. There is no section 102(a)(b) bar because it does not apply.
- (j) There is a section 102(a)(1) bar, because *B*'s patent was issued before *A*'s filing date. There is also a section 102(a)(2) bar, because the filing date of the application that issued as *B*'s patent was obviously before the issue date of *B*'s patent and also before *A*'s EFD.
- (k) *B*'s knowledge, because it was made public, is a section 102(a)(1) bar. While knowledge is not an activity specifically listed in section 102(a)(1), it became public as a result of *B* telling everyone he could about it, and was thus "otherwise available to the public." There is no section 102(a)(b) bar because it does not apply.
- (l) No section 102(a)(1) bar exists, because *E*'s patent issued after *A*'s EFD. However, a section 102(a)(2) bar exists, based on the filing date of *E*'s patent application on October 1, 2011, which is well before *A*'s EFD.

- (m) There is the potential for a section 102(a)(1) bar, because M patented the invention before A's EFD. However, the section 102(b)(2)(A) exception applies. This may be an appropriate case for a derivation proceeding (see chapter 8).

§ 5:8 Steps in the Flow Chart for Patentability

Step 2 in Flow Chart 3-2 in chapter 3 is to consider, based on dates alone, whether a reference, cited against the inventor's application or patent, is a possible statutory bar under section 102(a)(1) or 102(a)(2).

If the cited prior art reference is a published article, use, or sale, the date of publication, use, or sale determines whether the cited published article, use, or sale is a statutory bar under section 102(a)(1).

If the cited prior art reference is a foreign patent, the issue date of the foreign patent determines whether the cited foreign patent is a section 102(a)(1) statutory bar.

If the cited prior art reference is a U.S. patent, the issue date of the U.S. patent determines whether the cited U.S. patent is a section 102(a)(1) statutory bar. This applies to both the disclosure and the claims of the U.S. patent.

If the cited prior art reference is a U.S. patent or a published U.S. patent application, the filing date of the U.S. patent application, or in the case of a patent, the date on which the patent application that issued as a patent was filed, determines whether the cited U.S. patent or U.S. patent publication is a section 102(a)(2) statutory bar. This applies to both the disclosure and the claims of the U.S. patent. In the case of a PCT application that designates the United States as an elected state, the earliest claimed priority date that supports the disclosure determines whether the cited PCT application is a section 102(a)(2) statutory bar.

The EFD of the inventor's application or patent is also employed in Step 2 to ascertain if there is a possible section 102(a)(1) or 102(a)(2) bar. The EFD for Step 2 can be based on a section 119 provisional application, a section 120 continuation application, a section 120 CIP application, or a section 121 divisional application, or under sections 365(a), 365(b), or 365(c) if the inventor's application is based on a PCT application (Step 1 of Flow Chart 3-2).

If an exception under section 102(b)(1) (sub-step 3A of Flow Chart 3-2) or an exception under section 102(b)(2) (sub-step 3B of Flow Chart 3-2) applies, then the cited reference is avoided, and if there are no other statutory problems and no further cited references to consider, the patent can issue, or if issued, the patent is not anticipated based on that prior art.

A new 37 C.F.R. § 1.130 has been promulgated to provide a vehicle for inventors to have the benefit of the exceptions under section 102(b)(1) or section 102(b)(2), during prosecution of a patent application in the USPTO. This section, reproduced below, sets forth the requirements for establishing that one of the exceptions under section 102(b)(1) or section 102(b)(2) applies. The provisions of 37 C.F.R. § 1.130 are not available if the rejection is based upon a disclosure made more than one year before the effective filing date of the claimed invention. The USPTO will require the applicant to file a petition for a derivation proceeding (see chapter 8) pursuant to 37 C.F.R. § 42.401 *et seq.* if the rejection is based upon a U.S. patent or U.S. patent application publication of a patented or pending application naming another inventor and the patent or pending application claims an invention that is the same or substantially the same as the applicant's claimed invention, if the option to file a derivation proceeding is still available to the applicant at the time.

§ 1.130 Affidavit or declaration of attribution or prior public disclosure under the Leahy-Smith America Invents Act.

- (a) *Affidavit or declaration of attribution.* When any claim of an application or a patent under reexamination is rejected, the applicant or patent owner may submit an appropriate affidavit or declaration to disqualify a disclosure as prior art by establishing that the disclosure was made by the inventor or a joint inventor, or the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor.
- (b) *Affidavit or declaration of prior public disclosure.* When any claim of an application or a patent under reexamination is rejected, the applicant or patent owner may submit an appropriate affidavit or declaration to disqualify a disclosure as prior art by establishing that the subject matter disclosed had, before such disclosure was made or before such subject matter was effectively filed, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor. An affidavit or declaration under this paragraph must identify the subject matter publicly disclosed and provide the date such subject matter was publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.
 - (1) If the subject matter publicly disclosed on that date was in a printed publication, the affidavit or declaration must be accompanied by a copy of the printed publication.

- (2) If the subject matter publicly disclosed on that date was not in a printed publication, the affidavit or declaration must describe the subject matter with sufficient detail and particularity to determine what subject matter had been publicly disclosed on that date by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.
- (c) *When this section is not available.* The provisions of this section are not available if the rejection is based upon a disclosure made more than one year before the effective filing date of the claimed invention. The provisions of this section may not be available if the rejection is based upon a U.S. patent or U.S. patent application publication of a patented or pending application naming another inventor, the patent or pending application claims an invention that is the same or substantially the same as the applicant's or patent owner's claimed invention, and the affidavit or declaration contends that an inventor named in the U.S. patent or U.S. patent application publication derived the claimed invention from the inventor or a joint inventor named in the application or patent, in which case an applicant or a patent owner may file a petition for a derivation proceeding pursuant to § 42.401 *et seq.* of this title.
- (d) *Applications and patents to which this section is applicable.* The provisions of this section apply to any application for patent, and to any patent issuing thereon, that contains, or contained at any time:
 - (1) A claim to a claimed invention that has an effective filing date as defined in 35 U.S.C. 100(i) that is on or after March 16, 2013; or
 - (2) A specific reference under 35 U.S.C 120, 121 or 365(c) to any patent or application that contains, or contained at any time, a claim to a claimed invention that has an effective filing date as defined in 35 U.S.C. 100(i) that is on or after March 16, 2013.