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It's Printed, but Is It Published? More Informative Guidance from the PTAB

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In prior blog posts <u>here</u> and <u>here</u>, we explored various aspects of the Patent Trial and Appeal Board's ("PTAB") analysis of documents as printed publications during patent examination and *inter partes* review ("IPR"). The PTAB's Precedential Opinion Panel ("POP") has been busy reviewing various decisions in this area, and recently designated four of them as Informative. The decisions pertain to theses, drug package inserts and conference papers, and we discuss each of them here.

This Is Not Enough for a Thesis

In <u>Argentum Pharmaceuticals LLC v. Research Corporation Technologies, Inc.</u>, [1] the PTAB instituted the IPR, but held that the petitioner, Argentum Pharmaceuticals LLC ("Argentum") failed to carry its burden of showing that a Ph.D. thesis was sufficiently publicly accessible to qualify as prior art. Argentum argued: (1) In a district court litigation, the patent owner stipulated to public availability, thereby effectively admitting that the thesis qualifies as prior art; (2) the university at which the thesis is located denied a request for information regarding public access to the thesis; and (3) evidence indicates "that the University of Houston's theses were generally accessible to the public" in the relevant time frame.

The PTAB turned aside reason (1), stating that the patent owner may have had a different reason, in that forum, to enter into the stipulation, and that that itself did not constitute evidence.^[2] As to reason (2), the PTAB held that the refusal to provide information, by itself, is not sufficient. Finally, as to reason (3), the evidence that Argentum presented was personal knowledge of individuals, and not evidence of public accessibility itself. Consequently, the PTAB held that the thesis did not qualify as a printed publication.

This Is Enough for a Thesis

In <u>Seabery North America, Inc. v. Lincoln Global, Inc.</u>, [3] the PTAB instituted the IPR, finding that, for purposes of institution, the petitioner, Seabery North America, Inc. ("Seabery") made a sufficient showing that a Ph.D. dissertation was deposited in a library and indexed. As part of this showing, Seabery provided a declaration from the dissertation author's adviser, attesting to the adviser's

supervision of preparation. The adviser also attested to the university rules, requiring that the dissertation be deposited in the university's library. The adviser also testified that the dissertation is indexed in the national library system. The adviser testified further as to a copyright and publication date for a dissertation reprint, and of publication of excerpts based on the dissertation.

The patent owner, Lincoln Global, Inc. ("Lincoln") acknowledged the evidence, but argued that the evidence was insufficient. The PTAB disagreed with Lincoln, and found that, at the institution stage, the dissertation qualified as a prior art printed publication.

This Is Enough for a Drug Package Insert



In Sandoz Inc. v. AbbVie Biotechnology Ltd., [4]

the PTAB denied institution of the IPR, but held that the petitioner, Sandoz Inc. ("Sandoz"), made a sufficient showing that a 2003 Humira Package Insert (hereinafter referred to as "the Insert") qualified as a printed publication, and therefore as prior art, at least for purposes of instituting an IPR.

Sandoz argued that the Insert was publicly available on the website of the Food and Drug Administration ("FDA") no later than March 31, 2003, and relied on two pieces of evidence. First, Sandoz provided a screenshot of the FDA website from the Internet Archive service (known colloquially as the "Wayback Machine"), accompanied by an affidavit from the Office Manager of the Internet Archive, attesting to a March 31, 2003 date. Second, Sandoz presented unrebutted expert testimony, which the PTAB credited, to establish the accessibility of the insert on the website of the Food and Drug Administration ("FDA"). The expert testimony indicated that interested persons of ordinary skill in the art exercising reasonable diligence could have located the Insert on the FDA website.

The patent owner, AbbVie Biotechnology Ltd. ("AbbVie"), argued that Sandoz failed to meet its burden. First, AbbVie argued that existence on the FDA website failed to establish public accessibility. Second, AbbVie argued that lack of indexing or searchability on the FDA website indicates lack of public accessibility. Finally, AbbVie argued that the expert testimony, along with the Wayback Machine evidence, failed to establish actual dissemination.

In response, the PTAB held that, while indexing is probative of public accessibility, evidence of indexing is not required in all cases. The PTAB also held that Sandoz's expert testimony was sufficient to show that a person of skill exercising reasonable diligence would have located the Insert on the FDA website. Consequently, the PTAB held that the Insert qualified as prior art, at least for purposes of instituting the IPR.

This Is Not Enough for This Conference Paper

In <u>In-Depth Geophysical, Inc. v. ConocoPhillips Company</u>, ^[6] the PTAB denied institution, based on an insufficient showing that a paper allegedly presented at a conference qualified as a printed publication for purposes of instituting an IPR.

The petitioner, In-Depth Geophysical, Inc. and In-Depth Compressive Seismic, Inc. ("In-Depth"), relied on three pieces of information to establish that the conference paper qualified as a "Printed Publication" and therefore as prior art. First, In-Depth cited a website, researchgate.net, at which an abstract of the paper was available, and on which there was a button saying, "download full-text". The website showed a date for the conference paper. Second, In-Depth referred to a European Patent Office ("EPO") citation of the article in an action from an EPO Examiner, rejecting the European counterpart application to the US patent that was the subject of the petition. Third, In-Depth cited the patent owner's own citation to the article in a replacement specification in that EPO application.

The patent owner, ConocoPhillips Company ("ConocoPhillips") made several arguments in response. First, ConocoPhillips argued that the researchgate.net date is not identified as a publication date, and that there is no explanation anywhere as to what that date might represent. Second, ConocoPhillips argued that the paper itself merely lists a copyright date of 2012, and that the download date on the copy that In-Depth provided listed a download date within the one-year grace period of 35 U.S.C. § 102(b). Further, relying on declaration evidence, ConocoPhillips argued that historically, papers presented at the conference in question were only made available at and after the conference. Because the conference itself occurred within the one-year grace period, the paper was likely made available at the conference, not before, and therefore did not qualify as prior art. Finally, ConocoPhillips argued that citation of the article in the EPO does not show that the article is prior art under US law because the EPO standard for novelty ("absolute novelty") does not include a grace period.

The PTAB agreed with ConocoPhillips, making two points in particular. First, there did not appear to be any other acknowledged indicia of public availability, such as express publication dates, libraries, journal numbers, or International Standard Book Number ("ISBN") codes, or Library of Congress Control Number ("LCCN"). Second, the PTAB found that the declaration evidence about handling of papers at the conference in question was persuasive, noting the declarant's extensive experience with the conference's sponsoring organization both as a member and a presenter. In-Depth had an opportunity to rebut the testimony in a reply which the PTAB authorized for other reasons, but In-Depth failed to present any such rebuttal. Consequently, the PTAB held that the paper did not qualify as a printed publication.

Takeaways

The PTAB wears two hats, one as a reviewer of patent applications and one as an adjudicator of patent disputes. As an adjudicator, the PTAB places the burden on a petitioner to establish a document's status as a printed publication, and performs a fact-specific analysis. It behooves an IPR petitioner to think about the nature of the documents that form the basis of an IPR petition, and to take necessary steps to substantiate a document's status as a printed publication at the time of filing the petition. If that effort looks to be excessive, it would be worth considering whether, much less how, to use the potentially problematic document in the IPR.

[2] Apple, Inc. v. DSS Tech. Mgmt., Inc., Case IPR2015-00369, Paper 14, slip op. at 5 (PTAB Aug. 12, 2015) (requiring a "threshold showing" of public availability in order to institute trial); Hughes Network Systems, LLC v. California Institute of Technology, IPR2015-00059, Paper 34, slip op. at 4 (PTAB

Dec. 30, 2015).

[3] Case IPR2016-00840, Paper 11, October 6, 2016, designated Informative as to Section II.A.i. April 7, 2020.

[4] Case IPR2018-00156, Paper 11, June 5, 2018, designated Informative as to Section II.C.1. April 7, 2020 (n.b. there is no Section II.C.1 in this decision, but the discussion of printed publication as prior art occurs in Section III.C.1).

[5] See Voter Verified, Inc. v. Premier Election Sols., Inc., 698 F.3d 1374, 1381 (Fed. Cir. 2012); In re Klopfenstein, 380 F.3d 1345, 1350 (Fed. Cir. 2004) ("distribution and indexing are not the only factors to be considered in a § 102(b) 'printed publication' inquiry").

[6] Case IPR2019-00849, Paper 14, September 6, 2019, designated Informative as to Section I.E. April 7, 2020.

[7] See REG Synthetic Fuels, LLC v. Neste Oil, OYJ, IPR2018-01374, Paper 11 at 6 (PTAB Feb. 19, 2019). A date and copyright notice alone fail to shed sufficient light on a date of public accessibility. Additional evidence is necessary. See, e.g., Ford Motor Co. v. Cruise Control Techs. LLC, Case

IPR2014-00291, slip op. at 9-10 (PTAB June 29, 2015) (Paper 44).

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