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Federal Circuit Maintains Pre-AIA Interpretation of the On-Sale Bar for Public Sales

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In *Helsinn Healthcare S.A., v. Teva Pharm. USA, Inc.*, the Federal Circuit recently held that, despite changes to the statutory language of § 102 under the Leahy-Smith America Invents Act ("AIA"), the Court's pre-AIA interpretation of the on-sale bar remains the same with respect to public sales. Appeal No. 2016-1284, Slip Op. at 27 (Fed. Cir. May 1, 2017). In reversing the district court's decision, which held that a "public sale" under the AIA had to publicly disclose all of the details of the invention, the Court explained 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," a holding consistent with Federal Circuit precedent. *Id.*

The pre-AIA § 102(b) barred patentability where 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." 35 U.S.C. § 102(b) (2006) (emphasis added). With the passage of the AIA, Congress amended this section to bar patentability if the 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." 35 U.S.C. § 102(a)(1) (emphasis added).

In its appeal, Helsinn—as well as various amici, including the USPTO—argued that the inclusion of "otherwise available to the public" signaled congressional intent to require "that a sale make the invention available to the public in order to trigger application of the on-sale bar," which would exclude secret sales or incomplete disclosures of the invention. Slip Op. at 19. In response, Teva and other amici argued that "by reenacting the statutory term 'on sale'" from the pre-AIA § 102(b), Congress intended to maintain the pre-AIA interpretation of the term. *Id.*

This dispute initially arose from Teva filing an Abbreviated New Drug Application ("ANDA") for a generic 0.25 mg palonestron product and Helsinn subsequently filing suit, asserting four patents covering a 0.25 mg dose of palonestron. *Id.* at 9-10. All four of the asserted patents claimed priority to the same provisional application, filed on January 30, 2003, and as a result, shared the same critical date of January 30, 2002 with respect to the on-sale bar. *Id.* at 4. Teva argued that all four of Helsinn's patents were invalid because of two agreements that Helsinn entered into with MGI Pharma, Inc. on April 6, 2001, for the future marketing and distribution of Helsinn's palonestron product, the claimed invention of its four asserted patents. *Id.* at 6, 10. In particular, the Supply and Purchase Agreement between Helsinn and MGI, which was publicly announced in MGI's 8-K filing and included as a partially redacted attachment thereto, "disclosed all the pertinent details of the transaction other than the price and dosage levels." *Id.* at 21-22.

The Federal Circuit rejected Helsinn's argument that by redacting the dosage levels of its palonestron product it had avoided disclosing the invention and triggering the on-sale bar. *Id.* As the Court noted, "[r]equiring such a disclosure as conditional of the on-sale bar would work a foundational change in the

theory of the statutory on-sale bar." *Id.* at 22. Past Federal Circuit cases have not distinguished between sales and offers for sale with respect to application of the on-sale bar, nor have they required that "a sale be consummated," an offer accepted, or that, upon delivery, members of the public be able to "ascertain the claimed invention" for the invention to be disclosed to the public. *Id.* at 25. In line with past precedent the Court thus concluded that, despite the redaction of the dosage, the Supply and Purchase Agreement disclosed the invention to the public and constituted a sale of the claimed invention. *Id.* at 27.

The Federal Circuit acknowledged that its opinion in this case is narrow and does not address whether the AIA may affect the Court's interpretation of other aspects of § 102, such as "public use" or whether or not a sale is public. *Id.* at 21. Thus, it remains to be seen exactly how the AIA will change the legal landscape with respect to the on-sale bar, if at all.

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