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## Don't Overlook Evidentiary Issues In Post-Grant Proceedings

Law360, New York (June 13, 2016, 12:09 PM ET) -- From denying a famous hedge fund manager's inter partes review petitions, to upholding all claims at final written decision, the admissibility of evidence has played a key role in deciding the outcome of administrative proceedings before the Patent Trial and Appeal Board, such as IPR and post-grant review. But even with such impressive results, the admissibility of evidence remains an often ignored point.

Perhaps the PTAB's frequency in bypassing evidentiary challenges has swayed practitioners' focus away from issues that had them sweating the night before an evidence class final in law school. However, with such a powerful punch that can dispose of the case without the board even reaching the merits of the invalidity arguments, evidentiary challenges deserve a second look.

To know where to focus your attack — or shore up your petition — this article illustrates some evidentiary issues that have decided PTAB proceedings and provides some suggestions on where evidence can make or break a claim.

### All That's Fit to Print May Not Constitute Prior Art

Hedge fund manager Kyle Bass's first few world-famous IPR petitions were denied on evidentiary issues. In those petitions, the Coalition for Affordable Drugs sought to use two posters that were presented in meetings as prior art. The patent owner, in its preliminary response, argued that the posters did not qualify as prior art printed publications.

The PTAB agreed and refused to institute the IPRs, finding insufficient evidence to show that the posters were publicly accessible to qualify as prior art "printed publications" under the patent statutes. Although the posters had been listed on an information disclosure statement (IDS) during publication, a listing on an IDS did not constitute an admission that the cited posters qualified as prior art.

The PTAB then considered factors indicative of whether or not the posters qualified as prior art printed publications, including (1) how long the posters were presented at meetings; (2) the expertise of the audience viewing the posters; (3) the expectation that the displayed material would be copied; and (4) the ease of copying the displayed material. The PTAB expressly stated that the petitioner had provided insufficient evidence to address these factors. The only evidence that the posters had been presented in the public was the IDS. Because the evidence was insufficient to reach the threshold determination that the posters constituted prior art, the posters were excluded from consideration. The petition



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consequently faltered on this evidentiary stumbling block, and the PTAB refused to institute trial on the patent.

The PTAB has also ruled on the publicly accessible aspect of prior art with regard to research theses. This issue also arises in district court litigation from time to time, particularly where the dissertation remained within the enclave of the student's university and was not published at large. In one IPR, the thesis put forward as prior art stated within its text that it had been presented to and approved by faculty members. However, the petitioner did not submit any evidence to show that it was deposited in the university library, or that it was indexed, cataloged, or shelved in some manner to make it publicly accessible. The PTAB contrasted the circumstances with one where the proponent of the prior art obtained affidavits from university library staff to attest to the likely date for public availability of the dissertation. The PTAB then excluded the thesis from evidence.

Another evidentiary challenge that brought down an IPR involved the use of an operator's manual for an orthopedic device. The petitioner sought to use the manual in combination with the device, which it alleged had been on sale before the filing of the patent. This challenge presented two issues. First, IPRs are limited to patents and printed publications. Thus, the device itself was not proper prior art for the proceedings. Second, the petitioner failed to submit evidence substantiating its position that the manual was a printed publication available before the critical date. Instead, it simply relied upon the purported first sale date of the device as the date the manual became publicly available.

In another example, the patent challenger submitted a short publication that alluded to a pilot study to be performed with a pharmaceutical. A description of the pilot study itself was not included, nor were the results of the study. The challenger submitted the testimony of its expert who opined that the publication appeared to show a test that, if it had occurred, could meet the claim limitations. The PTAB disagreed. First, absent a description of the study, there was no evidence that the study would meet each limitation of the claims. Further, expert testimony to substantiate what might have been done, without a printed publication evidencing the occurrence of the test and its result, did not qualify as prior art admissible in an IPR.

## **Federal Rules of Evidence Apply**

The Federal Rules of Evidence require authentication of documents — proof that a presented item is what it purports to be. Authentication has crept into PTAB proceedings on various occasions, commonly in the analysis of webpages as prior art.

For example, an oft-used prior art source is the Wayback Machine website. To use information from the Wayback Machine as evidence, you must authenticate the webpages. Authentication may be done through testimony regarding the functionality of the Wayback Machine, or testimony from a witness having personal knowledge of the webpages. Failure to authenticate webpages leads to exclusion of the evidence. Lack of authentication has been case dispositive where the Wayback Machine was used to provide either prior art content or a date for the prior art disclosure.

Similar issues have arisen with clinical trials posted on the ClinicalTrials.gov website. In at least one case, the PTAB rejected the website evidence because its content could not be authenticated as of its asserted date of publication. The PTAB faulted the challenger for not providing a witness with personal knowledge or providing other evidence of the public accessibility or dissemination of the document as of the critical date.

The import of the Federal Rules of Evidence includes the rule against hearsay. Out-of-court statements offered for their truth are inadmissible absent an exception to the rule. As with authentication, hearsay has been a factor with internet evidence.

For example, in one matter, hearsay was used to exclude the use of dates printed on websites to prove when the information on the websites was publicly available. The dates on the website included dates next to a copyright notice and dates within the text describing pictures. The PTAB found these dates were out-of-court statements offered for their truth and not subject to any hearsay exception. With the loss of the printed dates, the websites could not be invalidating prior art.

## **Be Mindful of PTAB Rules**

The PTAB has its own specific trial practice rules, which have been case dispositive. For example, the rules require that a non-English exhibit must include both a translation and an affidavit attesting to the accuracy of the translation. This rule becomes important when non-English prior art is used as a primary reference to invalidate patents.

In one case, the PTAB excluded the translation of a non-English foreign patent application because no affidavit was filed attesting to the accuracy of the translation. Because the translation was excluded, the PTAB only looked to the drawing of the patent application and an expert's declaration regarding the reference. These sources did not provide adequate evidence to invalidate the claims.

## **Key Takeaways**

Evidentiary issues cannot be overlooked in PTAB trials. Missteps have been case dispositive. Just as in trial, key exhibits should be vetted for potential evidentiary issues:

### ***Is it a printed publication?***

If you are submitting something other than a research article from a scientific journal or a patent, keep in mind that the document alone may not be sufficient. For example, submission of a research thesis may require an affidavit from someone at the library or university with knowledge of the indexing, cataloging or availability of the document. Similarly, for a poster that was displayed at a research conference, evidence that the poster was accessible to conference goers and accessible for them to copy or photograph the information can help support the admissibility of the document.

Devices and their operating manuals can provide some unique challenges as prior art. First, because the device itself does not qualify as prior art, the manual must supply sufficient detail of the device features to illustrate the elements of the claims. Second, the manual will likely require some accompanying evidence to show when and how it was publicly available.

### ***Is the date and content of the prior art authenticated?***

Websites are some of the trickiest evidence because the content of the site can change over time. The challenge is to prove the content of the site existed on a particular date. This may entail finding a witness to substantiate the authenticity of the alleged content or providing some additional means of evidencing the content's availability at that time. One option is a representative of the archiving site to attest to the methods of preservation and the content and date of the site in question. For sites such as ClinicalTrials.gov, researchers in the field or those involved in the trial may be able to provide personal knowledge of the website's content and when it was first posted. Even more challenging may be websites that themselves are not the prior art, but contain links providing accessibility to the alleged prior art. This opens a second layer of challenge to demonstrate that the links themselves were functional as of the critical date and provided publicly accessible content. Such substantiation may go beyond what the archiving site can provide as a corroborating affidavit.

***Does the document contain hearsay without an applicable exception?***

Scientific articles and patents rarely face hearsay challenges. Thus, the straight and narrow submissions of this type of prior art should not raise concerns. Where less traditional art is submitted, such as webpages or where other documents are used for substantiation of expert opinion, hearsay objections may be asserted. The same rules as in court apply — namely, is there an exception that provides admissibility? In some cases, the exceptions covering business records and government documents may be of help. In other cases, for example with expert opinion, the underlying document may not be admissible, but the expert can rely on it so long as it is of the type an expert in the field would reasonably rely upon.

***Don't put off until tomorrow what you can do today.***

It is advisable to select prior art and assure its admissibility from the outset. Waiting until the discovery period to investigate or relying on the later submission of supplemental evidence to provide the necessary information can be risky. For references that may be challenging to qualify as printed prior art, it is advisable to undertake pre-filing discovery so that a stronger case can be made for its admission. It may also be wise to perform additional prior art searches to replace this more risky art with reference having easier admissibility.

**Evidence Rules!**

So — whether you liked rules of evidence in law school or gave them a wide berth — do not shirk from considering them when gathering evidence for post-grant proceedings. For petitioners, attention to evidentiary issues at the outset will increase the likelihood that the PTAB will focus on the merits of your arguments rather than dismiss the petition on a technicality. And for patent owners — spotting evidentiary issues in a petition can deliver a knockout punch that can stop a challenger in its tracks.

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