

PTAB Strategies and Insights

April 2020





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Dear,

The PTAB Strategies and Insights newsletter provides timely updates and insights into how best to handle proceedings at the USPTO. It is designed to increase return on investment for all stakeholders looking at the entire patent life cycle in a global portfolio.

This month you will find three articles covering:

- The Federal Circuit clarifies the notice requirements of the Administrative Procedure Act for motions to amend.
- The Federal Circuit's COVID-19 response suggests a new approach to oral argument, especially in PTAB cases.
- What evidence can demonstrate that a printed publication was publicly accessible?
- A review of our most recent client alerts

We welcome feedback and suggestions about this newsletter to ensure we are meeting the needs and expectations of our readers. So if you have topics you wish to see explored within an issue of the newsletter, please reach out to me.

To view our past issues, as well as other firm newsletters, please click here.

Best. Jason D. Eisenberg

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Recent Client Alerts

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THE FEDERAL CIRCUIT CLARIFIES THE NOTICE REQUIREMENTS OF THE ADMINISTRATIVE PROCEDURE ACT FOR MOTIONS TO AMEND

By: William H. Milliken

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By: Kristina Caggiano Kelly and Patrick Murray

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By: <u>Deborah Sterling</u>, Ph.D.

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RECENT CLIENT ALERTS

We wanted to share our recent client alerts with you and hope you find them informative. Please feel free to reach out to us if you have any questions.

- <u>Supreme Court Holds That PTAB Time-Bar Rulings</u> <u>Are Non-Appealable</u>
- PTAB Due Date Extensions Available Under CARES Act Amid COVID-19 Outbreak
- <u>USPTO Due Date Extension Available</u> <u>Amid COVID-19 Outbreak</u>
- <u>IP Hot Topic: Quick Tips for Navigating PTAB</u> Remote Procedures

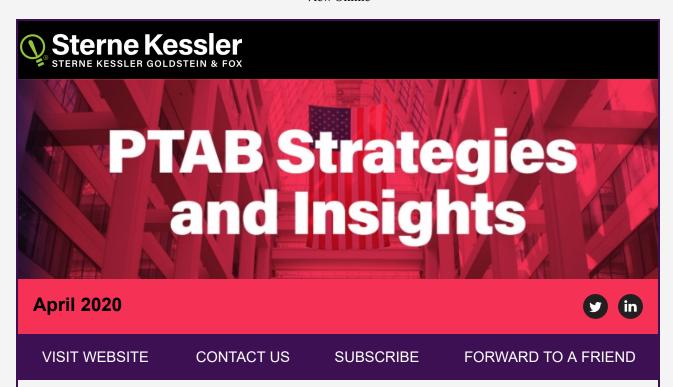


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WHAT EVIDENCE CAN DEMONSTRATE THAT A PRINTED PUBLICATION WAS PUBLICLY ACCESSIBLE?

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On April 7, 2020, the Patent Trial and Appeal Board (PTAB) clarified what evidence can demonstrate that an asserted reference qualifies as a printed publication. This two-section article will first address four decisions designated informative, which shed light on how a petitioner in an IPR might successfully show a reference is a printed publication. Secondly, it will address a fifth decision, designated precedential, that clarified the difference between the burden to show a reference is a printed publication during *ex parte* examination versus in an *inter partes* review (IPR).

PART I: Burden to show a prior art printed publication in IPR

The four decisions summarized below provide guidance for Petitioners about the types of evidence of public accessibility the PTAB finds compelling, whereas Patent Owners should note how to challenge such evidence when it is insufficient.

Petitioner unsuccessful:

In Argentum Pharmaceuticals LLC v. Research Corp. Techs., Inc., IPR2016-00204, Paper 19 (informative), the petitioner was unable to demonstrate that a doctoral thesis from the University of Houston was a printed publication. One argument was that the patent owner had already conceded public accessibility in an unrelated district court case. But the PTAB found it was not sufficient to demonstrate the same in the IPR because the concession was limited to the litigation and not applicable to the IPR. Nor did the PTAB find the petitioner's assertion that theses from University of Houston are generally publicly available enough. Petitioner argued that citations in academic papers to other University of Houston theses should be enough evidence. But the PTAB disagreed because none of the citations were to the thesis of interest. Denial by the University of the petitioner's request for information on public access to the thesis was equally unpersuasive to the PTAB.

In *In-Depth Geophysical, Inc. v. ConocoPhillips Co.*, IPR2019-00849, Paper 14 (informative), the petitioner was unable to demonstrate that a conference paper was a prior art printed publication. The petitioner relied upon an entry in the Researchgate website that listed the paper's title next to a date of "September 2012" – a date more than one year prior to the challenged patent's November 1, 2013 priority date. However, the petitioner presented no evidence as to what the Researchgate date meant. More damning was that the patent owner

provided expert testimony that the paper was presented in a conference in November 2012, and papers were generally not release until the first day of the conference: in this case, November 4, 2012, less than one year before the critical date. Based on this publication date, the reference did not qualify as prior art under AIA 35 U.S.C. § 102(b)(1). Even the fact that a European patent examiner had relied upon the same paper in an Office Action of the European equivalent was unpersuasive to the PTAB because of Europe's absolute novelty provisions, which do not contain a 1-year grace period like the U.S.

Petitioner successful:

In *Seabery N. Am. Inc. v. Lincoln Global, Inc.*, IPR2016-00840, Paper 11 (informative), the petitioner, like in *Argetnum* above, relied on a thesis, this time from the University of Bremen, Germany. The petitioner also provided testimony from the author's thesis advisor that: (1) the University's rules at the time the thesis was written required the thesis to be deposited at the library; (2) he personally confirmed it was deposited and available for public retrieval; (3) the work was indexed in Germany's national library system; (4) a reprint of the dissertation bears a copyright and publication date; and (5) excerpts based on the dissertation were published elsewhere. This was sufficient to demonstrate public accessibility for institution.

In Sandoz Inc. v. AbbVie Biotechnology Ltd., IPR2018-00156, Paper 11 (informative), the petitioner relied on a drug package insert providing evidence from the Internet Archive and Wayback Machine to demonstrate that the package insert was publicly available on the FDA's website. The petitioner also provided expert testimony that (i) a skilled artisan would know that labels for drugs were available for review on the FDA website, (ii) physicians could and did access that website, and (iii) a skilled artisan could have easily accessed the website and found the specific drug package insert relied on by the petitioner. While the PTAB denied institution on the merits, it did, nonetheless, find the proffered evidence sufficient at institution to show the drug package insert to be a printed publication.

PART II: Burden to show prior art printed publication in *ex parte* examination is different than that in IPRs

In *Ex Parte Grillo-Lopez*, Appeal 2018-006082 (precedential), the patent applicant was faced with the same potential prior art that a petitioner presented in IPR proceedings. In the IPR proceedings, the PTAB held that the petitioner did not carry its burden to establish that the publication in question was prior art. In the *ex parte* prosecution appeal, however, the PTAB held that the patent examiner established prior art status sufficiently to shift the burden to the applicant.

During prosecution, the Examiner had rejected Grillo-Lopez's patent application, in part, over a transcript of an FDA committee meeting. The Examiner asserted that the transcript was a printed publication by providing (i) publication of the Notice of Hearing of the July 25, 1997 meeting in the Federal Register, (ii) attendance of the hearing by interested members of the public, and (iii) legislation supporting public accessibility of FDA transcripts. Rather than rebut this evidence, Grillo-Lopez instead cited to PTAB decisions in which an IPR petitioner had failed to establish that the same or similar transcripts were printed publications.

In its appeal decision, the PTAB first clarified that burden framework during examination is different from that in an IPR. In a IPR, "at the institution stage, the petition must identify, with particularity, evidence sufficient to establish a reasonable likelihood that the reference was publicly accessible before the critical date of the challenged patent and therefore that there is a reasonable likelihood that it qualifies as a printed publication." However, as earlier PTAB decisions, held, in *ex parte* examination, "the examiner met his burden of proof by setting forth the nominal publication date. . . . The Patent and Trademark Office is in no position to establish any thing beyond that. The burden is clearly upon appellants to disprove the prima facie publication date established by the examiner." Based on this, the PTAB concluded that "the framework set forth [] for IPR proceedings does not apply to [patent] examination."

It is this difference in burden that allowed the PTAB to find that the Examiner could demonstrate public availability of an FDA transcript that had not been shown to be publicly available in an IPR: "Given the different legal frameworks and burdens for establishing a reference as prior art in IPR proceedings [compared to ex parte patent] examination, the Decision is not contrary to the Board decisions finding that a petitioner failed to meet its burden of showing that the FDA transcript is a printed publication."

This decision highlights the different between an examiner's low threshold to meet their burden

compared to a higher burden placed on a Petitioner for the same document.

* *

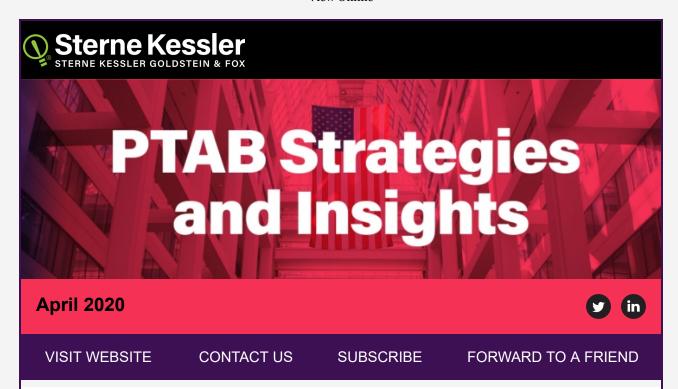
The takeaways here are two-fold. First, patent practitioners should not expect Examiners to meet a high burden to show that a reference is a "printed publication." Instead, practitioners should be prepared to present compelling rebuttal evidence. Second, post-grant practitioners challenging a patent should evaluate whether a prior art reference, whose status as a "printed publication" is arguable, might be better suited to file a request for *ex parte* reexamination rather than an IPR/PGR petition.

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In *Nike, Inc. v. Adidas AG*, No. 19-1262 (Fed. Cir. Apr. 9, 2020), the Federal Circuit offered important guidance to Patent Trial and Appeal Board (PTAB) litigants regarding how the notice requirements of the Administrative Procedure Act operate in the context of claim amendments during *inter partes* reviews (IPRs).

Adidas filed an IPR challenging the patentability of all claims of Nike's '011 patent. In response, Nike filed a motion to amend under 35 U.S.C. § 316(d), requesting cancellation of all claims and entry of substitute claims 47-50. Adidas opposed the motion, arguing that the substitute claims were unpatentable over a combination of three prior-art references. The Board agreed that the substitute claims would have been obvious and denied the motion to amend. On appeal, the Federal Circuit vacated the Board's decision, holding that the Board had failed to engage in "critical fact-findings needed for [the] obviousness determination."

On remand, the Board again found the proposed substitute claims unpatentable. In its analysis of claim 49, the Board relied on a prior-art reference called Spencer that, while in the record, had never been relied upon by Adidas in its obviousness arguments. Nike appealed a second time and argued that the Board violated the APA's notice requirements by failing to give Nike notice that it would rely on Spencer as an invalidating reference.

The Federal Circuit agreed. It held that, although "the Board may sua sponte identify a patentability issue for a proposed substitute claim based on the prior art of record," the Board "must provide notice of the issue and an opportunity for the parties to respond before issuing a final decision under 35 U.S.C. § 318(a)."

In other words, in addressing the patentability of substitute claims, the Board is *not* limited relying on "arguments and theories raised by the petitioner in its petition or opposition to the motion to amend"; the Board may rely on its own evaluation of the claims based on its consideration of the entire record. This only made sense, the panel explained, because any other rule would mean that the Board is unable to examine the patentability of proposed substitute claims at all in cases where the petitioner does not oppose a motion to amend. But, before relying on a theory of unpatentability not raised in the petition or an opposition to the motion to amend, the Board must explain the new theory to the patent owner and give the patent owner an opportunity to respond (through, for example, supplemental briefing or oral argument at the hearing). This notice, the *Nike* panel held, was compelled by § 554 of the APA and by the

Federal Circuit's own caselaw requiring the Board to "base its decision on arguments that were advanced by a party, and to which the opposing party was given a chance to respond." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016).

Applying these principles to Nike's case, the panel held that the Board had violated these notice requirements by failing to advise Nike of its intent to rely on Spencer in its obviousness analysis. "Nike," the panel explained, "had no notice that the Board might rely on Spencer to teach the limitations of substitute claim 49." The court accordingly vacated the Board's finding that claim 49 is unpatentable and remanded for further proceedings.

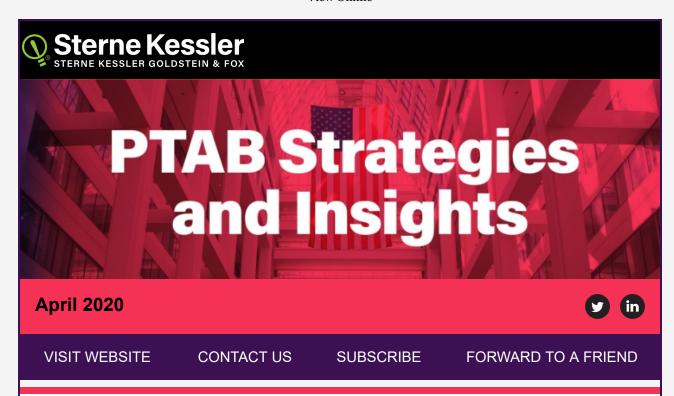
While the facts of *Nike* involved only a previously un-raised invalidating reference, the panel's holding appears to apply to any new argument that the Board might rely on in determining the patentability of proposed amended or substitute claims. So, for example, if the Board were to believe that a key term should be construed differently from the constructions proffered by the petitioner and the patent owner, the Board would need to provide both parties with notice of the potential alternative construction and an opportunity to submit arguments regarding that construction. The scope of the notice requirements outlined in *Nike* will likely be further refined in future litigation.

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The Federal Circuit is unique among the circuit courts, in that it grants oral argument as a matter of course for all represented appellants. Thus, unlike regional circuits with a well-established body of precedent regarding when oral argument is appropriate and when it is unnecessary, it is not clear what, if any, standard the Federal Circuit is applying in deciding when to cancel oral arguments.

Statistics may provide some insight. The table below summarizes the status of cases originally scheduled for oral argument in May. Although a limited data set, appeals from the Patent Office appear to be disproportionally impacted compared with other common types of appeals, with 50% of the originally scheduled oral arguments canceled.

In at least one case, however, the Federal Circuit has reversed its scheduled change. In *In re: Publicover*, an *ex parte* appeal from the Patent Office, the Federal Circuit reinstated oral argument after the appellant and its counsel contended that allowing the argument to take place would support diversity and inclusion initiatives within the legal profession, based on the attorney set to argue the case. It is possible that other types of justifications will also convince the Court to grant oral argument on a case-by-case basis, creating a body of precedent similar to that seen in regional circuits. We will continue to track and analyze this new trend in Federal Circuit jurisprudence.

May Federal Circuit Oral Arguments By Origin PTO (inter partes) Oral Argument Still On 10 Cancelled - Now on the Briefs 10 DCT Oral Argument Still On 12 Cancelled - Now on the Briefs CFC Oral Argument Still On 6 Cancelled - Now on the Briefs 2 **MSPB** Oral Argument Still On 3 Cancelled - Now on the Briefs 1 PTO (ex parte) 3 Oral Argument Still On Cancelled - Now on the Briefs 1 BCA Oral Argument Still On 2 Cancelled - Now on the Briefs 1 CAVC Oral Argument Still On 1 Cancelled - Now on the Briefs 1 CIT Cancelled - Now on the Briefs 1 ITC Cancelled - Now on the Briefs 1 **Grand Total** 59 Oral Argument Still On 37

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Cancelled - Now on the Briefs

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^{*} Originally 2 PTAB *ex parte* arguments were canceled, until *Publicover*'s cancellation was reversed.