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Patentees: Caveat Emptor of the 'On-Sale Bar'!




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The converse to the mantra of retailers holds true for members of the scientific community involved in transactions for patentable inventions: You buy it, you break it. Such is the maxim of barring validity under pre-AIA 35 U.S.C. § 102(b) based on a prior offer for sale.

A similar scenario exists post-AIA under 35 U.S.C. § 102(a), for patent applications filed on or after March 16, 2013 (with claims entitled to a priority date), but with two important caveats: (i) worldwide sales or commercial offers for sale are now considered; and (ii) arguably, the sale or offer needs to be ''public.''

After briefly summarizing the current state of the law regarding the on-sale bar, we discuss the U.S. Court of Appeals for the Federal Circuit's pending en banc appeal in *Medicines Co. v. Hospira, Inc.*, a pre-AIA case that relates to a challenge to overrule the ''no supplier exception'' principle to the on-sale bar, and the impact the decision may have on businesses engaged in contracting with manufacturing entities.

We also evaluate whether the courts may apply a ''public'' requirement to post-AIA § 102(a)'s ''on sale'' bar. We end with practice-based tips for practitioners regarding scenarios that may invoke the bar.

I. You Buy It, You Break It

Pre-AIA 35 U.S.C. § 102(b) prevented patents from being granted for inventions which have been on-sale in this country, more than one year prior to the date of the application for patent (the ''critical date'') in the U.S.[1] For such patents or applications, the on-sale bar is triggered if the party challenging validity can prove that the subject matter of the claim was, before the critical date, both: (1) the subject of a commercial offer for sale or a sale not for primarily experimental purposes; and (2) ready for patenting.[2]

Further, a patentee faced with an on-sale challenge to validity can raise the experimental use defense to the

[1] 35 U.S.C. § 102(b): ''A person shall be entitled to a patent unless - . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or *on sale in this country, more than one year prior to the date of the application for patent in the United States*.''

[2] *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67, 48 U.S.P.Q.2d 1641 (1998) (rejecting the Federal Circuit's ''totality of circumstances'' test, holding constructive reduction to practice can satisfy ready for patenting).

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bar.[3] This exception permits inventors to conduct testing to refine their inventions without losing the right to obtain a patent, even if it occurs in the public eye.[4] But, courts have held there can be no experimental use after an invention has been reduced to practice or an inventor realizes the invention as later claimed works for its intended purpose.[5] Also, the parties to a transaction need not recognize that the product offered for sale possesses the claimed characteristics, it is only necessary that it inherently does so.[6]

II. Today, No ''Supplier Exception'' or ''Public'' Requirement Exists—But Will There Be One Tomorrow?

Federal courts have ruled that there is no ''supplier'' exception to the on-sale bar; thus, a patentee's order to its supplier may trigger the on-sale bar.[7] What's more, any sales or commercial offers of a pre-AIA patented invention in the U.S., even if kept confidential, may trigger the bar.[8]

Whether a confidential offer for sale will trigger the bar post-AIA is less clear:

35 USC 102(b)	AIA 35 USC 102(a)
A person shall be entitled to a patent unless - (b) the **invention** was patented or described in a printed publication in this or a foreign country or **in public use** or on sale in this country, **more than one year prior to the date of application** for patent in the United States.	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 …

A key change to the on-sale bar post-AIA is that there is no distinction between activities conducted in the U.S. or abroad. Thus, more patent rights can be lost since a prior sale no longer needs to be in the U.S. On the other hand, a secret or non-public sale may no longer constitute prior art under the AIA, if courts hold that the phrase ''or otherwise available to the public'' modifies its antecedent, ''on sale,'' such that only ''public'' sales or offers qualify as prior art (significantly narrowing the scope of the bar and overturning decades of case law).[9] Such an interpretation, if adopted, would not bar patentability after confidential sales or commercial offers. Consequently, advocates of the ''supplier exception'' now seem to have a statutory basis for the proposal.[10]

However, ''plain meaning'' arguments can be made to support retaining the current understanding of the bar. Nothing in Section 102(a)(1) expressly limits the on-sale bar to publicly available sales/commercial offers; the amended statute says ''on sale,'' not ''publicly on sale'' or ''on sale to the general public.'' Since Congress re-enacted the familiar ''on sale'' language without change, it may have intended to retain the existing judicial interpretations of the on-sale bar.[11]

Against this backdrop, in *Hospira*, the Federal Circuit has agreed to consider en banc whether, for pre-AIA applications, there should in fact be a ''supplier exception'' or ''public requirement'' to the on-sale bar, ultimately narrowing its scope. The core question is the distinction between a ''sale'' and extended product development.

In deciding this case, the Federal Circuit has the opportunity to reevaluate the underlying policy rationale for the on-sale bar. The outcome has the potential to impact industries outside of the pharmaceutical arena and the life sciences.

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[3] *See EZ Dock v. Schafer Sys, Inc.*, 276 F.3d 1347, 1358, 61 U.S.P.Q.2d 1289 (Fed. Cir. 2002).

[4] *Id.*

[5] *In re Cygnus Telecomm. Tech., LLC Patent Litig.*, 536 F.3d 1343, 1356, 87 U.S.P.Q.2d 1801 (Fed. Cir. 2008).

[6] *Abbott Labs. v. Geneva Pharm.*, 182 F.3d 1315, 1319, 51 U.S.P.Q.2d 1307 (Fed. Cir. 1999).

[7] *Special Devices Inc v. OEA Inc.*, 270 F.3d 1353, 1354-57, 60 U.S.P.Q.2d 1537 (Fed. Cir. 2001) (''neither the statutory text, nor precedent nor the primary purpose of the on-sale bar'' allowed the Court to recognize a ''supplier exception to the on-sale bar'' as otherwise inventors could ''stockpile'' commercial embodiments of the patented invention before the critical date).

[8] *In re Caveney*, 761 F.2d 671, 675-76, 226 U.S.P.Q. 1 (Fed. Cir. 1985).

[9] Recently, the U.S. District Court for the District of New Jersey held a licensing-supply agreement between a healthcare company and a customer did not trigger the bar because the sale was not ''public'' per AIA § 102(a), rejecting a generic maker's argument that the AIA had not changed the adage that ''private'' sales of an invention are sufficient. *Helsinn Healthcare S.A. v. Dr. Reddy's Labs., Ltd.*, No. 11-03962 (D.N.J., Mar. 3, 2016) at 87, 100-101, 166 (acknowledging for claims with priority on or before March 16, 2013, the deal qualified as a ''sale'' pre-AIA; but, ''ready for patenting'' prong was not established pre- or post-AIA).

[10] Former Senator Kyl expressed that ''or otherwise available to the public'' should in fact modify ''on sale'' in the revised statute. Cong. Rec. S1370-71 (daily ed. Mar. 8, 2011). Because the modifier ''or otherwise available to the public'' is set off from a preceding series of antecedents by a comma, courts may conclude it applies to the on-sale bar.

[11] *Ariad Pharm. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344-45, 2010 BL 62410, 94 U.S.P.Q.2d 1161 (Fed. Cir. 2010) (en banc) (79 PTCJ 623, 3/26/10) (reenactment of identical Section 112 language found persuasive, since courts interpreted that language to provide for a separate written description requirement; ''If Congress had intended enablement to be the sole description requirement of § 112 [¶ 1], the statute would have been written differently.''); *In re Nuijten*, 500 F.3d 1346, 1356-57, n.5, 2007 BL 105088, 84 U.S.P.Q.2d 1495 (Fed. Cir. 2007) (74 PTCJ 631, 9/28/07) (by reenacting ''manufacture'' as a category of patentable subject matter, despite other changes to § 101, Congress intended to adopt pre-1952 judicial definitions of ''manufacture.'')

III. *TMC v. Hospira*

TMC v. Hospira[12] is an ANDA litigation over a generic drug application covering Bivalirudin (commercialized as Angiomax™), a blood-thinning drug. Back in 2005, owing to a ''failing'' batch of Bivalirudin (with high impurity levels), The Medicines Co. (TMC) attempted to create batches with levels of the Asp-Bivalirudin impurity below FDA's maximum requirement of 1.5 percent. During this testing period, TMC hired a consultant to investigate and consult with TMC's batch contract manufacturer, Ben Venue Laboratories.

The consultant (and patent-inventor) discovered new methods to minimize the impurity level to less than 0.6 percent. This discovery led to the patented invention and claims in two Orange-Book listed patents. TMC became the assignee of the two patents-in-suit, both with a critical date in July 2007. Both patents contain ''product-by-process'' claims[13] to methods of making the drug to reduce the impurity level to less than 0.6 percent.

A. District Court

In August 2010, TMC sued Hospira Inc. for patent infringement, based on Hospira's abbreviated new drug application (ANDA) filing.[14] At trial, Hospira contended that TMC's asserted claims were invalid under the on-sale bar because, before the critical date, TMC engaged in three separate transactions: (1) TMC paid Ben Venue over $300,000 to prepare three validation batches using the patented method; (2) TMC paid Ben Venue over $1m to manufacture eight commercial batches using the patented method; and (3) TMC contractually offered to sell the resulting product to Ben Venue's exclusive U.S. distributor, Integrated Commercial Solutions.[15]

The district court rejected Hospira's argument.[16] Though it found there was a prior reduction to practice of the claimed invention, it reasoned TMC's product was neither commercially sold nor offered because of the following factors: (i) Ben Venue sold only *manufacturing services*, not batches[17]; (ii) title to the batches remained with TMC[18]; (iii) the batches were experimental[19]; and (iv) the TMC-ICS distribution agreement was not a ''sales contract,'' but a distributorship agreement to enter into a future contract.[20]

B. Federal Circuit

Hospira appealed the finding that the asserted claims are not invalid under the on-sale bar. Hospira maintained its argument that the claimed invention was commercialized pre-critical date. TMC slightly changed course and argued there was no reduction to practice as the inventors did not appreciate the maximum impurity limitations of the claimed invention until after the critical date, when subsequent batches were manufactured according to TMC's new process.

In a reversal for TMC, the Federal Circuit panel reversed the district court, holding both patents invalid under Section 102(b)[21] reasoning that the Delaware court ''clearly erred'' in finding that the Ben Venue batches were not ''sold'' to TMC, and that they were prepared primarily for an ''experimental purpose.''[22]

A month later, Hospira (now Pfizer-owned) launched its generic version of Angiomax™. Later that fall, the full Federal Circuit vacated the panel opinion and granted TMC's petition for full rehearing en banc on the on-sale bar issue.[23] Regardless of the outcome en banc, whether the en banc court holds the patents to be valid is probably not dispositive for Hospira given that the district court independently held Hospira's product does not infringe TMC's patents.

C. Issues for the En Banc Court

The Federal Circuit requested that both TMC and Hospira address three core issues en banc: (1) Was there a ''commercial sale'' despite lack of title-transfer?; (2) Was the ''sale'' commercial or experimental?; and (3) Should the Federal Circuit overrule or modify the ''no supplier exception'' to the on-sale bar under *Special Devices*?[24]

With regard to the lack of title transfer, Hospira's brief argued that title transfer should not be required for the analysis because otherwise such a bright-line rule would encourage gamesmanship in contracts and remove flexibility in deciding a commercial offer for

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[12] *TMC v. Hospira, Inc.*, 791 F.3d 1368, 115 U.S.P.Q.2d 1587 (Fed. Cir. 2015) (90 PTCJ 2541, 7/10/15).

[13] Claim 1 of U.S. Patent No. 7,598,343 recites, in relevant part: . . . ''said batches prepared by a *compounding process* comprising: . . .(ii) efficiently *mixing a pH-adjusting solution* with the first solution to form a second solution, wherein the pH adjusting solution comprises a pH-adjusting solution solvent; and (iii) removing the solvent . . . and *wherein the batches have a maximum impurity level of Asp 9-bivalirudin that does not exceed about 0.6% as measured by HPLC*.''

[14] *TMC v. Hospira, Inc.*, No. 09-750-RGA, at *1 (D. Del., March 31, 2014).

[15] *Id*. Hospira relied on invoices for services that identified a ''charge to manufacture Bivalirudin lot(s)'' numbers and commercial product codes. Further, Hospira alleged that TMC entered into an exclusive distribution agreement with ICS containing a title-transfer clause.

[16] *Id*.

[17] *Id*. at *9

[18] *Id*. at *9-10.

[19] *Id*. at *11.

[20] *Id*. at *12.

[21] 791 F.3d at 1369.

[22] *Id*. The panel could not distinguish between the commercial sale of services resulting in the patented product-by-process here, and a commercial sale of products prepared by a patented method at issue in *D.L. Auld Co.* (barring product-by-process claims covering secret, unpatented method to sell goods unrevealing of method). It held the bar applies where the inventor commercially exploited the embodiment pre-critical date, even if there was no title-transfer. Here, the sale of manufacturing services to TMC resulted in batches valued greater than $10m each, enabling FDA approval. *Id*. at 1371.

Regarding ready for patenting, the panel upheld the district court's finding, but reasoned its rationale was flawed since the experimental use doctrine could preclude application of the bar, not just because it was raised sua sponte, but also because it failed to attribute experimental use to *both* prongs of the bar (only commercial offer). Regardless, experimental use could not occur after reduction to practice, *i.e*. when requisite batches were made for TMC. *Id*., at 1372. It was irrelevant whether TMC knew the process limitations consistently produced bivalirudin below 0.6 percent, since the batches satisfied limitations. *Id*.

[23] *TMC v. Hospira, Inc.*, No. 2014-1469 (Fed. Cir. Nov. 13, 2015) (en banc order) (91 PTCJ 160, 11/20/15).

[24] *TMC v. Hospira, Inc.*, *Id*. at *1.

sale, especially considering that *Pfaff v. Wells, supra* held that a completed sale is *not* required to trigger the bar. Hospira focused on TMC's ''commercial exploitation'' of the invention before the critical date, such as how the batches ''were released for commercial and clinical packaging, and [] restocked [TMC's] long-depleted commercial pipeline of Angiomax™.'' It also argued that there should *not* be a ''supplier exception'' as the statute does not differentiate between sellers when an invention is placed on-sale.

TMC's response brief advocated the same positions as before—namely, that: (i) Ben Venue's performance of manufacturing services to convert the API into a finished product does not trigger the bar, especially where it did not have any title to the products and where the patents-at-issue were product and product-by-process (not process or method) patents, relying on *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*[25]; (ii) neither Ben Venue nor TMC could sell the patented products pre-critical date as they were placed in quarantine pending quality control testing; and (iii) there was no commercial exploitation or ''stockpiling'' of the patented invention pre-critical date, particularly where the only evidence Hospira relied on was: (a) the potential sales price of each unapproved validation batch; and (b) FDA-mandated product codes, even if rejected.[26]

TMC likely will face an uphill battle in attempting to limit or eliminate the ''no supplier exception'' rule, since the court can point to the language of *Special Devices*, its progeny and their express invocation of Congress as the sole source of modification.[27] In *Special Devices*, OEA Inc. negotiated with its supplier, Coors Ceramics Co., to mass-produce a patented ''all-glass header'' relating to automobile air bags.[28] The court declined recognition of a ''supplier'' exception to the on-sale bar, and stated (in dicta) that even if an invention is stolen by a thief and sold to an innocent buyer, the bar would still be triggered.[29] The court further reasoned that its precedent precludes a ''supplier'' exception,[30] and that there is a policy of encouraging inventors to enter the patent system promptly.[31].

Additionally, it is worth noting that under judicial precedent, process steps are limiting and must be met in determining infringement of product-by-process claims.[32] Thus, as Hospira implies, it may not be as significant that the claims-at-issue are not process or method claims, or that there is no title transfer, since there has allegedly been a sale of manufacturing services creating products that meet claim limitations.[33] And even if the claims were solely process claims, the case law dealing with product-by-process claims in this area focuses on commercial exploitation of the ''invention,'' not an actual sale of a product that requires passage of title.[34]

TMC, however, is being supported by several amici. For instance, the Patent and Trademark Office is urging the Federal Circuit to recognize a ''supplier exception'' to the on-sale bar, arguing that the drug was not ''available to the public'' and that applying the bar to confidential supplier arrangements might prejudice small companies and inventors who lack ability to manufacture drugs in-house. The Houston IP Association separately contended that ''[i]f a company can't safely outsource its manufacturing needs, the experimental use exception is worthless where [the Federal Circuit] actually held that submitting data to the FDA was a commercial benefit.''

In contrast, the American Intellectual Property Law Association and the Intellectual Property Owners Association are requesting that the court partially overrule *Special Devices* to recognize that certain supplier transactions do not trigger the bar. Both argue that the court should trim the blanket rule since although there are no ''personal'' sales, ''Inventors can request another entity's services in developing products embodying the invention without triggering the on-sale bar.''[35] Also, both claim that unless a product containing or derived from the invention is ''sold'' to the public, the inventor is unlikely to benefit financially from the invention. Thus, under this rationale, a patent owner or its employees may stockpile patented products or products made using a patented product-by-process without implicating the bar.

Hospira argued that TMC's reliance on ''experimental use'' contradicts the district court record, such as the Ben Venue clinical batches encompassing thousands of vials ''for commercial use.'' Hospira also claims that TMC and its amici are seeking to exempt categories of transactions based on the parties, the type of claims, or the transactions' legal form—all of which contravene both Section 102(b) as well as the Federal Circuit's

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[25] 595 F.3d 1340, 93 U.S.P.Q.2d 1805 (Fed. Cir. 2010) (on-sale bar not triggered where inventor paid software company, by the hour, to develop specialized software based on inventor's specifications).

[26] TMC argued that Hospira improperly relied on evidence of the 8 subsequently manufactured commercial batches, as these were never raised in district court, and asserted that even if the Court considers them, all batches fall within the experimental use exception as made for regulatory purposes to verify the invention worked for its intended purpose. Interestingly, TMC contended that experimental use is an exception, not a negation, to the bar which can exist even after an invention is reduced to practice. But this would mean that the burden of proof/persuasion over validity arguably shifts to TMC—a position it likely did not intend to advocate for. *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 971, 220 U.S.P.Q. 577 (Fed. Cir. 1984) (patentee need not prove that a public use was experimental to assert an experimental use defense, since experimental use is a negation, not an exception, to the bar; the burden of proving invalidity rests with the challenger, but the burden of production on experimental use shifts to the patentee).

[27] *See Special Devices*, 270 F.3d at 1357.

[28] *Id.*, 270 F.3d at 1354

[29] *Id.* at 1354-55 (''By phrasing the statutory bar in the passive voice, Congress indicated that it does not matter who places the invention ''on sale''; it only matters that someone—inventor, supplier or other third party—placed it on sale.'').

[30] *Id., reviewing Brassler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 182 F.3d 888, 51 U.S.P.Q.2d 1470 (Fed. Cir. 1999).

[31] *Id.* at 1357

[32] *Abbott v. Sandoz*, 566 F.3d 1282, 90 U.S.P.Q.2d 1769 (Fed. Cir. 2009) (if product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though prior product was made by a different process).

[33] *See In re Thorpe*, 777 F.2d 695, 227 U.S.P.Q. 964 (Fed. Cir. 1985) (prior art pertinent only to a product is a proper ground for rejecting product-by-process claims).

[34] *Plumtree Software, Inc. v. Datamize, LLC*, 473 F.3d 1152 (Fed. Cir. 2006); *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 219 U.S.P.Q. 13 (Fed. Cir. 1983).

[35] *Trading Tech., supra*, 595 F.3d at 1361-62.

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prior rulings that commercial exploitation takes many forms. Further, importing a confidentiality or ''supplier exception'' would risk conflating ''sales'' under the bar with public use of inventions, except for commercial offers. And, that application of the bar will neither chill innovation nor prohibit a way of doing business, since upholding the prior panel decision would encourage inventors to apply for patents within one year of commercial exploitation of their inventions.

Any other ''public'' sale requirement or ''confidentiality'' exception, Hospira argued, would encourage inventors to game the system as they would only engage in secret sales of the invention, consequently delaying public disclosure, and ultimately extending patent terms while reaping commercial benefit. Further, experimental use is still a safeguard to many small drug companies worried about a manufacturer-agreement putting it under the risk of an invalidating ''sale,'' sufficient to dissuade the need for blanket immunity for all supplier-customer transactions.

Hospira will thus be an opportunity for the full Federal Circuit to address the applicability of the bar to product-by-process patent claims in the context of a sale of services, especially where the ''sold'' invention is not the product itself but instead a product derived from a disclosed and subsequently patented method of making the product. Oral arguments are scheduled for May 5, 2016.

IV. Some Takeaways for Practitioners in View of *Hospira*

The pre-AIA law surrounding the on-sale bar is complex, and most of this complexity carries over to the post-AIA world. Even though there is no bright-line rule in determining whether certain business activities prior to the critical date constitute a sale or an offer for sale, below are some takeaways—applicable regardless of *Hospira*'s decision to uphold or overrule the no ''supplier exception'':

A. For Patentees

- *IP*: Regularly update IP counsel and conduct frequent audits over research and development and commercial activities to draw attention to IP issues.
  - o Develop early claim strategies and provisional patent applications to match critical development dates, even if incomplete.
- *Control/access*: Retain control over experiments, and ensure only authorized testers have access and use over inventions.
  - o *Experimental use*: Make observations about the invention and whether it is fit for its intended purpose, not whether customer finds it suitable or it will be commercially successful.
  - o *Confidentiality*: Have all employees and suppliers execute confidentiality agreements; educate staff about when they can disclose company activities; and restrict access to information technology systems, especially those that contain R&D files.
  - o *Service contracts*: Structure supplier agreements as ''service manufacturing agreements'' rather than product purchase/requirement contracts, where patentees supply or purchase all raw materials and pay suppliers for assembly and manufacturing services (retaining rights with title-retention clauses).
- *Sales*: Avoid making any ''sales'' within claim limitations; ''use'' is more likely to be experimental if no sale is involved.
- *Focus on trade secrecy and confidentiality*[36]: Execute confidentiality and non-disclosure agreements over sales or offers for sale, to potentially avoid triggering the on-sale bar.
  - o Parameters around ''public availability'' of invention: Depending on the Federal Circuit's holding and when an invention becomes publicly available, if an invention is sold with accompanying non-disclosure agreements yet such sales still become widely prevalent, be prepared to execute restrictive measures over distribution and supply channels to prevent sales from reaching a critical mass.

B. For Patent-Defendants

- *Take early first- and third-party discovery* over pre-critical date development/supply contracts, inventors, supply chain personnel, etc., and *develop an on-sale bar theory at the outset of litigation*.
  - o Investigate: 1) financial/batch records to ascertain monetary consideration; 2) whether the alleged infringing product, even for testing purposes, expressly or inherently meets every claim limitation; and 3) substantiate invalidity analysis with expert testimony and claim charts.
- *Section 282 notice*: be prepared to meet obligations, 30 days pre-trial, and attempt to rely on patentee's documents.
- *''Public use''*: consider whether early marketing activities (including preliminary negotiations) over an invention involve an inventor's non-secret use of a process, intended for a commercial purpose without reaching the level of a commercial offer.[37]

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[36] If the Federal Circuit rules in *Hospira* that secret sales or commercial offers no longer qualify as prior art, the role of trade secrets may expand under the AIA.

[37] Though *Pfaff* narrowed the scope of the on-sale bar, the ''totality of the circumstances'' test is still applicable for ''public use.'' In light of obstacles *Pfaff* may create for litigants asserting the on-sale bar, ''public use'' is more flexible in supporting a pre- or post-AIA defense.

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