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The availability of priority challenges in post-grant proceedings offers a variety of strategic opportunities that may uniquely affect pharmaceutical and biopharma patents, the authors contend.

Using Priority to Challenge § 112 Support and Pre-AIA Status in Post-Grant Proceedings Before the PTAB

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Despite statutory limits on the scope of post-grant proceedings under the America Invents Act (AIA), the ability to challenge a patent's priority claim in an inter partes review (IPR) or post-grant review (PGR) proceeding can offer unique opportunities in the pharma and biopharma space. This article summarizes some recent examples and explores the strategic implications from the perspective of patent challengers as well as patent owner defendants.

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I. Introduction

Congress limited validity challenges in inter partes review to grounds based on novelty and nonobviousness.[1] But Congress did not specifically foreclose challenging the asserted priority date of the patent under review, allowing for IPRs based on intervening prior art. Similarly, the AIA limited the universe of patents that qualify for post-grant review to those resulting from an application having an effective filing date on or after March 16, 2013.[2] But, again, Congress did not foreclose challenging an asserted priority date to demonstrate that at least one claim in the patent has an effective filing date on or after March 16, 2013.

In general, the basis for a priority challenge is that, when an applicant files a continuing patent application, priority is asserted under 35 U.S.C. § 120. The validity of a priority date depends on whether the enablement and written description requirements of § 112 have been satisfied.[3] The practical consequence of this, as it has played out before the Patent Trial and Appeal Board (PTAB) over the past three years, is that priority provides a backdoor for challenging § 112 support in post-grant proceedings.[4]

[1] 35 U.S.C. § 311(b).

[2] Pub. L. No. 112-29, § 3(n), 125 Stat. 293 (Sept. 16, 2011).

[3] *See In re NTP, Inc.*, 654 F.3d 1279, 99 U.S.P.Q.2d 1481 (Fed. Cir. 2011) (82 PTCJ 465, 8/5/11).

[4] *See, e.g., Nissan N. Am., Inc. v. Bd. of Regents, Univ. of Tex. Sys.*, IPR2012-00037, Paper No. 24, pp. 8-9 (Mar. 19, 2013) ("[T]o determine whether a cited patent or printed publication is 'prior art,' we consider whether the [p]atent is entitled to [priority] benefit."); *SAP Am., Inc. v. Pi-Net Int'l, Inc.*,

Of particular interest to the pharma and biopharma industry, this article analyzes cases identified by screening IPR and PGR proceedings to reveal the subset where petitioners challenged priority based on § 112, first paragraph, to contest support for claims directed to a genus, similar to the fact patterns presented in *Ariad v. Eli Lilly*.[5] and, more recently, *AbbVie v. Janssen Biotech*.[6] A successful priority challenge based on § 112, first paragraph, permits intervening art to be used against the challenged patent and may cast an ominous cloud over the entire patent family. Therefore, it is valuable to understand how the PTAB treats priority challenges, and to what degree priority challenges are successful in initiating AIA trials.

Entitlement to priority under § 120 focuses on possession and enablement of the claimed invention as of the asserted priority date. By definition, a priority application will have been filed *before* the application claiming its benefit, which could be at a time when the field or technology was relatively nascent. As time passes, presumably the state of the art matures, rendering the relevant technology more developed and predictable.[7] Accordingly, the passage of time can reduce the extent of disclosure required to comply with § 112, first paragraph.

A challenge to a patent's priority claim is constructively a challenge to its *parent* under § 112, first paragraph, unless the issue boils down to new matter, e.g., new description added in a continuation-in-part or an expansive new claim not supported by the priority application. In contrast, when the patent under review is a straight continuation of its parent, both patents may be adversely impacted by a judgment that the written description is inadequate. Accordingly, not only may the patent under review be subject to intervening prior art under § 102 or § 103, but the written description it shares with its parent may be viewed as insufficient to support the subject matter.

Under *In re NTP*, an assertion of priority may be ineffective even among straight continuations, where the text of the priority application and the challenged patent are presumed to be identical.[8] While *In re NTP* involved an *inter partes* reexamination, it has been cited by the PTAB as a source of authority to analyze priority in IPR proceedings, despite statutory limits circumscribing its invalidation authority to § 102 and § 103.[9] By extension, the PTAB may be willing to examine priority entitlement based on § 112, first paragraph, among straight continuations.

II. Recent Cases Studies

We screened the PTAB's IPR docket for petitions challenging priority. Several IPR proceedings were identified, but the following were deemed to be of particular interest to the pharma and biopharma industry. As a complement to this study, PGR proceedings were analyzed to determine whether priority challenges have been used to sweep ''bridge patents''[10] into this venue for contesting validity. While PGRs are limited in availability to the first nine months after issuance, the petitioner may pursue grounds beyond § 102 and § 103, including § 112, first paragraph (written description, enablement), and § 101 (subject matter eligibility).

A. Exemplary Priority Challenges in Inter Partes Review Proceedings Filed Against Pharma and BioPharma Patents

What follows is an in-depth review of exemplary priority challenges in IPRs involving pharma and biopharma patents. These examples include situations in which:

(1) the challenged patent is a straight continuation of its parent, but the claims allegedly recite an unsupported genus;

(2) the challenged patent discloses the sequence of an extracellular protein but allegedly does not disclose an antibody capable of binding to it that produces the desired therapeutic effect; and

(3) the challenged patent claims a dosage limitation that is allegedly not supported by the experimental methods and results disclosed in the provisional application to which it claims priority.

In each instance, the petitioner asserted intervening prior art and challenged the patent's priority claim in its petition for inter partes review.

1. *Prism Pharma v. Choongwae Pharma*, IPR2014-00315

The claims at issue in *Prism Pharma v. Choongwae Pharma* are directed to conformationally constrained compounds that mimic the secondary structure of

IPR2014-00414, Paper No. 11, pp. 11-16 (Aug. 18, 2014) (holding the challenged claims were not entitled to priority and addressing intervening art); *SAP Am., Inc. v. Arunachalam*, IPR2014-00414, Paper No. 24, p. 21 (Aug. 17, 2015) (''A review of the disclosure for purposes of identifying the priority date for the claimed subject matter is appropriate and within the scope of *inter partes* review.'')

[5] *Ariad Pharm. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 2010 BL 62410, 94 U.S.P.Q.2d 1161 (Fed. Cir. 2010) (en banc) (79 PTCJ 623, 3/26/10).

[6] *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 111 U.S.P.Q.2d 1780 (2014) (88 PTCJ 651, 7/11/14). Jorge Goldstein, *Abbvie Deutschland and Unknown Embodiments: Has the Written Description Requirement for Antibodies Gone Too Far?*, Bloomberg BNA - *Patent, Trademark and Copyright Journal* (May 8, 2015) (90 PTCJ 1959, 5/8/15).

[7] *See Capon v. Eshhar*, 418 F.3d 1349, 1357-58, 76 U.S.P.Q.2d 1078 (Fed. Cir. 2005) (70 PTCJ 456, 8/19/05).

[8] Eric K. Steffe, Eldora L. Ellison, Christopher M. Gallo, *Strategies for Challenging Patents in Pharma and BioPharma in the Wake of In re NTP*, Bloomberg BNA - *Patent, Trademark and Copyright Journal* (Feb. 17, 2012) (83 PTCJ 549, 2/17/12).

[9] *See, e.g.*, *Rackspace US, Inc. v. PersonalWeb Technologies, LLC*, IPR2014-00058, Paper No. 10, pp. 15-16 (Apr. 15, 2014) (''We recognize that 35 U.S.C. § 311(b) limits a petitioner's challenge, in an *inter partes* review, to grounds of unpatentability under 35 U.S.C. § § 102 or 103 based on prior art patents and printed publications. However . . . 35 U.S.C. § 311(b) does not prohibit a petitioner from asserting a ground of unpatentabililty under 35 U.S.C. § § 102 or 103 based on an intervening printed publication or patent.'')

[10] In this article, the term ''bridge patent'' is used to denote a patent issuing from an application filed after the effective date of the AIA, but which claims priority to one or more applications filed *prior to* the effective date of AIA. The significance of this is that a bridge patent with a valid priority claim to a pre-AIA application would not be eligible for PGR. But a bridge patent with a priority claim that the petitioner establishes is invalid *would* arguably be eligible for PGR.

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reverse-turn regions of biologically active peptides.[11] The reverse-turn mimetics are described in the specification as interfering with protein-protein interactions in signal transduction pathways and as being useful for treating disorders modulated by such pathways, including cancer. In its petition for inter partes review, Prism asserted that the challenged claims of the '738 patent recite a genus of compounds that includes a particular chemical substitution at a position allegedly not disclosed previously in the priority chain. While Prism acknowledged that the specifications between the '738 patent and its priority application were ''essentially identical,'' it argued that the challenged claims were nonetheless unsupported.

Prism is an interesting case study because it demonstrates how the record during prosecution can influence the PTAB's decision on whether to institute trial. In particular, during prosecution, one of the inventors left the patent owner's employ to co-found petitioner's company and develop competing products. In an attempt to prevent a patent from issuing, the inventor/former employee delivered an unsolicited declaration to the prosecuting attorney, attesting that the claims did not satisfy § 112, first paragraph, and were not entitled to priority benefit. In response, the prosecuting attorney withdrew the claims from issue and submitted the declaration to the Patent and Trademark Office. After considering the declaration, the examiner rejected a subset of the claims under § 112, first paragraph. After additional claim amendments and an examiner interview, the claims were eventually allowed.

In its petition, Prism argued that despite having considered the declaration, the examiner had overlooked persistent § 112, first paragraph, defects which Prism argued rendered the priority claim invalid. In response to Prism's petition, patent owner Choongwae highlighted the identicality of the disclosures between the '738 patent and its priority application, argued that the issue had already been addressed during prosecution, and observed that the examiner's conclusion that the claims satisfy the written description requirement necessarily meant that the identical specifications of the ancestral applications do as well. Choongwae also urged denial of the petition under 35 U.S.C. § 325(d), which authorizes the PTAB to exercise its discretion to deny grounds of a petition because they raise the same or substantially the same art or arguments previously considered by the Office.

Ultimately, the PTAB declined to institute trial by exercising its discretion under Section 325(d). In denying the petition, the panel highlighted the litigious history between the parties and the relationship between the inventor/former employee and petitioner. The panel noted that the petition raised the same priority issue previously considered during prosecution, observing that the claims were allowed after both the examiner and his supervisor specifically considered whether the claims satisfied § 112, first paragraph, in view of the inventor declaration.

As such, this case represents a rare example of the PTAB crediting the examiner's analysis during original prosecution to deny institution. Generally speaking, the Board has been resistant to exercising its discretion under Section 325(d) to deny grounds based on art or arguments previously considered by the Office in other contexts, citing differences between prosecution, reexaminations and post-grant proceedings—e.g., burden of proof, evidentiary standards, etc.[12]

2. *Daiichi Sankyo v. Alethia Biotherapeutics*, IPR2015-00291

The patent challenged in *Daiichi Sankyo v. Alethia Biotherapeutics* is directed to methods of impairing osteoclast differentiation and inhibiting bone resorption by administering an antibody that binds Siglec-15.[13] The specification explains that modulating osteoclast differentiation with an anti-Siglec-15 antibody is useful for treating osteoporosis.

In its petition for inter partes review, Daiichi acknowledged that the priority document of the '181 patent discloses the complete sequence of Siglec-15, but argued that the priority document did not disclose any antibody that binds Siglec-15 capable of inhibiting bone resorption or impairing osteoclast differentiation. Furthermore, Daiichi argued that, as of the filing date of the priority application, Siglec-15 was not known as an extracellular protein, nor was it sufficiently well-characterized that an antibody targeting an extracellular domain and having the necessary therapeutic activity could be predictably made. As such, the priority document lacked adequate written description to support or enable the claimed subject matter, rendering it susceptible to intervening prior art.

In response, patent owner Alethia countered that the inventors were the very first to discover that Siglec-15 is required for osteoclast differentiation and bone resorption and that antibodies binding Siglec-15 could be useful therapeutically—a discovery it asserted is adequately described and enabled in the priority document. In support, Alethia argued that the priority document describes use of a standard model of osteoclast differentiation (i.e., treating osteoclast precursor cells with RANKL and M-CSF) to identify Siglec-15 whose expression is up-regulated during osteoclast differentiation. And that it also describes validation of Siglec-15's function using small hairpin RNA knockdown assays and rescuing the Siglec-15 knockdown phenotype in mouse osteoclasts using human Siglec-15.

With its response, Alethia also re-submitted an expert declaration previously filed during prosecution. According to the declaration, the priority document's description of the new function of Siglec-15 in osteoclastogenesis was ''thorough and the results convincing'' and ''a person who has ordinary skill and is familiar with the field of antibody therapy for bone diseases would have recognized that the inventors of the [parent] application made an important contribution to the field by discovering this new function of Siglec-15 in osteoclast formation/differentiation in 2006.'' Alethia also asserted that osteoclastogenesis assays were standard in 2006 and routinely used to predict the osteoclast differentiation or bone resorption inhibitory activity.

Similar to the arguments made in *Prism*, Alethia urged the panel to exercise its discretion under Section

[11] *See* U.S. Patent No. 8,318,738.

[12] *Customplay, LLC v. Clearplay, Inc.*, IPR2013-00484, Paper No. 10 (Nov. 26, 2013) (''while the examiner's analysis is helpful, it is not binding on this proceeding''); *Macauto U.S.A. v. BOS GmbH & KG*, IPR2012-00004, Paper No. 18 (Jan. 24, 2013) (''[w]e have reviewed the declarations and agree with Petitioner that they should not have been given determinative weight by the Examiner'').

[13] *See* U.S. Patent No. 8,168,181.

325(d) and deny the petition because the same written description and enablement issues had been previously considered by the Office in a divisional of the priority application, which issued with claims directed to antibodies that bind to Siglec-15 and inhibit osteoclast differentiation or the bone resorption activity of osteoclasts. Alethia explained that the arguments made by Daiichi based on § 112, first paragraph, were no different than those addressed by the Office in closely related patent applications involving similar subject matter.

In deciding to institute trial on the '181 patent, the panel ultimately agreed with the petitioner, Daiichi, that the priority document lacked sufficient written description to support the challenged claims. Unlike in *Prism*, the panel declined to exercise its discretion under Section 325(d) to deny the petition, observing that the scope of the claims in the divisional ''differ[s] significantly from the scope of the challenged claims.'' Specifically, the panel disagreed with Alethia that the Office's consideration of these issues in other applications was relevant to this case.

Thus, as a bookmark on the issue of *Ariad*-like attacks, *Daiichi* offers some anecdotal insight into the PTAB's reasoning and its receptiveness to such challenges.

3. *Eli Lilly v. Los Angeles Biomedical*, IPR2014-00752

The patent challenged in *Eli Lilly v. Los Angeles Biomedical* relates to methods of treating fibrotic conditions with cGMP type 5 phosphodiesterase (PDE-5) inhibitors—e.g., sildenafil.[14] According to the specification of the '903 patent, the claimed PDE-5 inhibitor is administered at a dosage up to ''1.5 mg/kg/day,'' which is roughly equivalent to the dose ingested by men with an on-demand single 100 mg tablet. The treatable fibrotic conditions indicated in the '903 patent include Peyronie's disease, erectile dysfunction, and arteriosclerosis.

In its petition for inter partes review, Eli Lilly asserted that the challenged claims are not entitled to the priority date of their provisional for lack of written description support relating to the dosage limitation: ''up to 1.5 mg/kg/day.'' In particular, Eli Lilly contended that the provisional application does not recite the limitation or any equivalent disclosure, such as, a disclosure regarding conversion of the rat dosage to human dosage.

In its response, the patent owner Los Angeles Biomedical countered that the conversion from rat dosage to human dosage was well known in the art, citing various sources of contemporaneous literature.

In the decision instituting trial, the panel sided with Eli Lilly, noting that the provisional only disclosed one experiment in which sildenafil was administered orally to rats via their drinking water at a concentration of 100 mg/L for 45 days. The panel explained that there is no evidence to support a conclusion that the rats in the experiment drank a daily amount of water such that the dose they received was exactly 10 mg/kg/day. Therefore, even assuming that the conversion from rat dosage to human dosage was well known in the art, the skilled artisan could not have derived an upper dosage limit of 1.5 mg/kg/day, in the manner claimed.

The PTAB recently confirmed its priority analysis in a final written decision finding the challenged claims unpatentable. First, the panel addressed assertions by Los Angeles Biomedical in its patent owner response: that the rat model used in the provisional application was well known in the art; that the conversion of drug dosages between rats and humans was also well known; and that the safe and effective doses of sildenafil, vardenafil and tadalafil were publicly available as of the priority date, each of which was below the 1.5 mg/kg and would have been obtained using those well-known methods of conversion from rats to humans. Second, the panel addressed Eli Lilly's response that the provisional application only discloses one data point, and does not provide support for the ''up to'' limitation.

Eli Lilly further contended that the calculations offered by Los Angeles Biomedical rely on assumptions not disclosed in the provisional, such as male human weight and rat height and the weight. As in its institution decision, the panel sided with Eli Lilly noting that ''Patent Owner does not point us to where such disclosure appears in the provisional application, contending only that the information was well known . . . . [T]he ordinary artisan would not have immediately discerned that limitation from . . . [the] provisional.''

This case provides some insight into how closely the PTAB will review a priority claim relying on experimental testing, including its review of the methods and any results disclosed. While the panel arrived at its decision independent of what would have been known in the art, it accepted and considered such evidence.

B. Sweeping Bridge Patents into Post-Grant Review by Challenging Pre-AIA Priority and New Matter Once Claimed

The statutory provision authorizing post-grant review (PGR) requires that the challenged patent ''contains or contained at any time . . . a claim to a claimed invention that has an effective filing date . . . that is on or after'' March 16, 2013, i.e., PGR proceedings are only available for challenging patents subject to the first-inventor-to-file provisions of the AIA.[15] The availability of PGR may be important for petitioners seeking a larger variety of grounds upon which to assert invalidity, e.g., both paragraphs of § 112, first paragraph, § 101, as well as § 102 and § 103.

As of Oct. 13, 2015, 14 petitions for PGR have been filed. Of those, seven challenge priority by contesting the earliest effective filing date of at least one claim. Challenging priority benefit for a bridge patent issuing from an application filed ''post-AIA'' (i.e., after March 16, 2013) but claiming priority to one or more applications filed ''pre-AIA'' (i.e., before March 16, 2013) is one way to establish that the patent is eligible for post-grant review.[16]

Of those proceedings involving a priority challenge, three were deemed particularly noteworthy and are dis-

[14] *See* U.S. Patent No. 8,133,903.

[15] Pub. L. No. 112-29, § 3(n), 125 Stat. 293 (Sept. 16, 2011).

[16] Notably, initiating PGR on a patent that falls outside the statutory scope of PGR is arguably a jurisdictional issue (like eligibility for covered business method review), in that the determination implicates the PTAB's ultimate ''invalidation authority'' and should therefore be subject to judicial review. *See Versata Dev. Grp., Inc. v. SAP Am., Inc.*, 793 F.3d 1306, 1320-21, 115 U.S.P.Q.2d 1681 (Fed. Cir. 2015) (90 PTCJ 2626, 7/17/15) (holding that judicial review is not precluded with respect to exercise of the Office's invalidation authority).

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cussed in more detail below. One issue to monitor as these cases progress is whether the PTAB treats priority challenges seeking to sweep patents within the statutory scope of PGR the same as it has treated priority challenges seeking to introduce intervening art. Another issue to monitor is the PTAB's interpretation of ''contains or contained *at any time*.''[17] Specifically, whether a claim that once recited new matter (even if amended prior to issuance not to include the new matter) is still subject to PGR because *at one time* it contained new matter.

1. *LaRose Industries v. Choon's Design*, PGR2014-00008

In *LaRose Industries v. Choon's Design*, the petitioner LaRose challenged the patent's priority date in an attempt to sweep it within the scope of PGR. The patent owner, Choon's Design, responded that LaRose lacked ''standing'' to bring a PGR, characterizing its priority challenge as ''an obvious 'end run' around'' the statute.

As an additional defense, Choon's Design argued that LaRose's arguments rested upon proposed claim interpretations that were ''transparent[ly]'' calculated to read out support in the priority document. Choon's Design also offered a detailed rebuttal outlining support for each limitation in the priority document. This PGR was terminated prior to the PTAB issuing a decision addressing these arguments.

2. *Inguran, LLC v. Premium Genetics*, PGR2015-00017

The patent in *Inguran, LLC v. Premium Genetics* claims priority through a chain of applications extending back over a decade through a series of disclosures that the petitioner, Inguran, admitted are ''identical to the [challenged patent's] specification.'' Nonetheless, Inguran argued in its petition that the claims at issue are only entitled to the 2014 filing date of the application from which the patent issued.

Specifically, the patent relates to techniques and systems for physically separating particulate or cellular components in a fluid mixture into multiple fluid flows using differential sedimentation, holographic optical trapping and similar manipulation techniques (e.g., laser steering, optical traps, fluorescent activated cell sorting).[18] Inguran argued that the priority documents only support separation into separate channels, whereas the challenged claims recite separation into a single channel. According to Inguran, this recitation is contrary to the focus of the ancestral specifications, in which Inguran alleges every embodiment describes the physical separation of particles into different channels rendering it unsupported.

Like *LaRose*, the patent owner Premium Genetics argued in response that the priority challenge is an ''end-run around the statutory requirements for post-grant review,'' specifically that Inguran's '' 'effective filing' date argument is, in reality, simply an argument that the '395 patent claims lack written description support in the '395 patent's own specification.''

Premium Genetics distinguishes prior PTAB decisions cited by Inguran as inapposite because they involve priority challenges in inter partes review proceedings, which fall under a different statutory scheme than PGR. In addition to its procedural challenge, Premium Genetics highlights the fact that ''the '395 patent shares an identical specification with applications going back to at least September 3, 2014'' (i.e., that it is not a continuation-in-part but rather a straight continuation) and that the Notice of Allowability issued during prosecution specifically indicates that the underlying application was ''examined under the pre-AIA first to invent provisions.''

Also, similar to *LaRose*, Premium Genetics argues that the petitioner is improperly adding limitations to the claims for the purpose of arguing that they lack support in the priority document. Premium Genetics defends is priority claim on the merits and urges that the petition be denied.

This proceeding is noteworthy because the petitioner has made arguments regarding the sufficiency of the priority document that would apply with equal force against the patent itself. This exemplifies the strategy of challenging the written description of the patent by challenging the written description of the parent. The patent owner has responded by characterizing Inguran's tactic as an end-run around the statute, attempting to sweep in a patent that should enjoy immunity from PGR based on its priority claim through a series of straight continuations.

This proceeding is still awaiting a decision on institution. The panel recently denied the petitioner's request for additional briefing on ''whether the Board should perform an effective filing date analysis of the '395 Patent.'' A decision by the PTAB on whether priority challenges are available to the same extent as they are in inter partes review would be significant, and likely subject to review on appeal.

3. *Front Row Tech. v. MLB Advanced Media*, PGR2014-00023

The challenged patent in *Front Row Technologies v. MLB Advanced Media* claims priority to a pre-AIA application. Interestingly, the petitioner Front Row has not asserted that the claims under review lack written description support. Rather, Front Row asserts that *at one time*, prior to issuance, the claims existed in a form that could only be accorded a post-AIA filing date for lack of written description support in the priority document.

Specifically, the patent owner MLB amended the claims of the patent under review to recite a limitation that prompted the examiner to reject them under § 112, first paragraph. MLB later amended the claims and overcame the rejection, replacing the unsupported limitation with another that the examiner found allowable. Front Row contends that ''[a]lthough the Applicant subsequently amended the claims with [a supported limitation] in place of the [unsupported limitation], the application was already subject to the AIA.''

This proceeding is noteworthy because it presents the ''contains or contained *at any time*'' issue reflected in the statutory provision governing PGR. That is, the statutory provision sweeping in patents that ''at any time'' contained language that is not entitled to a pre-AIA filing date. This provision has significant implications in the context of prosecution, where bridge applications may be compromised by amendments that arguably introduce matter not supported by a pre-AIA

[17] 125 Stat. 293 (emphasis added).
[18] *See* U.S. Patent No. 8,933,395.

disclosure. Once the amendment is made, the ability to reverse the effect appears to be impracticable, but ultimately depends on how the statute is interpreted. This proceeding is still awaiting a decision on institution and may prove to be of some consequence.

III. Strategic Implications

Given the PTAB's apparent willingness to analyze priority in the context of post-grant proceedings, petitioners and patent owners alike should be prepared to address the issue on the merits before and after institution. While the implications vary, there are strategic opportunities and calculated risks that both petitioners and patent owners should consider.

For Petitioners. For petitioners, the ability to assert intervening prior art, cast a cloud over a common specification, and utilize PGR proceedings are just some of the opportunities offered by a successful priority challenge. But, a failed challenge to priority may result in a reaffirmation of entitlement, and one not easily unseated or reviewed if decided conclusively at the institution phase.[19]

Also, it has yet to be seen how the PTAB will address priority challenges predicated on the petitioner's proposed claim constructions. For example, a priority challenge may arguably depend upon the PTAB's adoption of a construction that renders the claims unsupported by the disclosure.[20] In such situations, the patent owner may be able to argue that the claims require a construction under which the petitioner's challenge fails. And while the patent owner's preliminary response is generally barred from including new testimonial evidence,[21] a preexisting expert or inventor declaration (or non-declaratory evidence) may be sufficient to address the issue, and support a claim construction determination in patent owner's favor.[22]

Furthermore, in cases where a district court has already construed the terms at issue, it will be interesting to observe how the PTAB responds, given recent decisions reiterating the importance of construing claims in light of the patent's intrinsic record and, in some cases, the associated judicial record.[23] These recent decisions have reversed the PTAB, seemingly for not tethering its application of the broadest reasonable interpretation to settled principles of claim construction.

A petitioner should likewise consider including art that is non-intervening, such that if the petitioner loses its priority challenge at the institution phase, a trial may still be initiated on the non-intervening art. This matters because an outright denial of a petition is non-appealable and, practically speaking, unreviewable.[24]

For Patent Owners. For patent owners, addressing issues of priority up front during prosecution, e.g., developing a record while an application is still pending, may provide a basis to oppose a priority challenge under 35 U.S.C. § 325(d).[25] However, as gleaned from cases where Section 325(d) arguments referred to distantly or indirectly related applications without a straight continuation lineage, the PTAB seems more skeptical that the issues are truly ''the same.'' And while submitting preexisting declaratory evidence to the PTAB has had mixed results, offering evidentiary support for a claim can only enhance such arguments, e.g., regarding what the skilled artisan would have understood. Only in rare cases will attorney argument alone be a more potent defense than one supported by evidence, regardless of whether the PTAB credits it at the institution phase.

As discussed above with respect to the current limitations on submitting new testimonial evidence with a preliminary response, patent owners should consider the advantages of developing a record favoring patentability and priority entitlement when the record is open and available for them to do so. While there will be opportunities to submit evidence once trial is initiated, the ideal scenario is not to be involved in a trial at all.

Finally, as the first IPRs are being decided by the U.S. Court of Appeals for the Federal Circuit on appeals from final decisions, a priority challenge may prove critical for petitioners and patent owners alike.[26] Presently, the scope of judicial review remains unsettled.[27]

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[19] *In re Cuozzo Speed Technologies*, LLC, 793 F.3d 1268, 1274, 115 U.S.P.Q.2d 1425 (Fed. Cir. 2015) (barring appeal of issues decided at the institution phase); *but see Versata v. SAP*, 793 F.3d at 1322 (holding that there may be judicial review of an institution phase determination if made pursuant to the PTAB's ''invalidation authority,'' as in eligibility for covered business method review).

[20] *See, e.g.*, *Dr. Reddy's Lab v. Pozen*, IPR2015-00802 (''Petitioner has built a house of cards based on an unreasonably broad claim interpretation . . . . [A]s properly construed, the [patent] claims are entitled to [their] priority date''); *LaRose Industries v. Choon's Design*, PGR2014-00008 (''[Petitioner offers claim constructions] for the transparent reason of attempting to preclude the claims from covering any of the embodiments disclosed in the specification.'')

[21] *See* 37 C.F.R. § 42.107(c).

[22] *But see U.S. Patent & Trademark Office*, *Notice of Proposed Rulemaking Entitled ''Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board,''* 80 FED. REG. 50720-747 (Aug. 20, 2015) (proposing changes to 37 C.F.R. § § 42.108 and 42.208 governing the patent owner preliminary response to allow patent owners to submit testimonial evidence).

[23] *See Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298, 115 U.S.P.Q.2d 1198 (Fed. Cir. 2015) (90 PTCJ 2392, 6/19/15) (''That is not to say, however, that the Board may construe claims during IPR so broadly that its constructions are *unreasonable* under general claim construction principles.''). *See also Power Integrations, Inc. v. Lee*, 797 F.3d 1318, 1326, 116 U.S.P.Q.2d 1137 (Fed. Cir. 2015) (90 PTCJ 2895, 8/14/15)(''The fact that the board is not generally bound by a previous judicial interpretation of a disputed claim term does not mean, however, that it has no obligation to acknowledge that interpretation or to assess whether it is consistent with the broadest reasonable construction of the term.'')

[24] *In re Dominion Dealer Solutions, LLC.*, 749 F.3d 1379, 110 U.S.P.Q.2d 1780 (Fed. Cir. 2014) (88 PTCJ 18, 5/2/14) (holding denial of institution is not appealable and mandamus is not warranted).

[25] *See, e.g.*, *Prism Pharma v. Choongwae Pharma*, IPR2014-00315.

[26] *See, e.g.*, *Luv N' Care Ltd v. Munchkin, Inc.*, IPR2013-00072 (finding design patent claims unpatentable over intervening prior art after denying entitlement to priority in the final decision) (affirmed by the Federal Circuit via Fed. Cir. R. 36).

[27] *In re Cuozzo*, 793 F.3d at 1274 (the petition for rehearing *en banc* was denied in a fractured precedential opinion, resulting in a revision to the original opinion, and the case is currently on appeal to the Supreme Court); *Versata v. SAP*, 793 F.3d at 1322 (distinguishing *In re Cuozzo*, rehearing en banc denied, candidate for appeal to the Supreme Court); *Achates*

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Consequently, if denied its priority claim at the institution phase, a patent owner should attempt to preserve the issue for appeal. This may involve a number of considerations. For example, a decision granting or denying priority at the institution phase may be considered permanently wedded to that unreviewable determination.[28]

However, it remains to be seen whether introducing new facts may provide a basis for assessment of the issue during trial, thereby giving the issue life beyond the decision on institution—one that is reviewable on appeal of the final written decision. A challenge to the Office's jurisdiction to institute a PGR on the basis of a priority challenge may also be considered reviewable on appeal based on an analogy to covered-business method review eligibility and the Federal Circuit's assessment of the PTAB's ultimate invalidation authority in *Versata*.

IV. Conclusion

The availability of priority challenges in post-grant proceedings offers a variety of strategic opportunities that may uniquely affect pharma and biopharma patents. Understanding the dynamics of these challenges, and whether they may be reviewed on appeal is critical to both launching them and defending against them.

Reference Publ'g, Inc. v. Apple Inc., No. 2014-1767, 2015 BL 317953, at *5 (Fed. Cir. Sept. 30, 2015) (90 PTCJ 3340, 10/2/15) (distinguishing *Versata* based on its relevance to issues that ''uniquely and fundamentally related to the Board's 'ultimate authority to invalidate' '').

[28] *Achates*, No. 2014-1767, 2015 BL 317953, at *5 (suggesting that merely addressing the same issue again in the final written decision does not authorize judicial review if the underlying determination was part of an unreviewable institution decision).