

Keywords: AIA 35 U.S.C. § 102(a)(1); on-sale bar; secret sale

General: A secret (i.e., non-public) sale or sale that does not disclose the invention is still prior art under 35 U.S.C. § 102(a)(1). A nondisclosure agreement does not provide safe harbor against the on-sale bar.

Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.
586 U. S. (2019) Supreme Court No. 17-1229
Decided January 22, 2019

I. Facts

Helsinn obtained four patents directed to reducing chemotherapy-induced nausea and vomiting by using unexpectedly low concentrations of palonosetron. The four patents at issue each include claims directed to a 0.25 mg dose of palonosetron, and each claims priority to a provisional patent application filed on January 30, 2003. Three of the patents – U.S. Patent Nos. 7,947,724; 7,947,725; and 7,960,424 (hereinafter the “pre-AIA patents”) – were filed in 2005 and 2006 while the fourth patent – U.S. Patent No. 8,598,219 (hereinafter the “post-AIA patent”) – was filed in May 2013 (after the effective date of the AIA).

In April 2001, nearly two years before applying for a patent, Helsinn entered into a License Agreement and a Supply and Purchase Agreement with MGI Pharma, Inc. (“MGI”), which was announced in a joint press release and in MGI’s Form 8-K (“8-K”) filing with the Securities and Exchange Commission. The 8-K included partially redacted copies of both agreements, whereby specific dosage covered by the agreements (i.e., 0.25 mg and 0.75 mg doses) was not made available to the public. Subsequently, in 2011, Teva filed an application with the FDA seeking approval to market a generic 0.25 mg palonosetron product. Teva’s application included a statement that the claims of the four patents were invalid and/or not infringed. Helsinn then brought suit under the Hatch-Waxman Act, alleging infringement by Teva’s application for the generic product of the claims in the four patents.

The District Court found that the Supply and Purchase Agreement was a sale under pre-AIA § 102(b), but not under post-AIA § 102(a)(1). The pre-AIA patents were, however, maintained, by a finding that the claimed invention was not reduced to practice before the critical date of January 30, 2002 and, therefore, was not ready for patenting.

With respect to the post-AIA patent the District Court held that the AIA changed the meaning of the on-sale bar and that § 102(a)(1) now “requires a *public* sale or offer for sale of the claimed invention.” The court concluded that, to be “public” under the AIA, a sale must publicly disclose the *details* of the invention. Accordingly, the District Court found that the post-AIA patent was not invalid.

Subsequently, the Federal Circuit overturned both of the District Court’s rulings, invalidating all 4 patents. The Federal Circuit found that the patents were ready for

patenting, and, thus, the pre-AIA patents were invalidated. Additionally, the Federal Circuit decided that the Supply and Purchase Agreement amounted to a public sale, and, even though the invention was not disclosed publicly, the details of the invention need not be publicly disclosed in the terms of sale, and, thus, the post-AIA on-sale bar applied. The Federal Circuit held that the AIA did not change the meaning of the on-sale bar of § 102.

II. Issues

Did the Federal Circuit err in finding that the AIA did not change the meaning of the on-sale bar?

III. Discussion

The Supreme Court affirmed the Federal Circuit ruling and stated that a commercial sale to a third party who is required to keep the invention confidential may place the invention “on sale” under § 102(a)(1).

The Supreme Court noted that under pre-AIA, the on-sale bar was determined to apply to inventions that were “the subject of a commercial offer for sale” and “ready for patenting.” *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67 (1998). It was also noted that the pre- and post-AIA language was substantially similar, with the difference being the additional language of “or otherwise available to the public.” The Supreme Court made the point to decide whether or not the additional language altered the meaning of the “on-sale” bar.

The Supreme Court concluded that because Congress maintained the same language in the first part of under § 102(a)(1), They “must be considered to have adopted also the construction given by this court to such language, and made it a part of the enactment.” The additional language was considered a catchall clause, and if Congress had meant to change the meaning of the previous language, the additional language was “a fairly oblique way of attempting to overturn” the pre-AIA interpretation.

The change to § 102 by adding “or otherwise available to the public” was not seen as enough of a change to conclude that Congress intended to alter the meaning from what was previously interpreted.

IV. Conclusion

The court affirmed the Federal Circuit judgment and found that the catch-all clause added to AIA 35 § U.S.C. 102(a)(1) does not invalidate years of case law interpreting the “public use” and “on sale” statutory language, in the absence of a clear repudiation by Congress.

V. On-Sale Bar Pre-AIA and Post-AIA:

Pre-AIA: 35 U.S.C. 102: 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, ...

Post-AIA: 35 U.S.C. 102(a)(1):

(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; ...