

Protecting Innovation While Justices Ponder Helsinn V. Teva

By **David Gornish** (December 13, 2018, 10:56 AM EST)

A substantial aspect of a patent attorney's practice involves advising clients about whether their inventions are sufficiently unique over the prior art to merit a patent. The term "prior art" essentially refers to types of information or activities that predate a given patent's filing date, as set forth in the Patent Act. Prior art is the primary evidence by which patentability is measured. If an invention lacks novelty or is obvious in view of the prior art, the invention is not patentable. On the other hand, if a given activity or piece of information is not prior art, it is effectively inadmissible for the purpose of demonstrating that the invention is obvious or lacks novelty. Therefore, in any patentability assessment, determining what qualifies as prior art is a threshold question.



David Gornish

Generally, whether evidence constitutes prior art hinges on its public accessibility before a patent's filing date. For example, earlier patents, printed publications and public uses (e.g., trade show demonstrations) are typical forms of prior art. The policy behind the patentability-negating power of such prefilings evidence is the law's "reluctance to allow an inventor to remove existing knowledge from public use."^[1]

There is another category of prior art in the United States, which historically has not required public availability to negate patentability, that of "on-sale" prior art. Under the 1952 Patent Act, the "on-sale bar," as it has come to be known, rendered an invention unpatentable if it was "on sale" in the U.S. more than one year before a patent application's filing date. The date immediately prior to this one-year grace period is known as the "critical date." The on-sale bar applies not only to sales prior to the critical date, but to commercial offers for sale as well, whether or not ultimately accepted and acted upon. The on-sale bar was predicated on the notion that an inventor should not be permitted to profit from commercializing an invention while waiting until much later to seek to extend exclusivity by applying for a patent.^[2] Accordingly, commercial utilization — not necessarily public availability — had been the linchpin of the on-sale bar. Indeed, in many instances, courts have found "secret" sales or offers for sale to constitute prior art under the 1952 Patent Act.^[3]

However, there is a possibility that the law could soon change in this regard. The 2011 Leahy-Smith America Invents Act modified the statutory definition of the types of things that constitute prior art. The altered statutory language may suggest that "on-sale" activities that are not public no longer qualify as prior art. This issue is now before the U.S. Supreme Court in *Helsinn Healthcare SA v. Teva Pharmaceuticals USA Inc.*^[4] The court heard oral arguments on Dec. 4, 2018, and will render a decision during the first half of 2019.

Steps to Safeguard Innovation Now, Before the Supreme Court Decision

As we await the decision in *Helsinn*, there are steps innovators may take to safeguard their confidential commercial activities from becoming patent-negating prior art. Innovators may look to guideposts that the U.S. Supreme Court established for navigating the on-sale bar two decades ago in *Pfaff v. Wells Electronics Inc.*[5] Notwithstanding that *Pfaff* was a pre-AIA decision, *Pfaff*'s on-sale bar framework is unlikely to be overruled in *Helsinn*. Neither party in the *Helsinn* briefs questioned *Pfaff*'s post-AIA applicability to the on-sale bar. The *Helsinn* lower courts, which applied *Pfaff*, never suggested it may no longer be good law. Moreover, during the *Helsinn* oral argument, the justices and counsel referenced *Pfaff* several times, with no one proposing that the case should or would be overruled.

Under *Pfaff*, the on-sale bar applies when two conditions are met during the relevant time [6]: (1) the claimed invention was the subject of a commercial offer for sale; and (2) the claimed invention was ready for patenting.[7] *Pfaff* instructs what an innovator can do to avoid creating self-inflicted "on-sale" prior art.

Starting with the first *Pfaff* prong, a commercial offer for sale is "one which the other party could make into a binding contract by simple acceptance." [8] This aspect is analyzed under commercial contract law principles. In any transaction or discussion, once commercial terms such as price, quantity, delivery, etc., are raised, the on-sale bar may be implicated. Therefore, if a patent application has not been filed, at the very least, one should take steps to reduce the likelihood that exchanges between parties could create a sales contract "by simple acceptance." Such precautions may include, e.g., one or more of the following: (1) not reducing such exchanges to writing; (2) qualifying discussions as providing only general estimates; (3) declaring that terms discussed are merely preliminary and that managerial approval is a precondition to providing a binding offer; and (4) "renting out" rather than selling (transferring title to) the invention. These precautions are not necessarily foolproof but may reduce the likelihood that transactions constitute "activities that would be understood to be commercial sales and offers for sale in the commercial community." [9]

The takeaway from the second *Pfaff* prong is even more compelling. If the claimed invention is indeed "ready for patenting," then the solution is straightforward: first file a patent application. An invention is "ready for patenting" if it is reduced to practice (i.e., actually made) or is "depicted in drawings or described in writings of sufficient nature to enable a person of ordinary skill in the art to practice the invention." [10] Sometimes at the invention ideation and mining stage, it is not entirely clear whether a given concept is sufficiently ripe for filing. Nevertheless, even if it appears that an invention is "unfinished," it is prudent to file on the best information that exists before engaging in any activity that could possibly be construed as an offer for sale. A provisional patent application is a perfect instrument to secure an early patent filing date. This process requires coordination between sales and legal teams, e.g., by a project manager. Timely filing of a provisional patent application is indeed an ounce of prevention that is worth a pound of cure in the on-sale context.

The outcome of *Helsinn* will certainly be of interest to the patent community and to industry generally. However, regardless of that outcome, relying on the "secret" status of an offer for sale, is not an ideal first-line argument to support a patent's validity. Best practices for innovators engaged in early stage commercialization, as set forth above, will go a long way in rendering the outcome in *Helsinn* largely irrelevant to them.

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[1] [Pfaff v. Wells Electronics Inc.](#) , 525 U.S. 55, 64 (1998)

[2] [Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.](#) , 153 F.2d 516, 520 (2d Cir. 1946) (An inventor “shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly,” via a patent.).

[3] See, e.g., [Hamilton Beach Brands Inc. v. Sunbeam Products Inc.](#) , 726 F.3d 1370 (Fed. Cir. 2013); [Brasseler U.S.A. I LP v. Stryker Sales Corp.](#) , 182 F.3d 888 (Fed. Cir. 1999); [Bone Care International LLC v. Pentech Pharmaceuticals Inc.](#) , 2012 WL 1068506 (N.D. Ill. March 29, 2012).

[4] Case No. 17-1229, in the Supreme Court of the United States.

[5] 525 U.S. 55.

[6] The relevant time according to the pre-AIA statute is prior to the critical date. The relevant time according to the AIA is prior to the application filing date.

[7] *Pfaff*, 525 U.S. at 67.

[8] [The Medicines Company v. Hospira Inc.](#) , 881 F.3d 1347, 1351 (Fed. Cir. 2018).

[9] *Id.* (internal quotations omitted).

[10] *Hamilton Beach*, 726 F.3d at 1375.