Leo Pharmaceuticals *Decision Provides New Weapon for Patent Invalidation in Proceedings before the Patent Trial and Appeal Board*

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The Federal Circuit, on an appeal from an *inter partes* reexamination proceeding, overturned the conclusion of the Patent Office Board of Patent Appeals and Interferences (the Board) of obviousness and rejected the Board's analysis of objective indicia of nonobviousness in *Leo Pharmaceutical Products, Ltd. v. Rea* (Federal Circuit 2013).[1] Although the decision resulted from an *inter partes* reexamination in favor of nonobviousness, it still substantiates the viability of a challenge to a patent as obvious via an *inter partes* review (IPR) proceeding established by the America Invents Act (AIA) because, according to the court, the obviousness evaluation process requires considering all of the evidence and arguments in concert.

This article discusses the opportunities afforded a patent challenger in an IPR proceeding as highlighted in the *Leo Pharmaceutical* opinion. Although the patent holder prevailed, this decision provides strategies for a patent challenger in future IPR cases. First of all, during IPR, a challenger may be able to impact the scope of the originally granted claims to force a patentee to narrow its scope, which may result in a finding of non-infringement in a subsequent litigation. Secondly, the court reiterated that the US Patent and Trademark Office (PTO) must give claims their broadest reasonable construction consistent with the specification. In doing so, the court indirectly permits the challenger an opportunity to identify citable prior art that falls within this scope, thereby potentially undermining the patentability of the claims based on an obviousness argument. Thirdly, the court noted that an invention can be the recognition and solution of a problem; thus, a challenger may be able to present prior recognition by one of skill in the art of the problem patentee ostensibly solved. Finally, the court noted that "consideration of the objective indicia is part of the whole obviousness analysis, not just an afterthought." Therefore, a challenger may be able to weaken a patentee's nonobviousness indicia by presenting its own information and data regarding those same indicia. Because all information must be considered together during the obviousness analysis, attacks on the viability of patentee's position will be fully considered, potentially undermining patentee's case and resulting in maintenance of the obviousness rejection.

Inter Partes Review

Although the *Leo Pharmaceutical* decision was based on an *inter partes* reexamination, since the passage and implementation of the AIA, a new procedure entitled *inter partes* review became available. IPR essentially replaces *inter partes* reexamination and is similar to reexamination in some respects, but different in others. For example, IPR may be used for anticipation and/or obviousness invalidity challenges to a patent under 35 U.S.C. §§ 102 and 103. However, the challenge can be based only on allegedly prior art patents and/or printed publications. As a result, offers for sale or sales occurring before the priority date of the patent, for example, cannot be presented via an IPR proceeding.

In addition, the challenger (or petitioner) will be estopped by the final written IPR decision, but only to the extent of the permitted challenges on the grounds established by the IPR institution; that is, petitioner will not be permitted to raise anticipation and/or obviousness challenges based on patents and/or printed publications in another later proceeding, including court litigation, under the established grounds.[2] As stated in 35 U.S.C. § 314: "[t]he petitioner in an *inter partes* review … may not assert or maintain a proceeding before the Office … on any ground that the petitioner raised or reasonably could have raised during that *inter partes* review." Nonetheless, petitioner will be able to present challenges based on sales, offers for sale, and requirements under 35 U.S.C. § 112, such as enablement and written description, in an alternative proceeding. If, however, a decision is made by the Patent Trial and Appeal Board (PTAB) of the PTO not to institute IPR, then estoppel does not apply. Accordingly, it is essential that petitioner carefully consider the viability of its challenges under IPR versus the estoppel effect from any resulting decision.

Moreover, IPR only can be initiated no later than one year after the serving of a first litigation complaint alleging infringement of the patent by petitioner.[3] Note that an IPR petition may be filed against a patent unless that patent is eligible for a post grant review (PGR) proceeding. Further, the filing of an IPR petition may or may not influence the judge to stay litigation in lieu of the IPR proceeding, depending on the status of the litigation, whether the IPR is initiated, whether all claims are addressed, and other factors.

IPR does present, however, an expedient and potentially cost-savings approach, because after the petition is granted, the proceedings must be completed within one year, after institution of the IPR, under 35 U.S.C. § 316(a)(11) (although the proceedings may be extended up to six additional months for good cause). In addition, discovery is more limited than in a litigation context. Given the proceeding's compressed timeline, as well as strict page limitations for IPR documents, it is essential that the petitioner present its best detailed arguments and evidence, and also avoid redundancies.

The IPR proceeding will be decided by a PTAB panel composed of three administrative patent judges. These patent judges, by virtue of being specialized judges, generally possess more experience with patent validity and technology issues, and thus may be expected to have a better comprehension of such issues than a typical federal district court judge who may not hear many patent cases. Therefore, given the PTAB judges' expertise, IPR may provide an advantageous forum for more complex technology and invalidity arguments to be fully comprehended.

During the IPR, the PTAB will construe the claims based on the broadest reasonable interpretation of their language, thereby providing a greater opportunity for the invalidity challenge to be successful.

After the IPR petition is filed, the patent owner has the option of filing a preliminary response within three months of the petition filing date, in which to argue the IPR should not be instituted. The patent owner should consider carefully the advantages and disadvantages of a response, because the patent claims cannot be amended, and evidence to rebut the petition cannot be presented at that time.[4] In addition, the patent owner needs to evaluate the impact its statements may have on any concurrent litigation, and to consider that the response gives the petitioner a preview of the owner's strategy during the IPR, if instituted. The response also may, in fact, limit the patent owner's later statements and strategies, in the event the IPR focus shifts or unexpected events arise. However, a persuasive response could result in the denial of the IPR petition and thus avoid the IPR proceeding.

Therefore, an IPR presents a valuable alternative to court litigation, in which to challenge the validity of a patent. Various aspects of an IPR proceeding are still being interpreted, with future decisions by the PTAB and Federal Circuit influencing the scope and significance of IPR, especially regarding the scope of estoppel and regarding the impact of inconsistent findings or decisions between the PTAB and courts.

Impacting Scope of Patent Claims through IPR

As a practical matter, even if a patent challenger ultimately is unsuccessful in invalidating a patent through IPR, he may be able to sufficiently narrow the scope of the patent claims to avoid or prevail in a potential infringement lawsuit. In *Leo Pharmaceutical*, Leo Pharmaceutical Products (Leo Pharma) was the owner of US Patent No. 6,753,013 (the '013 patent), which, as issued, contained claims directed to dermal compositions of a vitamin D analog, a corticosteroid, and a solvent (*e.g.*, POP-15-SE). The issued claims embrace Leo Pharma's commercial embodiment (*i.e.*, Taclonex® ointment) for treating psoriasis.

A third party dermatology company initiated a challenge of the '013 patent through the filing of a request for *inter partes* reexamination. The third party requester asserted that at least one substantial new question of patentability existed against each of the claims of the '013 patent. In particular, the third party requester alleged that the claims were anticipated or rendered obvious by a number of references, some previously considered during prosecution, as well as newly cited references. The requester contended that the references, either alone or in combination, taught topical compositions of vitamin D

and/or a corticosteroid formulated with a solvent. A reexamination subsequently was ordered.

Leo Pharma argued throughout the reexamination that its compositions were novel and non-obvious over the cited art due to its compositions being storage stable and non-aqueous. However, because Leo Pharma relied on this distinction, it was forced to amend its claims accordingly during the course of the reexamination to include this limitation.[5]

In this case, the challenger was able to impact the scope of the originally granted claims during the reexamination and force the patent owner to narrow the scope of the claims by adding the phrase "storage stable and non-aqueous." Similarly, in IPR, a patent challenger or accused infringer may be able to successfully assert arguments resulting in a narrower claim. Such a narrowing may be sufficient to yield a finding of non-infringement in a subsequent litigation against the challenger.

Broadest Reasonable Claim Construction Expands Scope of Potentially Invalidating Prior Art

The court reiterated that the PTO must give claims their broadest reasonable construction consistent with the specification. In this regard, the court admonished the Board's construction of the claim term "storage stable" based on the disclosure of a single accelerated stability study in the specification as "impermissibly narrow" and "something far short of its broadest reasonable meaning."[6]

Thus, the court indirectly presents the challenger with an opportunity to identify additional citable prior art that falls within this scope, thereby potentially undermining the patentability of the claims based on an obviousness argument. In other words, the greater the scope of the claims, the greater the likelihood that a challenger may successfully cite art, which falls within the claim scope and renders the claims unpatentable.

Recognition and Solution of a Problem Can Be Inventive

The court noted that an invention can be the recognition and solution of a problem. The court cited to its opinion in *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*[7] to support the proposition that an invention can result from the recognition of a problem. In the district court, the judge had set aside the jury verdict in granting a motion for judgment as a matter of law (JMOL) and found the patent claims obvious. The court based its decision on its belief that the art identified the problem to be solved by the patent and concluded that it would have been obvious to design a device to solve that problem. However, the Federal Circuit in *Cardiac Pacemaker* reversed, stating:

> [r]ecognition of the problem of treating complex heart arrhythmias does not render obvious the eventual solution. Recognition of a need does not render obvious the achievement that meets that need. There is an important distinction between the general motivation to cure an uncured disease (for example, the disease of multiple forms of heart irregularity), and the motivation to create a particular cure. There can of course arise situations wherein identification of the problem is itself the invention.[8]

Based on the evidence provided, the Federal Circuit concluded a reasonable jury could have reached the verdict of nonobviousness.

In *Leo Pharmaceutical*, the Federal Circuit rejected the Board's finding of obviousness of the claimed compositions over three references and its conclusion that the patent was "simply a combination of elements found in the prior art,"[9] stating that "[t]he inventors of the… patent recognized and solved a problem with the storage stability of certain formulations—a problem that the prior art did not recognize and a problem that was not solved for over a decade."[10] In this regard, the court noted "[t]he '013 patent teaches that the previous combination formulations were not storage stable, because vitamin D and corticosteroids have divergent pH requirements for optimum stability."[11] Furthermore, once Leo Pharma had recognized this stability problem, it began testing the stability of various compositions containing vitamin D analogs and corticosteroids and discovered "several ingredients—including almond oil, propylene glycol, and water—did not solve the problem,"[12] whereas a different group of solvents (*e.g.*, polyoxypropylene 15 stearyl ether or POP-15-SE) did solve the stability problem. The court further noted that the prior art either discouraged the combination of vitamin D analogs and corticosteroids in a single formulation, or attempted the combination without recognizing or solving the storage stability problems associated with the combination.

If the recognition and solution of a problem may be inventive; conversely, a challenger may be able to present prior recognition by one of skill in the art of the problem allegedly recognized by the inventors and could potentially defeat an argument that the inventors recognized and solved a problem. Such recognition would be considered during the overall obviousness determination. However, as the court found in *Cardiac Pacemakers*, even a well-recognized problem may have a nonobvious solution.

Analysis of Objective Indicia of Nonobviousness Considered in Concert with a *Prima Facie* Case of Obviousness

Finally, the court turned to the Board's analysis of the objective indicia of nonobviousness presented by Leo Pharma. Within the Federal Circuit's discussion of obviousness in *Leo Pharmaceutical*, it based its decision, in part, on prior obviousness decisions, which are briefly summarized to provide a historical context for the present decision.

The Federal Circuit primarily relied on *In re Cyclobenzaprine*[13] to provide its interpretation of the Supreme Court's 2007 decision in *KSR International Co. v. Teleflex, Inc.*[14] concerning obviousness. Identifying an alleged invention as obvious always has been a vexing proposition due to the technology at issue continuing to evolve, and the legal determination of obviousness made long after the inventive event. However, for *In re Cyclobenzaprine,* the Federal Circuit concluded that the district court's determination of obviousness was in error, because the district court failed to consider the lack of a known pharmacokinetic (PK)/pharmacodynamic (PD) relationship for the claimed drug formulation. According to the appellate court, the inventors had to ascertain the correct PK/PD profile in order to formulate a therapeutically effective, extended-release version of cyclobenzaprine hydrochloride, which was the claimed invention. No one in the art knew the PK/PD relationship and, as a result, no one could formulate the dosage for the extended-release product having a therapeutic effect.

In characterizing the *KSR* decision in the *In re Cyclobenzaprine* opinion, the court stated:

> [w]here a skilled artisan merely pursues "known options" from "a finite number of identified, predictable solutions," the resulting invention is obvious…. Where, however a defendant urges an obviousness finding by "merely throw[ing] metaphorical darts at a board" in hopes of arriving at a successful result, but "the prior art gave either no indication of which parameters were critical or no direction to which of many possible choices is likely to be successful," courts should reject "hindsight claims of obviousness."[15]

In other words, obvious to try alone is not sufficient for a finding of obviousness unless there are a finite number of solutions. The court also reiterated that obviousness must be assessed at the time of the invention and there must be a reasonable expectation of success.

Moreover, the court cited *Stratoflex, Inc. v. Aeroquip Corp.*[16] as requiring consideration of all objective evidence before reaching a conclusion regarding obviousness. Considering all of the evidence together would guard against a hindsight analysis, in the court's view. *Stratoflex* also was cited for the proposition that, in a litigation context, the burden of invalidity via obviousness does not require a shift in the burden of proof. The party alleging invalidity still has the burden even if the patent owner presents secondary considerations. These secondary considerations, or objective evidence, as presented during *In re Cyclobenzaprine*, included failure of another in developing an extended-release formulation and a long-felt need for such a formulation, because the immediate-release formulation had existed for decades. The court asserted that this evidence was persuasive in its determination of nonobviousness.

The approach used by the court for *In re Cyclobenzaprine* was consistent with that in *Rolls-Royce, PLC v. United Technologies Corporation,*[17] also cited by the Federal Circuit in *Leo Pharmaceutical.* The Federal Circuit affirmed the district court's conclusion that the Rolls-Royce patent would not have been obvious in view of United Technologies Corporation's (UTC) patent application. In reaching its decision, the Federal Circuit found that a key element required by the Rolls-Royce claim was not disclosed in the UTC application. Even though UTC also argued that the Rolls-Royce invention would have been obvious to try; the court determined that the invention would not have presented itself as an option at all, because one of skill in the art would not have any reason to try the invention. The premise of the court's analysis was that "the possible approaches and selection to solve the problem must be 'known and finite.'…The important question is whether the invention is an 'identified, predictable solution' and an 'anticipated success.'"[18] In this case, the court focused on the fact that the selection of choices for further investigation was broad and a particular selection was not obvious unless there was some motivation for the skilled artisan to pursue that selection.

Furthermore, Rolls-Royce had presented secondary considerations that validated the district court's decision, including solving a long-felt need, improved efficiency, commercial success, and industry accolades. Rolls-Royce established a nexus between these considerations and the claimed fan blade. For all of these reasons, the Federal Circuit affirmed the nonobviousness decision of the district court.

With respect to objective indicia of nonobviousness, Leo Pharma presented evidence of the improved stability of the claimed compositions during the reexamination proceeding. Patent owner Leo Pharma's position throughout the reexamination was that the claimed "storage stable non-aqueous" compositions solved the

incompatibility and poor storage stability associated with prior attempts to combine vitamin D and corticosteroids into a single composition despite their disparate pH requirements for storage stability. Leo Pharma further argued that a single composition was desired to combat the lack of patient compliance that accompanied therapeutic regimens requiring the separate application of a formulation of vitamin D and a formulation of a corticosteroid at different times during the day.

In supporting its position, Leo Pharma provided declarations describing various studies showing that an improper choice of solvent produces incompatibility problems when one attempts to make a combined formulation of vitamin D and corticosteroid. In particular, a declaration of '013 patent inventor Erik Didriksen described stability studies of vitamin D and/or corticosteroids in aqueous alcohol vehicles and various pH levels showing "unacceptable complete degradation" of the vitamin D compound at acidic or neutral pH, and "unacceptably high degradation" of corticosteroids at alkaline pH.[19] A further declaration of '013 patent co-inventor Gert Hoy demonstrated that the incompatibility problem was not simply solved by employing a non-aqueous solvent; but rather, the problem was more complex.[20]

Futhermore, Leo Pharma supported the stability of its compositions by pointing to stability studies provided in the specification indicating that the claimed non-aqueous composition of vitamin D and betamethasone dipropionate in POP-15-SE was stable when stored for three months at either 25 °C or 40 °C.[21] Leo Pharma also provided additional information regarding the stability of further combinations of vitamin D analogues and corticosteroids with other recited solvents.[22]

Here the court criticized the Board's reasoning that "the strong case of obviousness outweighs the experimental evidence and testimony about the advantages of the claimed composition."[23] Rather, the court noted that "consideration of the objective indicia is part of the whole obviousness analysis, not just an afterthought."[24] Indeed, in this case "the objective indicia of nonobviousness are crucial in avoiding the trap of hindsight when reviewing, what otherwise seems like, a combination of known elements."[25]

However, a challenger may be able to weaken patentee's nonobviousness indicia by presenting its own information and data regarding those same indicia. Taking the storage stability issue of the *Leo Pharmaceutical* case as an example, the challenger may discover flaws in the patentee's experimentation regarding stability or show its own results evidencing instability. Because all information must be considered together during the obviousness analysis, attacks on the viability of patentee's position will be fully considered, potentially undermining patentee's case and resulting in a finding of obviousness.

Obviousness Analysis after *Leo Pharmaceutical*

To date, the PTAB has decided only a few appeals of obviousness rejections, in which the *Leo Pharmaceutical* decision was cited. During its analysis of the obviousness issue in *Ex parte Deorkar*, *et al.*,[26] the PTAB concluded that the claimed invention was obvious. The subject matter of the invention concerned chromatographic media used to separate proteins, in which the media comprised epoxidized polyacrylate or polymethacrylate polymeric resin particles derivatized by reaction with polyethyleneimine (PEI) on the surface of the polymer and then functionalized.

According to the PTAB, some of the prior art, Muranaka, disclosed epoxidized polyacrylate or polymethacrylate particles derivatized with PEI for use in chromatographic protein separation. Another cited reference, Ramsden, was directed to functionalizing PEI bound to the surface of silica particles. Appellants argued that this reference did not teach functionalizing PEI for the purpose of solving the stability problem associated with using silica particles at high pH. However, the PTAB described Ramsden as teaching that functionalizing PEI bound to silica particles provided marked advantages, including good hydrolytic stability, in separating proteins. As a result, Muranaka and Ramsden together indicated that "silica particles and polymeric particles, such as epoxidized polyacrylate or polymethacrylate particles, can be interchangeably used with polyethyleneimine (PEI) or functionalized polyethyleneimine (PEI) in chromatography for the protein separation purposes, with the use of the functionalized polyethyleneimine imparting a superior protein separation result relative to the use of the non-functionalized polyethyleneimine "[27]

The PTAB noted that the reason or motivation provided by the art was not identical to the problem being solved by Appellants, but such a reason did not need to be identical so long as one of ordinary skill in the art would have been led to the claimed subject matter. For these reasons, the PTAB affirmed the Examiner's determination of obviousness.

Next, the PTAB reviewed Appellants' assertion of unexpected results to overcome the alleged obviousness. The question was presented as: Were the unexpected results sufficient to outweigh the evidence of obviousness reflected in the collective teachings of Muranaka and Ramsden? The information provided by Appellants included examples and figures in the specification, and a declaration executed by the first listed inventor, Deorkar.

The Deorkar Declaration was excoriated for not describing what epoxidized particles, reaction conditions, and solvents were used in a comparison between non-functionalized particles and functionalized particles for separating proteins. Moreover, according to the

PTAB, the Declaration contradicted a statement in the specification in which non-functionalized particles were represented as useful in separating proteins. In addition, it was not shown that the Declaration or the examples in the specification were compared to a specific example in Muranaka, which was the closest prior art. Further undermining the Appellants' assertion of unexpected results, the showings were not reasonably commensurate with the scope of the claims. In conclusion, the PTAB determined that the "preponderance of evidence weighs most heavily in favor of obviousness."

In this initial decision, *Leo Pharmaceutical* was not addressed, but it was considered in the PTAB's decision of November 29, 2013[28] after Appellants' request for rehearing. Appellants opined that the PTAB erred in not considering the problem addressed and solved by the invention, and they cited *Leo Pharmaceutical* in support of their position. Although the PTAB granted the request for rehearing and reconsidered its August 2013 decision, it maintained the obviousness determination. It envisioned Muranaka as teaching how to address the stability problem for separating proteins, and Ramsden for suggesting how to functionalize particles also for separating proteins, which was the same purpose as the claimed invention.

As to *Leo Pharmaceutical*, the PTAB appears to have declined to follow that decision and returned to *KSR* in stating the following:

> However, *Leo Pharmaceutical Products, Ltd.* does not control the outcome of this case…It is important to note that the Court of Appeals for the Federal Circuit limited *Leo Pharm. Prods., Ltd.* to a situation where the applied prior art did not provide any apparent reason for one of ordinary skill in the art to arrive at the claimed subject matter not only due to the failure of the applied prior art to recognize and address the problem found by Appellants, but also due to the divergent teachings and express disclaimer in the applied prior art that would have precluded one of ordinary still in the art from arriving at such combination. This interpretation of *Leo Pharmaceutical Products, Ltd.* is consistent with *KSR*…, which states…[t]he first error of the Court of Appeals in this case was to foreclose this reasoning by holding that courts and patent examiners should look only to the problem the patentee was trying to solve…Under the correct analysis, any need or problem known…at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.[29]

In our view, the PTAB may have construed *Leo Pharmaceutical* more narrowly than intended by the Federal Circuit, when the PTAB stated that there must not be any reason for the skilled artisan to make the invention and that the prior art also must preclude one from arriving at the combination in order for *Leo Pharmaceutical* to apply. It appears that the PTAB is reverting to a strict *KSR* analysis and is using a more stringent nonobviousness test.

Nonetheless, *Ex parte Deorkar* provides important lessons on how unexpected results are to be presented, such as including necessary experimental information and verifying that the declaration is not inconsistent with statements in the specification. In any event, future applicants should be aware that use of the problem-solution analysis of *Leo Pharmaceutical* will not automatically result in a finding of nonobviousness.

Another request for reconsideration of an obviousness decision in view of *Leo Pharmaceutical* was presented to the PTAB in *Ex parte Yasuo Sudo*[30] (December 5, 2013). In this case the PTAB maintained its position that the claimed invention was obvious. Appellant asserted that the rehearing request included arguments not previously raised based on *Leo Pharmaceutical*. According to the PTAB, Appellant did not show good cause and did not indicate that it was relying on any new legal theories from *Leo Pharmaceutical*. It should be noted that the PTAB specifically stated: "Appellant's arguments based on obvious-to-try and prior art not recognizing the problem solved by Appellant are all based on old legal theories which Appellants could have argued but did not…."[31]

In any event, the PTAB determined that *Leo Pharmaceutical* did not control the outcome of the case. In particular the court stated:

> [u]nlike *Leo Pharm. Prods., Ltd.*, this case involves the issue of whether or not the variables relied upon by Appellant as the novel aspect of the invention are known result-effective variables…On this record, Appellant has not shown that the variables relied upon are not known result-effective variables. Nor has Appellant shown that one of ordinary skill in the art would not have been able to optimize such result-effective variables through routine experimentation.[32]

Thus, it appears that the PTAB seemingly has shifted the burden of proof and has required Appellant to prove a "negative"; that is, to establish the variables relied on are not known. We believe this decision also retreats from the Federal Circuit's intent in *Leo Pharmaceutical* due to the shifting of the burden of proof.

The Federal Circuit's belief in *Leo Pharmaceutical* is reinforced by *In re Eaton*,[33] although the opinion is nonprecedential. The court reversed the PTAB's obviousness decision on the basis of *Leo Pharmaceutical*. The

application in this case claimed a method of treating psoriasis by administering a vitamin complex, wherein the claim language recited that the complex composition was "essentially free of anti-oxidants," and the specification mentioned that one of the anti-oxidants especially to be avoided was vitamin C. The first prior art reference, Jungkeit, disclosed a vitamin complex for the treatment of psoriasis, which contained two anti-oxidants: (1) vitamin C and (2) vitamin E. These vitamins comprised about 10 times the amount of the other vitamins. The second cited reference, Mantynen, provided a composition containing vitamin E, as the major component, for treating psoriasis, and taught that the compounds within the composition acted synergistically, but did not produce significant improvements in psoriasis when administered alone. According to the PTAB, adjusting the concentrations of the various vitamins to arrive at an optimum workable range was obvious.

The court, however, asserted that the motivation to modify Jungkeit or Mantynen to be "essentially free of anti-oxidants," as claimed, was not established. The court stated: " '[i]n the face of such divergent composition with express disclaimers of the other's contents,' the record demonstrates neither a motivation to 'adjust' those synergistic concentrations nor a motivation to combine them. See *LeoPharm*…. Therefore, this court reverses the Board's obviousness determination."[34]

In *Ex parte Robert Erwin van den Berg* (September 25, 2013),[35] the PTAB distinguished *Leo Pharmaceutical* and held that the claimed invention was obvious; thereby affirming the Examiner's conclusion of obviousness based on a preponderance of the evidence. The invention concerned an improved gasification reactor for preparing a mixture of carbon monoxide and hydrogen.

Interestingly, the PTAB relied on *In re Wright*,[36] and asserted that the present facts were more similar to those in *Wright* than to those in *Leo Pharmaceutical*. The age of one of the cited prior art references was argued by Appellants as indicating nonobviousness, given that reference predated another cited reference by 10 years. In response, the PTAB stated:

> However, "[t]he mere age of the references is not persuasive of the unobviousness of the combination of their teachings, absent evidence that, notwithstanding knowledge of the references, the art tried and failed to solve the problem." *In re Wright*… Appellants fail to direct our attention to any evidence indicating that the art tried and failed to solve a problem that their mist injecting means solves, nor do we find any. Recently, our reviewing court again considered the issue of age of the prior art references and the length of time to recognize and solve a problem as *indicia* of non-obviousness. See *Leo Pharm*… Therein, the court found the inventors recognized and solved a problem not recognized or solved for over a decade from the date of the latest pertinent prior art. Unlike the facts before the *Leo* court, but similarly to the facts before the *Wright* court, here the prior art recognized the problem…and the prior art solved the problem….[37]

Based on the PTAB's determination in *van den Berg*, age of a reference alone is not sufficient to establish nonobviousness.

Conclusion

IPR, as a recently enacted procedure, is mostly untested with only one IPR proceeding having been fully decided by the PTAB to date. The first decision on the merits, *Garmin USA, Inc. v. Cuozzo Speed Tech,*[38] was decided in favor of the petitioner. In particular, in its opinion in *Garmin,* the PTAB panel sided with petitioner Garmin and ordered the cancellation of all three of the challenged claims of US Patent No. 6,778,074. Thus, while the patent community awaits additional IPR decisions from which to gain insight as to effective strategies, patent challengers may, in the meantime apply lessons learned from *inter partes* reexamination cases to IPR proceedings.

1. Leo Pharm. Products., Ltd. v. Rea, 726 F.3d 1346 (Fed. Cir. 2013).
2. *See* 35 U.S.C. § 315(e)(2).
3. *See* 35 U.S.C. § 315(b).
4. *See* 37 C.F.R. § 42.121.
5. Patent owner added the requirement that the compositions be "storage stable and non-aqueous" to the preamble of Claim 1 during reexamination in patent owner's Amendment of November 13, 2013. The limitation that the composition be non-aqueous was previously recited in Claim 8 (and Claim 9 which was identical to Claim 8) of the '013 patent. The limitation that the composition was both storage stable and non-aqueous was contained in Claim 22 of the '013 patent.
6. *Leo Pharm*., 726 F.3d at 1352.
7. Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 381 F.3d 1371 (Fed. Cir. 2004).
8. *Id.* at 1377.
9. Leo Pharm., 726 F.3d at 1353.
10. *Id.*
11. *Id.* at 1349.
12. *Id.*
13. In re Cyclobenzaprine Hydrochloride Extended—Release Capsule Patent Litig., 676 F.3d 1063 (Fed. Cir. 2012).
14. KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (2007).
15. Cyclobenzaprine Hydrochloride, 676 F.3d at 1070, *cert. denied*, 133 S. Ct. 933, 184 L. Ed. 2d 725 (U.S. 2013).
16. Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fed. Cir. 1983).
17. Rolls-Royce, PLC v. United Technologies Corp., 603 F.3d 1325 (Fed. Cir. 2010).
18. *Id.* at 1339.
19. Declaration under 37 C.F.R. § 1.132 of Erik Didriksen submitted with Patentee's Amendment of November 13, 2013.
20. Declaration under 37 C.F.R. §1.132 of Gert Hoy submitted with Patentee's Amendment of November 13, 2013 described results of a study in which a non-aqueous composition with propylene glycol as a solvent was not stable.
21. Patent owner's Amendment of November 13, 2013 citing Example 2, at col. 10, line 50 to col. 11, line 43 of the '013 patent.

22. Declarations under 37 C.F.R. § 1.132 of Gert Hoy submitted with Patentee's Amendment of November 13, 2013.
23. *Leo Pharm*., 726 F.3d at 1357.
24. *Id*.
25. *Id*. at 1358.
26. Ex parte Deorkar, et al. 2013 WL 4636999 (Patent Tr. & App. Bd.).
27. *Id*. at 3. [Au: What case is this?]
28. Ex parte Deorkar, et al., 2013 WL 6217838 (Patent Tr. & App. Bd.).
29. *Id*. at 2.
30. Ex parte Yasuo Sudo, 2013 WL 6328569 (Patent Tr. & App. Bd.).
31. *Id*. at 1.
32. *Id*.
33. In re Eaton, 2013-1104, 2013 WL 6124398 (Fed. Cir. Nov. 22, 2013).
34. *Id*.
35. Ex parte Robert Erwin van den Berg, 2013 WL 5487150 (Patent Tr. & App. Bd.).
36. In re Wright, 569 F.2d 1124 (CCPA 1977).
37. *Robert Erwin*, 2013 WL 5487150 at 4.
38. Garmin USA, Inc. v. Cuozzo Speed Tech, 2013 WL 6355081 (Patent Tr. & App. Bd.).