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Federal Circuit Clarifies AIA On-Sale Bar Provision Applies Where Existence of Sale Is Public

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Yesterday, the Federal Circuit provided much-anticipated guidance on the scope of the America Invents Act's "on-sale" bar provision. *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., et al.,* Nos. 2016-1284, 2016-1787 (Fed. Cir. 2017). Specifically, the Federal Circuit held that under the America Invents Act's ("AIA") on-sale bar provision, a patent can be invalidated if the existence of the sale is public, even if the details of the invention were not publicly disclosed. This decision reversed the lower court's determination that under the AIA, only public sales trigger the on-sale bar. The decision provides guidance for companies looking to protect intellectual property, but also provides potential fodder for companies seeking to invalidate patents that may be asserted against proposed generic versions of drugs in the United States.

The on-sale bar prohibits the patenting of an invention that is on sale for more than one year before the filing date of a patent application. This provision was codified at pre-AIA 35 U.S.C. § 102(b), which bars the patentability of an invention that was "…on sale in this country, more than one year prior to the date of the application for patent." With the enactment of various provision of the AIA between 2011 and 2013, Congress amended § 102 to bar the patentability of an "invention [that] 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). While it is well established under pre-AIA law that a secret sale (i.e., sale or offer for sale that had been kept secret from the public) may trigger the on-sale bar, there was some question whether the AIA changed the law by reciting "otherwise available to the public." This issue arose in *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*

Helsinn owned several patents directed to formulations of palonosetron for treating chemotherapy-induced nausea. One of these patents was governed by the AIA. Almost two years before the filing of the first patent application, Helsinn entered into a License and Supply and Purchase Agreement with MGI Pharma. These agreements were publically disclosed in a joint press release and in MGI Pharma's Form 8-K filing with the SEC. Partially redacted versions of the agreements were included with the Form 8-K filing.

During a suit brought by Helsinn under the Hatch-Waxman Act, alleging infringement of the patents by Teva Pharms. USA, Inc. (who had filed with the FDA an Abbreviated New Drug Application, or "ANDA" seeking approval to sell a generic version of the drug), Teva argued that the previously publically disclosed agreements between Helsinn and MGI Pharma barred patentability under the AIA's on-sale provision at 35 U.S.C. § 102(a)(1). Judge Mary Cooper of the District of New Jersey disagreed with Teva, holding that the "otherwise available to the public" language in the AIA changed the law and that only public sales triggered the on-sale bar. Judge Cooper further determined that Helsinn's sale did not disclose details of the invention and, as such, was not public.

On appeal, the Federal Circuit disagreed with Judge Cooper. The court held that for the AIA's on-sale bar to apply, it was not necessary that the details of the invention be disclosed to the public. In reaching its decision, the court rejected Helsinn's arguments that the phrase "otherwise available to the public" was intended to limit the scope of the on-sale bar to public sales, as allegedly evidenced by statements made on the floor of the Senate during debate of what became the AIA. The court stated that the "floor statements did not identify any sale cases that would be overturned by the amendments" and, further, that in the present case the existence of the sale was public as the Supply and Purchase Agreement was announced in a Form 8-K filing with the SEC. The Supply and Purchase Agreement "disclosed all the pertinent details of the transaction other than the price and dosage levels." Further, the court noted that there were "no floor statements suggesting that the sale or offer documents must themselves publicly disclose the details of the claimed invention" and if that was Congress' intent, then "it would do so by clear language." In sum, the Federal Circuit ruled that AIA revisions to the language of 35 U.S.C. § 102, did not change the meaning of the on-sale bar as to require a public disclosure of the details of the invention.

While the Federal Circuit's ruling in *Helsinn* clarifies that the AIA on-sale bar provision does not depart from the pre-AIA provision, it did so in a fact-specific manner. Notably, *Helsinn* involved the public disclosure of a sales agreement. The Federal Circuit specifically stated that "[w]e do not find that distribution agreements will always be invalidating under § 102(b). We simply find that this particular Supply and Purchase Agreement is." As such, given *Helsinn*, prior to the public disclosure of any agreements involving inventive subject matter, companies will be well served to take steps to ensure that appropriate steps have been taken to obtain patent protection for the relevant subject matter. Additionally, ANDA filers seeking a basis to invalidate Orange Book-listed patents would do well to investigate potential disclosures of agreements that might serve as invalidating sales under the AIA's on-sale bar provision.

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