

Prior Art: When On Sale Is Not 'On Sale'

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Pursuant to Section 102 of the Patent Act, the “on-sale” bar can invalidate a patent when the claimed invention has been the subject of a commercial sale or offer for sale, and the invention is ready for patenting. Prior to the enactment of the Leahy-Smith America Invents Act, certain sales of (or offers to sell) the claimed invention — including a purely private transaction involving the patent applicant — could trigger the on-sale bar. However, the AIA amended the language of the patent statute, sparking discussion as to whether the on-sale bar now requires that sales or offers to sell be “public” to qualify as invalidating. In a case of apparent first impression, a district court in New Jersey recently interpreted the amended statutory language to require just that. The district court’s decision is currently on appeal to the Federal Circuit.



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Before the enactment of the AIA, Section 102 of the Patent Act provided in relevant part that “[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.” The Federal Circuit has construed the pre-AIA statute to apply the on-sale bar even if a patentee’s commercial activities took place in secret.[1]



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The AIA amended the Patent Act to (among other things) regroup the categories of prior art under Section 102 and to add the clause “otherwise available to the public.” Section 102 now provides in relevant part that “[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.” This amendment, in addition to other statutory changes and aspects of the AIA’s legislative history, has created uncertainty as to whether the final clause — “otherwise available to the public” — modifies the clauses that come before it (thus requiring sales or offers to sell to be available to the public to qualify as invalidating) or instead serves solely as its own residual category of prior art.

The issue recently came to the fore in a case before the district court in New Jersey.[2] The *Helsinn Healthcare SA* case involved four related patents on intravenous formulations of palonosetron for reducing chemotherapy-induced nausea and vomiting. Because of the different effective filing dates of the asserted patents, three were subject to the patent provisions in effect prior to enactment of the AIA, and the fourth was subject to the AIA.

Among other defenses, the accused infringer asserted invalidity of all four patents under the on-sale bar based on a supply and purchase agreement for the future sale of the claimed palonosetron product. An appendix to the agreement included a qualitative description of the formulation of the products to be purchased. The agreement was subject to a confidentiality provision.

The district court found that the supply agreement was a “sale” under the pre-AIA on-sale bar because it was a contract for a future commercial product. The court noted that the agreement contained terms typical for contract of sale — that is, terms relating to the product, the quantity to be sold, and the price. Further, although at the time of the agreement the product was awaiting U.S. Food and Drug Administration approval, the appendix to the agreement specified the exact dosages and concentrations that were in the pending FDA filings. Thus, according to the court, its analysis of whether the agreement satisfied the “sale” prong of the on-sale bar under a pre-AIA analysis ended there.

However, in determining whether the same supply agreement was a “sale” under the post-AIA on-sale bar, the district court stated that it is not sufficient that a sale or offer for sale merely occur. Instead, the court interpreted the on-sale bar under the AIA to require that the sale or offer for sale make the claimed invention “available to the public.” Under this interpretation, the court found that the supply agreement was not a “sale” under the post-AIA on-sale bar because the confidential sale did not make the claimed invention available to the public. And while a Form 8-K and a press release made the existence of the agreement available to the public, the documents did not make the claimed invention itself — i.e., the palonosetron formulation — available to the public.

Although it is not entirely clear which arguments the court ultimately found persuasive, the district court appeared to rely on the following reasoning for its interpretation of the post-AIA on-sale bar. First, in analyzing the plain language meaning of the amended statute, the court stated that it was guided by a “common sense” approach to statutory interpretation — in this case, reading the statute such that the clause “otherwise available to the public” modifies each of the preceding clauses in the statute. Second, the court found “instructive” the U.S. Patent and Trademark Office’s examination guidelines, which have interpreted the AIA to exclude from prior art secret sales or offers to sell (such as sales activity among individuals having an obligation of confidentiality to the inventor). Third, with respect to the legislative history, the court found “crucial” a committee report that, among other things, cited certain Senate hearings in which some of the AIA’s sponsors expressed the intent to require that a claimed invention be made available to the public for the on-sale bar to apply. Finally, the court found that its interpretation comported with what it believed to be Congress’ overarching goal “to modernize and streamline” the United States patent system, including with respect to the identification of prior art.

The district court’s reasoning is currently being challenged on appeal. According to the appellants, the AIA’s text, structure, legislative history and purpose all confirm that a product can be “on sale” privately by the patent applicant and still qualify as prior art. First, the appellants argue that in ordinary usage, an item is “on sale” whether sold privately or publicly by the patent applicant. AIA Section 102’s use of the term “on sale” alone does not distinguish between inventions on sale “publicly” and those sold “privately,” in contrast with the surrounding statutory bars to patentability that on their face require public activity (e.g., an invention “described in a printed publication,” an invention in “public use,” etc.). Second, the appellants argue that, for almost two centuries, courts have treated “on sale” as a term of art that extends to an applicant’s private sales and commercial exploitation for policy reasons independent of the overarching pre-AIA policy of encouraging an inventor to enter the patent system promptly (e.g., prohibiting the commercial exploitation of the design beyond the statutorily prescribed time period).

Third, the appellants argue that Congress did not change the meaning of “on sale” by adding the phrase “otherwise available to the public.” They argue that, instead, the phrase “to the public” modifies only the last antecedent — “otherwise available” — and that the clause as a whole is meant to capture disclosures using future technology (e.g., video recordings streamed over the internet) not otherwise captured by the preceding clauses in Section 102.

Fourth, the appellants argue that the district court’s reading of “on sale” would render meaningless the word “publicly” in Section 102(b), a provision providing certain exceptions to the bars set forth in Section 102(a) (including the on-sale bar). According to the appellants, Section 102(b) distinguishes between “disclosures” and “public disclosures” — a distinction that is coherent only if Section 102(a) covers certain private (in addition to public) disclosures. Fifth, the appellants argue that the committee report upon which the district court relied, as well as statements on the Senate floor, cannot accomplish what was not accomplished in the statute itself. In particular, the appellants note that, although early iterations of the AIA eliminated the phrase “on sale” (thus removing that category altogether), the version that Congress ultimately adopted retained the “on sale” language. Finally, the appellants argue that the USPTO’s interpretation is not entitled to deference, but even if it were, such deference cannot save an incorrect agency interpretation.

The district court’s ruling has several potential implications. If the Federal Circuit agrees with the court’s interpretation, the most obvious result will be a narrowing of available prior art under the AIA — that is, some contracts that constituted a “sale” under the pre-AIA on-sale bar will no longer qualify under the AIA. This could render inapplicable many pre-AIA cases regarding nonpublic activity that was nevertheless found to be invalidating. For example, under the pre-AIA statute, commercial exploitation by the inventor of a machine or process can bar patentability even where the machine or process was kept secret. Under the district court’s interpretation, sales of a product made by a secret process may no longer bar patentability of that process. The Helsinn Healthcare appeal that could provide clarity regarding some or all of these issues is still being briefed, so a Federal Circuit ruling is unlikely until early to mid-2017. Until that time, the district court’s ruling has injected a note of uncertainty into the scope of the on-sale defense under the AIA.

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DISCLOSURE: WilmerHale filed an amicus brief on behalf of amici curiae Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization in connection with the Helsinn Healthcare appeal.

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[1] See, e.g., *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357 (Fed. Cir. 2001). The Federal Circuit is currently considering en banc whether it should overrule or revise the principle in *Special Devices* that there is no “supplier

exception” to the pre-AIA on-sale bar of 35 U.S.C. § 102(b). *The Medicines Co. v. Hospira*, 805 F.3d 1357 (Fed. Cir. 2015).

[2] *Helsinn Healthcare S.A., et al. v. Dr. Reddy’s Labs. Ltd.*, No. 11-3962 (MLC), 2016 WL 832089 (D.N.J. March 3, 2016).