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4 PTAB Lessons On Scope Of On-Sale Prior Art

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Petitioners in post-grant review and covered business method proceedings under the America Invents Act can present challenges to patentability based on "on-sale" prior art. This is not the case in inter partes review proceedings, which are limited to challenges based on patents and printed publications.[1] Thus, PGRs and CBMs provide petitioners with a greater array of prior art to develop patentability challenges.

Under pre-AIA law, the on-sale bar can be triggered by both public and private sales and offers for sale.[2] Under the AIA, a person is 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."[3] The new statute raises the question of whether the scope of the on-sale bar has changed under the AIA. The Federal Circuit has yet to construe the AIA's on-sale bar provisions. However, recent PTAB decisions offer guidance on this issue.

1. **On-sale activity must be made "available to the public" to constitute prior art under the AIA.**

   The scope of the AIA's on-sale bar provisions was at issue in Dr. Reddy's Labs. Ltd. et al. v. Helsinn Healthcare SA, PGR2016-00008 (PTAB Aug. 17, 2016). In such case, the patent owner entered into several supply and purchase agreements with a customer, MGI Pharma Inc. Details concerning such agreements were made available in MGI's Form 8-K U.S. Securities and Exchange Commission filings and the patent owner's press releases. The petitioner asserted that such SEC filings and press releases constituted on-sale prior art under AIA § 102. The petitioner did not argue that the SEC filings and press releases were publicly available. Rather, the petitioner argued that "the [AIA] did not change the law to require that 'on sale' activity be 'public' in order to qualify as invalidating prior art."[4]

   The PTAB panel disagreed. The panel reasoned that the phrase "otherwise available to the public" in the statute modified the previous clauses.[5] Based on this interpretation, the panel concluded that "the sale must make the claimed invention available to the public in order to trigger the on-sale bar."[6] The panel adopted the reasoning of the district court in a related litigation, Helsinn Healthcare SA v. Dr. Reddy's Labs. Ltd., No. 11-3962, 2016 WL 832089, 39 (D.N.J. March 3, 2016). In that case, the district court determined that AIA § 102(a)(1) "requires a public sale or offer for sale of the claimed invention."[7] The district court stated that "[t]he new requirement that the on-sale bar apply to public sales comports with the plain language meaning of the amended section, the USPTO's interpretation of the amendment, the AIA Committee Report, and Congress's overarching goal to modernize and streamline the United States patent system."[8]

   Thus, petitioners seeking to assert on-sale prior art should bear in mind that private sales activity may not trigger the on-sale bar under the AIA.

2. **Evidence of on-sale activity must demonstrate that the claimed invention was available to the public.**

   In Dr. Reddy's, the panel determined that, although the SEC filings and press releases made public the existence of the supply and licensing agreements, the petitioner "has not shown that the heavily redacted SEC filings or the press releases, devoid of detail, made the claimed invention available to the public."[9] Specifically, the panel determined that the SEC filing was redacted to remove information pertinent to features recited in the claims such as dosages and concentrations.[10] The panel determined that, absent such details, the agreements did not make "the claimed invention" available to the public, and thus denied institution.[11]

It is therefore critical to support challenges based on on-sale prior art with sufficient evidence which demonstrates that all of the features of the claimed invention were made available to the public through the sale.

3. "Legitimate concerns" with the petitioner's on-sale evidence are not always fatal to institution.

In Altaire Pharmaceuticals Inc. v. Paragon Bioteck Inc., PGR2015-00011 (PTAB Nov. 14, 2016), the petitioner presented an obviousness challenge based on two of the petitioner's products sold and distributed to a customer. The petitioner provided test results and testimony to demonstrate that the sold products possessed certain claim elements.[12] In response, the patent owner challenged the reliability of the petitioner's testing methodology by relying on inventor testimony submitted during prosecution of the patent.[13] The panel was not persuaded by the patent owner's argument and instituted trial. Specifically, the panel determined that (1) the patent owner did not sufficiently explain how the inventor's testimony demonstrated the unreliability of the petitioner's testing methodology, and (2) evidence characterized by the patent owner as a "study" was merely an excerpt from a laboratory notebook containing handwritten notes and insufficient test results which did not support the petitioner's arguments.[14]

Interestingly, while the panel admitted that the patent owner raised "legitimate concerns" regarding the petitioner's testing methodology, the panel concluded that such concerns did not preclude institution.[15] The panel explained that, "upon institution, a post-grant review proceeding provides the opportunity for discovery of 'evidence directly related to factual assertions advanced by either party in the proceeding.'"[16] Thus, the fact that the patent owner would have opportunities to further develop the record and challenge the petitioner's evidence during trial weighed in favor of the panel's decision to institute.

In Altaire, the noted deficiencies in the petitioner's on-sale evidence eventually caught up to the petitioner during trial and in the panel's final written decision. The patent owner's arguments which persuaded the panel to rule in its favor were similar to arguments advanced in the patent owner's preliminary response and deemed (at the time) to be unpersuasive for purposes of institution.[17] That is, arguments which were unsuccessful at institution were ultimately successful after conducting the trial and in view of a fully developed record.

4. The weight given to on-sale testimonial evidence of on-sale activity will depend on the quality of the underlying facts or data.

In addition, the panel determined that the testimony relied on by the petitioner was entitled to little or no weight because it failed to explain the manner in which the test was performed and how the data was generated, and thus did not meet the requirements of 37 C.F.R. § 42.65(b).[18] Specifically, the panel noted the petitioner's assertion that the test data shows the petitioner's product meets certain claim limitations, but determined that the "only declaration submitted with the Petition ... fail[ed] to explain, among others, how the test was performed and how the data was generated."[19] The panel stated that the patent owner's knowledge of the details of the petitioner's test method did not relieve the petitioner's duty to provide these details to the panel.[20] Thus, as with all other testimonial evidence submitted to support a challenge to patentability, the weight given to testimony supporting an on-sale challenge will depend on the quality of the underlying facts or data upon which the testimony is based.

Conclusion

There is limited administrative and judicial guidance on the scope of on-sale prior art under the AIA. Notably, the PTAB decisions discussed above are nonprecedential, and the Federal Circuit has not yet opined on this issue. Nevertheless, the above decisions provide valuable guidance for navigating on-sale prior art issues. First, the PTAB has determined that, under the AIA, sales activities must be made available to the public to constitute prior art. Second, petitioners should ensure that on-sale prior art evidence sufficiently discloses the features of the claimed invention to the public. Third, as with all other testimonial evidence, petitioners should bear in mind that the weight given to testimony submitted to support on-sale prior art will depend on the quality of the underlying facts or data. Fourth, patent owners should not automatically abandon arguments which are unsuccessful during the institution stage. As seen in Altaire, the PTAB may view arguments in a different light after conducting a trial and with the benefit of a fully developed record.

[1] 35 U.S.C. §§ 321(b) and 282(b)(2); AIA § 18(a)(1)(C); 37 C.F.R. §§ 42.204(b)(2) and 42.304(b)(2).

[2] 35 U.S.C. § 102(b) [pre-AIA]. See also Medicines Co. v. Hospira, Inc., 827 F.3d 1363, 1376 (Fed. Cir. 2016).

[3] 35 U.S.C. § 102(a)(1).

[4] Dr. Reddy's Labs., PGR2016-00008, Paper 2, at 39-42 (PTAB Feb. 5, 2016).

[5] Id.

[6] Dr. Reddy's Labs., PGR2016-00008, Paper 11, at 18-20 (PTAB Aug. 17, 2016).

[7] Helsinn Healthcare S.A. v. Dr. Reddy's Labs., Ltd., No. 11-3962, 2016 WL 832089, 45 (D.N.J. March 3, 2016)

[8] Id.

[9] Dr. Reddy's Labs., PGR2016-00008, Paper 11, at 20 (PTAB Aug. 17, 2016).

[10] Id. at 16.

[11] Id. at 20.

[12] See Altaire Pharmaceuticals, PGR2015-00011, Paper 14, at 11 (PTAB Nov. 16, 2015).

[13] Id. at 12.

[14] Id. at 12-13.

[15] Id. at 13-14.

[16] Id. at 15 (citing 35 U.S.C. § 326(a)(5); 37 C.F.R. § 42.51).

[17] See id. at 13; Altaire, PGR2015-00011, Paper 48, at 17-20 (PTAB Nov. 14, 2016); Altaire, PGR2015-00011, Paper 7, at 16-18 (PTAB Aug. 24, 2015).

[18] See Altaire Pharmaceuticals, PGR2015-00011, Paper 48, at 14 (PTAB Nov. 14, 2016); see also 37 C.F.R. § 42.65(b).

[19] See Altaire Pharmaceuticals, PGR2015-00011, Paper 48, at 14 (PTAB Nov. 14, 2016).

[20] See id. at 17.