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Sterne Kessler Goldstein Fox
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Perspectives on the PTAB Newsletter

The *Perspectives on the PTAB* Newsletter is designed to be a valuable resource for all stakeholders in the global patent arena throughout the patent life cycle. To that end, articles will provide perspectives from both sides of the "v" with an eye toward providing the most current thinking on how to increase return on investment and the value of US patents. Depending on the topic, this 360 degree approach will be explored within an article or across a series of related articles.

This month we tackle three important issues:

1. The Turning Tide of Adoption of the Lead Compound Analysis Is Favoring Patent Owners at the PTAB
2. 325(d) Part III – Patent Owner Tools for Obtaining Denial of Institution under 35 USC 325(d)
3. Board Guidance on Federal Circuit Remands – Standard Operating Procedure (SOP) 9

While the staff of our Newsletter have plans to explore many issues, we welcome feedback and suggestions to ensure we are meeting the needs and expectations of all our readers. So if you have issues you wish to see explored either within an issue of the Newsletter, please reach out to me.

Thank you.

Best regards,
Jason

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In this issue

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The Turning Tide of Adoption of the Lead Compound Analysis Is Favoring Patent Owners at the PTAB

By: Olga A. Partington, Ph.D. and Jason D. Eisenberg

The PTAB is starting to provide teeth to the Federal Circuit's lead compound analysis making it more difficult for petitioners to successfully challenge chemical patents in AIA proceeding, as well as providing patent owners more tools to secure patents during prosecution.

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By: Trent W. Merrell and Jason D. Eisenberg

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Procedure (SOP) addressing the conduct of cases remanded from the Federal Circuit to the Patent Trial and Appeal Board (PTAB). New “SOP 9” provides instructions to panels of the PTAB as well as guidance to the public on how remand proceedings are to be conducted.

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Pre-2000 structurally similar compounds rendered chemical claims obvious

Historically, obviousness of chemical compounds was assessed under the standard articulated in the Federal Circuit's 1990 decision in *In re Dillon*.[i]

Under this approach, the claimed compound was *prima facie* obvious if the compound was structurally similar to the prior art compound, and the prior art provided any reason to makes the claimed compound.[ii] Thus, there was no requirement that the given prior art compound had more beneficial properties than other prior art compounds. There was also no requirement that the prior art compound had the same utility as the claimed compound.[iii]

Under the *Dillon* standard, any reason for modifying a structurally similar prior art compound with a stated utility was sufficient to establish a *prima facie* case of obviousness.

Post-2000 the USPTO and PTAB demonstrated a slower progression to embrace the lead compound framework than the federal courts

Seventeen years ago, the Federal Circuit articulated a new approach for assessing the obviousness of a chemical compound—the Lead Compound Analysis (LCA).[iv]

Under this approach, there must be a reason for a POSA to select a prior art compound as a "lead," and a reason to modify the prior art compound with a reasonable expectation of success.[v] A key distinction between the *Dillon* approach and the LCA is that to qualify as a "lead," the compound must possess some beneficial property that somehow distinguish it from other prior art compounds. Thus, by focusing on the most promising prior art compound rather than the closest prior art compound, the LCA imposes a much higher burden for showing obviousness in chemical arts.

While the federal courts were analyzing chemical compound claims under the LCA, the Board continued to focus on the closest prior art approach.

For example, in *Ex parte Cao*, the Board refused to apply the LCA in analyzing obviousness of a positional isomer.[vi] In fact, the Board made it clear that the chemical obviousness does not always require identification of a lead compound: "[t]he Eisai court did not promulgate a per se rule that

chemical compounds can only be held obvious if a lead compound is first identified … [and] did not overrule the long-standing principles that … one who claims a compound, per se, which is structurally similar to a prior art compound must rebut the presumed expectation that the structurally similar compounds have similar properties."[vii]

Cases that followed seemed to be consistent with the Board's reluctance to operate under the LCA approach.

In *Ex parte Mayorga*, the Board found that one of 24 compounds qualified as a lead compound, despite the fact that it was not the most potent compound.[viii] In Board's view, "good activity relative to the other compounds" was sufficient for its selection as the lead.[ix]

In *Ex parte Gaul*, the Board was not persuaded by an argument that another prior art compound would been a better lead: "the ordinary artisan would not have picked just one compound."[x]

In *Ex parte Dong*, the Board found that the lack of biological data for prior art compound was not fatal for selecting one of the compounds as a lead, effectively ignoring the LCA: "[w]e are not persuaded, however, that [the lead compound cases] mandate that the only compounds useful for evaluating obviousness are those for which the prior art had provided specific comparative data."[xi]

The Tide Has Turned—the LCA is Faring Well for Patent Owners in IPRs

Despite this initial reluctance to accept the LCA, the Board has been operating under a strict LCA framework in IPR proceedings – which appears may lead to more denials of institution for patent owners or at least patent owner wins at final written decision. So petitioners need to better address LCA in their petition to increase their change for success.

In *Sawai USA v. Nissan Chemical Industries LTD.*, the Board denied institution, finding that because the prior art "does not disclose any biological or pharmacokinetic data" for the alleged lead compound, the prior art "provides no suggestion that this compound … should serve as a lead compound."[xii] The Board continued to state that "structural similarities alone are not enough to inform a lead compound selection," expressly rejecting the *Dillon* approach.[xiii]

In *Mylan Laboratories Limited v. Aventis Pharma S.A.*, the Board similarly found that there was no evidence to establish "whether a particular compound performs better or worse than [another prior art compound]," thus rejecting petitioner obviousness arguments.[xiv]

In *Fustibal LLC v. Bayer Healthcare LLC*, the Board denied institution because "the Petitioner nowhere engages in a 'lead compound analysis' and … merely assumes—without explanation—that the POSA would select [the lead compound] for modification."[xv]

Most recently, in *Incyte Corporation v. Concert Pharmaceutical, Inc.*, the Board denied institution because petitioner failed to show that a POSA would have selected the alleged prior art compound as the lead.[xvi] According to the Board, it was not enough that the alleged lead compound was FDA approved because it did not distinguish it "from the panoply of known compounds in the prior art."[xvii]

All-in-all, the trend is clear—the Board is now strictly adhering to a lead compound framework when assessing obviousness of chemical compounds in AIA proceeds, and during prosecution. Thus, the predictions that chemical compound challenges might be more successful in AIA proceedings—based largely on Board's decisions in *ex parte* appeals—have not materialized. And both sides of the “v” need to take this into consideration to be successful.

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[i] *In re Dillon*, 919 F.2d 688 (Fed. Circ. 1990).
[ii] *Id.* at 692.
[iii] *Id.*
[iv] *Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 f.3d 1339 9Fed. Cir. 2000).
[v] *Otsuka Pharm. Co. Ltd. v. Sandoz Inc.*, 678 F.3d 1280, 1291 (Fed. Cir. 2012)
[vi] *Ex parte Cao*, Appeal 2010-004081 (BPAI Sept. 19 2011).
[vii] *Id.* at 7-8.
[viii] *Ex parte Mayorga*, Appeal 2010-012157 (BPAI Sept. 29, 2011)

[ix] *Id.* at 8.
[x] *Ex parte Gaul*, Appeal 2011-010047, at 6 (BPAI Jan. 28, 2013)
[xi] *Ex parte Dong*, Appeal 2011-010047, at 6-7 (PTAB Jan. 28, 2013)
[xii] IPR2015-01647, Paper 9 at 14.
[xiii] *Id.*
[xiv] IPR2016-00627, Paper 10 at 12.
[xv] IPR2016-01490, Paper 9, at 17.
[xvi] IPR2017-01256, Paper 9, at 17.
[xvii] *Id.*

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The Board Gives Section 325(d) Sharp Teeth—Part III —Things Are Looking Up for Patent Owners

By: Trent W. Merrell and Jason D. Eisenberg

This is the third of a three-part series discussing developments around Section 325(d). Part one appeared in our October 2017 newsletter and part two appeared in our November 2017 newsletter.

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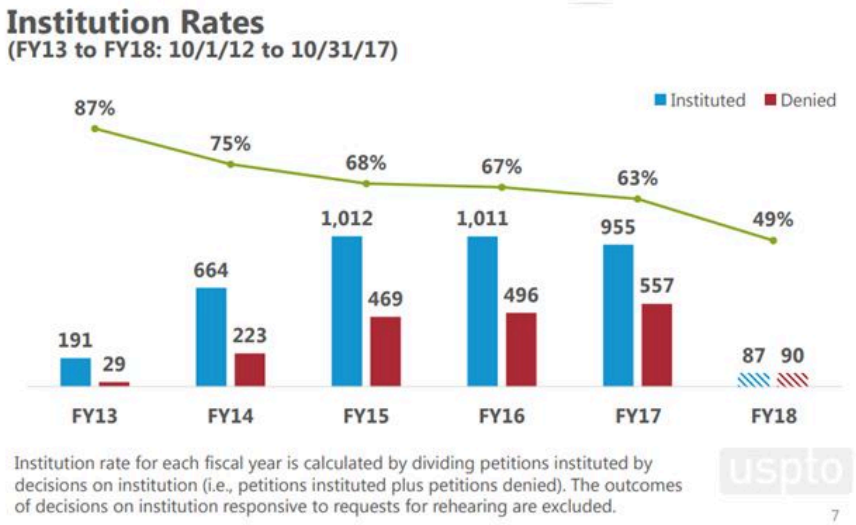

USPTO Trial Statistics[i]

As we previously reported, Congress granted the Board broad discretionary power to deny institution of AIA proceedings under 35 U.S.C. §325(d) - denial is discretionary if Petitioner uses "the same or substantially the same prior art or arguments previously presented to the Office." Though infrequently given as a reason for denial for the first few years following passage of the AIA, it is becoming a very common reason for denial. The Board has repeatedly exercised this discretion and denied institution when the "same or substantially the same prior art or arguments" were presented during original prosecution.[ii], [iii], [iv]

In *Telebrands Corp. v. Tinnus Enterprises, LLC*, the Board denied the institution of a petition under § 325(d) that challenged a patent directed to a system and method for filling containers with fluids. In its petition, Telebrands asserted the same prior art that was expressly considered by the

Examiner during original prosecution. Telebrands argued that the PGR record was different than the one before the Examiner because the testimony of its expert witness was not before the Examiner and because one of the issues presented in the petition included the inherent characteristics of the prior art references. The Board found that "the Examiner's explanation shows that he expressly considered the issues of inherency, and offered detailed findings why the functional limitations related to the elastic fastener were not necessarily present in the art at issue." Ultimately, the Board exercised its § 325(d) discretion to deny institution "because the same art and arguments were considered by the Examiner during the original prosecution."

In *Dorco Co. v. Gillette Co*, The Board declined institution under § 325(d) of a petition filed against a patent covering a razor blade with a hard coating. The petitioner's asserted grounds comprised some prior art references not expressly considered during original prosecution, but the Board determined that the grounds "merely raise[ ] the same issues that the Office has already considered and rejected." The Board thus declined institution under § 325(d) where the equivalent art was raised before the Examiner and where the petitioner's expert declaration "does not add facts or analysis substantially beyond what was considered by the Office during prosecution."

In *Alarm.com Inc. v Vivint, Inc.*, the Board declined institution where the petitioner relied on a patent owner's contentions in an earlier proceeding involving the same parties, the same patent, and the same claims, and where the petition sought to cure deficiencies that were in the petitioner's capacity to avoid in the earlier petition. For example, the Board found that "[t]hese facts suggest that at least this latest proceeding is a case of undesirable, incremental petitioning, in which a petitioner relies on a patent owner's contentions or a Board decision in an earlier proceeding or proceedings involving the same parties, the same patent, and the same claims to mount another…challenge after an earlier, unsuccessful or only partially successful challenge, by fixing deficiencies, noted by the Board, that were within the petitioner's capacity to avoid in the earlier petition or petitions."

On October 18, 2017, an expanded PTAB panel designated *General Plastic Industrial Co. Ltd. v. Canon Kabushiki Kaisha*[v] as a precedential case. The PTAB "precedential" designation was limited to Section II.B.4.i. of the decision, which adopts the seven factors for evaluating follow-on petitions first laid out in *NVIDIA Corp. v. Samsung Elec. Co.*[vi]

Section 325(d) arguments are very relevant in quashing follow-on petitions and such arguments have been successful in avoiding institution. We will step away from §325(d) for a moment to discuss the Board's broader discretion under §314(a).

In *General Plastic*, the Board explained that under §314(a), the Director has discretion to institute an inter partes review. Under 37 C.F.R. § 42.108(a) "the Board ***may*** authorize the review to proceed on all or some of the challenged claims and on all or some of the grounds of unpatentability asserted for each claim" (emphasis added)). There is no *per se* rule precluding the filing of follow-on petitions, but the Board adopted a seven-factor test as a measure to help prevent undue inequities and prejudices against Patent Owners. The factors include:

1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;
2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it;
3. whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition;
4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition;
5. whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent;
6. the finite resources of the Board; and
7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.

While the Board gives weight to and addresses each factor, it appears that the General Plastic panel seemed the most concerned about Factor 3. For instance, the Board stresses that its intent on formulating the factors was to "take undue inequities and prejudices to Patent Owner into account" and to stop petitioners from benefiting from receiving and having the opportunity to study Patent Owner's Preliminary Response, as well as our institution decisions on the first-filed petitions, prior to its filing of follow-on petitions. Specifically, the Board held that the "filing of sequential attacks against the same claims, with the opportunity to morph positions along the way, imposes inequities on [Patent Owner]."

Time appears to be another key issue with the Board. Factors 2-5 each describe some element of time. It appears that time may be the Patent Owner's best friend. That is, in each of Factors 2-5, as more time passes between the first-filed petition and any follow-on petitions, more scrutiny will be applied to any articulated rationale for the time elapsed between the filings.

Upon summarizing the factors, the Board characterized them as being "non-exhaustive" and explained that "additional factors may arise in other cases for consideration, where appropriate." So additional factors may be added to the list in the future. Did you hear the loud collective gulp and/or sigh of relief coming from Petitioners and Patent Owners across the country? These factors will certainly change PTAB litigation strategies in "war rooms" spanning the globe.

Given the rise of §325(d) as a reason for non-institution in the last year, and now the rigid factors that are evaluated with respect to follow-on petitions, the most critical Petitioner decision is the selection of the right prior art. Consequently, the most critical step for Patent Owner is thwarting the first institution. The recent developments bode well for the general outlook for Patent Owners.

Conclusion

As we detailed in the previous issues, there are countless nuances that can tilt the scales in favor of either party. While it can be difficult to predict with certainty how a PTAB panel might decide on a follow-on petition or on a §325(d) issue, especially without knowing the specific panel members or the nuances of each fact pattern, experienced PTAB practitioners can help you manage that nuance and ambiguity. As a firm with more PTAB proceedings than nearly any firm, Sterne Kessler has the experience – including time spent researching and studying these issues – to help you navigate the ambiguity around follow-on petitions and §325(d) denials.

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[i] USPTO, Trial Statistics IPR, PGR, CBM Patent Trial and Appeal Board October 2017. (Accessed on December 14, 2017 at https://www.uspto.gov/sit.es/default/files/documents/trial_statistics_october_2017.pdf)
[ii] *Telebrands Corp. v. Tinnus Enterprises, LLC*, PGR2017-00015, Paper 16 at 8-12 (PTAB Oct. 11, 2017).
[iii] *Dorco Co. v. Gillette Co.*, IPR2017-00500, Paper 7 at 18 (PTAB June 21, 2017)
[iv] *Alarm.com Inc. v Vivint, Inc.,* IPR2016-01080, paper 11 at 11-12 (PTAB November 17, 2016.)
[v] *General Plastic Industrial Co. Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357 (PTAB September 6, 2017) (Paper 15).
[vi] *NVIDIA Corp. v. Samsung Elec. Co., Case IPR2016-00134* (PTAB May 4, 2016) (Paper 9).

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On November 16, 2017 the U.S. Patent and Trademark Office posted a new Standard Operating Procedure (SOP) addressing the conduct of cases remanded from the Federal Circuit to the Patent Trial and Appeal Board (PTAB). New "SOP 9" provides instructions to panels of the PTAB as well as guidance to the public on how remand proceedings are to be conducted. At a high level, the new SOP seeks to formalize the criteria for authorizing additional briefing, the introduction of new evidence, and the availability of additional oral hearings. The SOP confirms the PTAB's goal of completing remand proceedings within six months of the Federal Circuit's mandate. The SOP also directs panels of the PTAB to proactively consult with the Chief Judge, the Deputy Chief Judge, or one of the Vice Chief Judges within a month of the Federal Circuit decision. The SOP explains that this consultation procedure is intended in part to allow PTAB leadership to consider whether an expanded panel and precedential designation are warranted.

Because the SOP has not been formally promulgated, it does not have the force of law. Nevertheless, it provides important guidance to those involved in remands on how the PTAB will conduct remand proceedings. *First*, the SOP provides that parties in remanded trial cases are to contact the PTAB within **ten business days** after the Federal Circuit's mandate. *Second*, the SOP indicates that teleconferences with the parties and the PTAB should take place within a month of the mandate. *Third*, prior to communicating with the PTAB, the SOP asks the parties to meet and confer "in a reasonable and good faith attempt to propose a procedure on remand." The issues that the parties are expected to consider are:

(1) whether additional briefing is necessary;
(2) subject matter limitations on briefing;
(3) the length of briefing;
(4) whether the parties should file briefs concurrently or sequentially;
(5) if briefs are filed sequentially, which party should open the briefing;
(6) whether a second brief from either party should be permitted;
(7) the briefing schedule;
(8) whether either party should be permitted to supplement the evidentiary record;
(9) limitations, if any, on the type of additional evidence that will be submitted;
(10) the schedule for submitting additional evidence, if any; and
(11) any other procedural issues.

The SOP categorizes the issues on remand (e.g., erroneous claim interpretation, failure to consider the evidence, inadequate explanation by the PTAB, erroneous application of law, lack of due process or denial of APA rights, improper consideration of the arguments) and then indicates whether additional briefing, new evidence, or an additional oral hearing is likely to be allowed in

each scenario. In the case of remanded PTAB trial proceedings (i.e., *inter partes* review, covered business method review, post-grant review, and interferences), additional briefing is likely to be authorized in every category except for "inadequate explanation" by the PTAB. The SOP notes that additional evidence—which may itself require additional briefing to address objections and require cross-examination—is unlikely to be allowed in any scenario unless there has been a due process or APA violation that justifies reopening the record. The same applies to additional oral hearings, which are unlikely to be authorized unless it is necessary to afford due process.

The above guidance differs for remands of *ex parte* examination (i.e., patent applications) and *ex parte* reexaminations. For those examinational proceedings, as distinct from PTAB trials, prosecution will not ordinarily be reopened unless there has been a due process violation that requires the applicant or patent owner to file a response (e.g., to a new ground of rejection). The SOP also addresses the impact of a party's attempt to obtain Supreme Court review. It states that "[i]n **all cases**, absent good cause, proceedings on remand generally will not be stayed once the Federal Circuit has issued its mandate, even when a party has petitioned the Supreme Court for a writ of certiorari." It provides that in trials, a party may contact the panel and request authorization to file a motion to stay the remand for this reason. The panel may order briefing on the issue or resolve it through a conference call. The primary consideration will be whether any judgment by the Supreme Court would impact the PTAB's decision on remand.

In the case of trials, the SOP generally notes that remand procedures are guided by the scope of the remand, the substance of the Federal Circuit's decision (e.g., its reasoning and instructions), as well as considerations of efficiency and economy "to secure the just, speedy, and inexpensive resolution of every proceeding." 37 C.F.R. § 42.1(b); *see also* 35 U.S.C. §§ 315(b), 326(b). With these overarching considerations in mind, the PTAB is likely to continue its existing practice of entertaining focused briefing limited to issues remanded to it by the Federal Circuit. The PTAB is unlikely to allow additional evidence or another oral hearing unless due process requires it. As was the *ad hoc* practice prior to this SOP, parties should meet and confer promptly after a Federal Circuit decision and plan to contact the PTAB within in ten business days of mandate to secure whatever process they believe is needed to resolve outstanding issues.

This SOP also creates an interesting process for having PTAB panels consult with PTAB leadership to evaluate whether a decision should be designated precedential. The SOP explains that the Chief Judge may elect to expand the panel assigned to the remanded case to, for example, address an issue of "importance." The SOP highlights that this may occur where a remanded case involves any "novel, evolving, or contentious issues of law or policy (i.e., not limited to the particular case) or raises any issues of particular importance to the Office or the patent community)." It remains unclear what level of deference "precedential" designations will receive upon review by the Federal Circuit, but this new initiative to identify candidates for a precedential designation suggests that the Office is interested in using it more frequently.