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IP Law News

INSIGHT: Supreme Court Clarifies Applicability of ‘On-Sale’ Bar to Patented Inventions

By Gaby L. Longsworth and Matthew S. Bodenstein Posted Feb. 1, 2019, 4:00 AM

A recent U.S. Supreme Court decision sends a message to attorneys advising clients on patents: In-house teams should communicate and coordinate supply and purchase agreements and patent timing. The bottom line, say attorneys with Stene, Kessler, Golstein & Fox, is don’t wait to file a patent application.

A Jan. 22 U.S. Supreme Court decision affirmed a ruling that Helsinn Healthcare SA’s patents on anti-nausea medicine Aloxi were invalid because the company had disclosed the drug formulation two years before seeking the patents.

In its unanimous decision affirming the Federal Circuit, the Supreme Court held that the catchall phrase in 35 U.S.C. § 102(a), “or otherwise available to the public,” did not change long-standing precedent regarding application of the on-sale bar.

As a result, commercial sales of an invention by an inventor to a third party who is obligated to keep the invention confidential can qualify as prior art under 35 U.S.C. § 102(a)—the addition of the catchall to 35 U.S.C. § 102 notwithstanding.

Relevant Facts

In 2000, Helsinn Healthcare S.A. ("Helsinn") entered into two agreements related to its then-unmarketed palonosetron product: a license agreement and a supply and purchase agreement.

The license agreement granted third party MGI Pharma Inc. ("MGI") rights to sell specified palonosetron doses in the U.S. in exchange for upfront and royalty payments. The supply and purchase agreement obligated MGI to purchase these doses exclusively from Helsinn in exchange for Helsinn agreeing to supply as much of the drug as MGI needed.

Although the agreements were not publicly available, redacted versions of the agreements were included in MGI’s 8-K filing with the SEC, and the deal was mentioned in MGI press releases.

Between 2003 and 2013, Helsinn filed four patent applications that eventually matured into patents claiming the subject matter covered by both agreements. The last application, filed in 2013, matured into U.S. Patent No. 8,598,219 ("the ‘219 patent") and was subject to the provisions of the Leahy-Smith America Invents Act (AIA).

The district court, analyzing these facts, held that the invention claimed in the ‘219 patent was not “on sale” within the meaning of the AIA, because the “catchall” changed the scope of the on-sale bar. As a result, publicly disclosing the existence of the supply and purchase agreement, absent more, didn’t make the 0.25 mg dose claimed in the ‘219 patent available to the public.

The Federal Circuit disagreed and reversed the district court, holding that the AIA did not modify the scope of the on-sale bar, and that under Federal Circuit precedent, public knowledge of a sale even in the absence of a detailed description of what was sold was, in and of itself, sufficient to trigger the on-sale provisions of the AIA.

The Supreme Court broadly agreed with the Federal Circuit but went one step further, holding that even if the existence of the sale was not public (i.e., if it was a completely secret, undisclosed sale), the on-sale bar provisions of the AIA could nonetheless be triggered.

The Supreme Court Opinion

According to the Court, *Pfaff v. Wells Electronics, Inc., 525 U. S. 55 (1998)*, set forth the operative precedent for determining whether an invention was "on sale" within the meaning of pre-AIA 35 U.S.C. § 102(a). Slip Op. at 1.

The Court further concluded that because *Pfaff* and its related cases did not "further require that the sale make the details of the invention available to the public," and because Congress "reenacted" the pre-AIA statutory language in the AIA, "a commercial sale to a third party who is required to keep the invention confidential may place the invention 'on sale' under the AIA." *Id*. at 1-2.

Although the Court considered whether the catchall phrase modified the reach of the on-sale bar, it concluded that if Congress had intended to change the meaning of the on-sale bar, "adding the phrase 'or otherwise available to the public' to the statute would be a fairly oblique way of attempting to overturn that settled body of law." *Id*. at 7-8 (internal quotations omitted). Rather, the catchall phrase merely "captures material that does not fit neatly into the statute's enumerated categories but is nevertheless meant to be covered." *Id*. at 8.

Analysis

The Supreme Court's decision affirms the pre-AIA body of "on-sale" case law, and in particular *Pfaff*. Moreover, the Court made explicit that it doesn't matter whether a sale is entirely secret (i.e., whether the existence of the sale itself had not been publicly disclosed) or even partly disclosed.

Rather, the lone inquiry is whether the invention claimed was the subject of a commercial offer for sale and whether the invention was ready for patenting at the time the offer was made. *See*, *Pfaff*, supra.

Accordingly, and because *Pfaff* still controls, parties negotiating commercial agreements need to be extra vigilant. In-house teams should communicate and coordinate supply and purchase agreements and patent timing. The bottom line: Don't wait to file a patent application.

File an application covering the subject matter in a potentially relevant agreement immediately, or at least within the one year grace period in the U.S.

Additionally, clearly distinguish between manufacturing service contracts and contracts for the sale of the product. Coordinating business developments and keeping these guidelines in mind should substantially reduce the risk of inadvertently triggering the "on sale" bar.

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