

IP Alert: Helsinn v. Teva at the Supreme Court: Did the America Invents Act Change the On-Sale Bar?



Helsinn v. Teva **at the Supreme Court: Did the America Invents Act Change the On-Sale Bar?**

By Sarah A. Kagan

The U.S. Supreme Court entertained very lively oral arguments December 4, 2018, on the definition of prior art under the Leahy-Smith America Invents Act (AIA). Pub. L. No. 112-29, 125 Stat. 284, 285-286 (2011). When Congress used terms from the pre-AIA statute in its drafting, did the meaning of those pre-AIA terms change or did the pre-AIA case law interpreting those terms carry forward? The Federal Circuit ruled that there was no change to the term “on sale,” because the legislative history did not clearly demonstrate that Congress intended to overturn any prior “on sale” cases. To the Federal Circuit, the use of “on sale” meant that all past case law on the meaning of “on sale” was still in effect, including its case law that the term covered private, secret, on-sale activities. Those nonpublic sales activities could invalidate patents under its case law.

During the oral arguments at the Supreme Court, each party discussed canons, rules of statutory construction, and rules of English language grammar to persuade the Court that the party’s position was meritorious.^[1] Despite all the arguments, the plain meaning of terms, as commonly understood, seemed to be most persuasive. The key provision of the law that requires statutory interpretation is Section 102(a)(1) which reads:

(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.

The key portion of Section 102(a)(1) that requires statutory interpretation is the phrase “or otherwise available to the public.” Does that addition to the statute serve one or two functions? Does it simply add a fifth category of prior art, in addition to (1) patents, (2) printed publications, (3) public uses, and (4) on sale? Or does it also modify (and narrow) any prior categories, in particular “on sale?”

Initially petitioner Helsinn seemed to stake out the difficult position that its interpretation of the AIA, that private sales were excluded from prior art, was not a change of the meaning of “on sale,” but a mere clarification that agreed with all Supreme Court holdings but drew back from Federal Circuit holdings. Some justices, however, seemed prepared to acknowledge that the catch-all phrase (“or otherwise...”) affected the meaning of “on sale.”

Teva, the respondent, argued it would be “strange” that Congress would use the term to both expand and contract the pre-AIA categories of prior art, which it would have done if the term served two functions. Helsinn urged that the term indeed is bifunctional, giving examples of other cases where the Supreme Court interpreted “otherwise” as performing both narrowing and expanding functions.

Teva tried to use a sports example to make its point, which even self-proclaimed Yankees super-fan, Justice Sotomayor, did not buy. It argued that if a statute said “don’t engage in football, baseball, or swimming, or any other activity that involves use of a ball,” no one would think that it changed the meaning of swimming. Different justices tried examples of their own otherwise-like phrases to arrive at the plain meaning of the term. Perhaps the most successful example of an otherwise-like phrase like the statute was Justice Kagan’s pastry example: Don’t buy peanut butter cookies, pecan pie, brownies, or any dessert that otherwise contains nuts. Can one buy nutless brownies? Teva answered yes to Justice Kagan’s hypothetical. Justice Kavanaugh then told Teva that he thought Teva gave the wrong answer on the brownies, given its position on the interpretation of “on sale.”

A similar expression of support for the plain meaning came from Justice Alito. He hypothetically rewrote the statute to comport explicitly with Teva’s construction. He said that if the statute said “patented, described in a printed publication, or in public use, on sale publicly, on sale privately, or otherwise available to the public,” it would be nonsense. He found it difficult to get over the implication of the plain meaning of “otherwise,” i.e., that all the other things that preceded it are public.

The United States, as amicus curiae supporting Helsinn, staked out a position that the sale at issue from Helsinn to MGI had particular qualities preventing it from qualifying as an on-sale bar. First, MGI was not an ultimate consumer, but only a distributor. And second, passing of title to the product was subject to a number of contingencies.^[2] The U.S. urged the Court to look to the actual purpose and effect of the sale at issue. The Court should view the supposed sale as a financing agreement, the U.S. urged.

Justice Sotomayor seemed bothered by the malleability of the term “on sale” as the U.S. proposed, because she could find no definition of the term in the historical record to support it. Justice Sotomayor and Teva both seemed to disagree with the U.S. position,

stating that sales to distributors were actual sales. Teva pointed out that distributors sell over 90 percent of pharmaceuticals in the U.S.

Despite the care taken by Helsinn and the U.S. to characterize the AIA as not having changed but merely clarified the law, at least some of the justices pushed back against that proposition. Some justices seemed to think that the language of the statute was not ambiguous and its clear meaning might mandate the outcome.

As Teva seemed to sense the tide turning against it during the argument, it reminded the Court not to focus on the structure of the sales contract, because that was not in the question certified for review. The key to the question certified was the confidentiality of the invention. It argued that confidentiality would be too large a loophole by which vendors could avoid the on-sale bar. Teva also raised the distinction between “available to the public” and “under a confidentiality agreement,” the issue in the question granted certiorari. These are not, it implied, merely opposite halves of the same pie. The arguments of Helsinn and the U.S. related to the former, Teva, said, but the latter is more problematic, as it could be easily manipulated by a savvy seller to convert mass sales into non-statutory events.

The definition of prior art is one of the most fundamental issues in both patent procurement and litigation. The decision of the Court in this case is likely to have a significant effect.

Click [here](#) to read the transcript of arguments in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc.*

Click [here](#) to download a printable version of this article.

[1] For example, the series modifier rule, the rule of last antecedent, and the *noscitur a sociis* canon of construction (the meaning of a word may be known from its companions).

[2] Neither party raised in the hearing the issue of regulatory approval, which Helsinn had not obtained at the time of the contract with MGI. The lack of regulatory approval would have prevented sales to end users at that time. This may be one of the contingencies.

Posted: December 5, 2018