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IP FRONTIERS

What's on sale? The latest on the patent novelty requirement

On Jan. 22, 2019, the Supreme Court provided its decision in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*[1] Despite receiving little publicity outside the patent world, it nonetheless has implications for small businesses. The decision provided clarification to the statutory changes made by the America Invents Act (AIA) to the novelty requirement, specifically the on-sale bar, under 35 U.S.C. 102(a). As the latest in a series of decisions limiting pre-patent application activity by expanding the meaning of "on sale," businesses should consider including patent filing with any supply, distribution or sales strategy.

One of the conditions for receiving a patent is that an invention must be for something new or novel. However, novelty is more than making sure that an invention is unique. Under 35 U.S.C. 102(a), "[a] person shall be entitled to a patent unless 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." As long as these acts were committed one year or less before the "effective filing date" (e.g. in many but not all cases, the application filing date) of a patent application, then these disclosures should not be considered prior art. If a sale was made more than one year prior to filing a patent application, the on-sale bar will likely be triggered. The consequences of triggering the bar include application rejection or, if the patent issues, a finding that the patent is invalid.

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The on-sale bar has existed in some form since the early 1800s. The bar was included in patent statutes because Congress did not want to allow inventors to make the knowledge associated with an invention available to the public and then withdraw access to that knowledge through a patent. Nor did Congress want to allow inventors to try to circumvent the patent term period. The patent statute prior to the AIA included language invalidating sales made within the United States more than one year prior to submitting a patent application, but the AIA extended the on-sale bar to include sales made anywhere. In doing so, the revised statutory language raised questions as to whether only public sales, and not private or "secret" sales, would be barred.

Over 20 years ago the Supreme Court, in *Pfaff v. Wells Electronics, Inc.*[2], stated that if there was a "commercial offer for sale" and the invention was "ready for patenting," then the invention was considered "on sale" under the pre-AIA statute. This analysis is still valid for determining whether a sale occurred within the meaning of the statute, post-AIA.

Thereafter, in multiple appeal cases involving *The Medicines Co. v. Hospira, Inc. (2016, 2018)*[3], the Court of Appeals for the Federal Circuit (CAFC) decided that a distribution agreement also may constitute an offer for sale. In the first case, a manufacturing agreement that used a process under the patent in dispute and provided a finished product to The Medicines Co. was not considered a commercial sale. The CAFC determined that an agreement with a third party to produce a product by the patented process was merely a contract for manufacturing services.

However, in the second case, a distribution agreement with a third party was considered a commercial sale. The CAFC stated that commercial agreements between a supplier or distributor and the patent holder were not considered exempt from the on-sale bar. The CAFC further determined that under a supplier or distributor agreement, if there is a change in title, then a sale has occurred.

For example, a title transfer may occur when the supplier received blanket authority to market or disclose the invention. Other factors for consideration include whether products made by a licensed process were sold, or whether there was a secrecy agreement between the parties in the use of a process or device. The CAFC indicated that no individual factor determined a sale and that each situation was fact-specific. The commercial nature of the transaction between parties was at the core of the analysis to determine whether there was a sale. The court's analysis further relied on

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agreement language as interpreted using the Uniform Commercial Code. The lesson of these decisions is that parties should be very careful in drafting their agreements and in the way that they act.

In addition, under the prior statutory regime, public use and the on-sale bar could be intertwined. For example, in 1984, in *Kinzebaw v. Deere & Co.*[4], the CAFC indicated that a use that is secret but results in exploiting the invention for commercial purposes is likely to trigger the on-sale bar. Thus, the definition of commercial use has generally been quite expansive. However, with the AIA, the language concerning public disclosure changed and brought with it questions about the meaning and extent of the on-sale bar.

The *Helsinn* decision focused on whether a secret or private sale was still a sale under the post-AIA "on sale bar" statute. *Helsinn* had entered into a licensing agreement and a supply and purchase agreement with MGI Pharma Inc. The agreements were publicly reported but the details, including details about the patented process, were kept secret. Both agreements were ultimately deemed to be sales by the Supreme Court.

Specifically, the court determined that a secret sale was nonetheless a sale under the post-AIA on-sale bar statute because *Helsinn* made the agreement more than one year prior to submitting a patent application. The Supreme Court reasoned that the surrounding language in Section 102(a), "…in public use, on sale, or otherwise available to the public," did not change the meaning of "on sale" to only require public sales of an invention. The court further stated that a sale or offer for sale does not need to make the invention available to the public to act as a bar, and there is no requirement that more than one item needs to be sold, since a single item can trigger the on-sale bar.

In conclusion, the *Helsinn* decision merges the new language back into the old interpretation of "on sale." The current state of affairs should make inventors and small companies wary. Large companies may be able to design, test and manufacture products in-house while smaller companies have to outsource and rely on outside suppliers and/or distributors. With startups, the ability to obtain funding for manufacturing, testing, or even the patent application, often rely on or result in invention sales.

Small companies and startup entrepreneurs should be particularly careful about timing their patent applications to ensure that they are made within the one-year grace period, so as not to trigger the on-sale bar. Manufacturing, distribution, and testing agreements invoking a potentially patentable invention should also be carefully worded and care should be taken to avoid activities that are considered commercial, especially if agreement performance extends beyond the one-year period. Ideally, a patent application should be submitted well before the end of the one-year grace period.

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[1] 139 S.Ct. 628, 586 U. S. ____ (2019).
[2] 525 U.S. 55 (1998).
[3] 827 F.3d 1363 (Fed. Cir. 2016), and 881 F.3d 1347 (Fed. Cir. 2018).
[4] 741 F.2d 383 (Fed. Cir. 1984)

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