IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Discretion to Institute Trials Before the Patent Trial and Appeal Board	Docket No. PTO-C-2020-0055 85 Fed. Reg. 66502

COMMENTS OF THE COALITION AGAINT PATENT ABUSE

November 30, 2020

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The Coalition Against Patent Abuse writes to express concerns that the increased use by the Patent Trial and Appeal Board ("PTAB") of discretionary denials will result in the delayed entry of generic competition and increase the cost of prescription drugs for Americans. The recent changes the U.S. Patent and Trademark Office ("USPTO") has made in its approach to discretionary denials, meaning denials based on something other than the actual merits of the petition, are unraveling Congress's efforts to reduce the harms caused by low-quality patents. As a result, these discretionary denials are trending significantly upward.[1] Instead of continuing down this path by codifying current policies and practices, the PTO should re-prioritize patent quality and restore the IPR system to its proper focus—resolving the problems of erroneously-granted patents.

INVALID PATENTS INTERFERE WITH PRICE-LOWERING GENERIC AND BIOSIMILAR COMPETITION

Generic competition on small molecule drugs save Americans an average of 79% over the pre-competition prices.[2] And while biosimilar competition is nascent, it is projected to save patients 15%-45% over the next five years, possibly more.[3] Indeed, other countries have already enjoyed larger price decreases due to the expiration of biologic drug patents and the entry of biosimilar competition. For example, AbbVie itself has discounted the biologic drug Humira by 80% in some countries due to the entry of competition.[4]

[1] https://www.unifiedpatents.com/insights/2020/10/21/ptabdistrict-court-trial-date-denials-spiraling-upward-ptab-discretionary-denials-third-quarter-report
[2] https://www.fda.gov/media/133509/download
[3] https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024
[4] https://www.fiercepharma.com/pharma/abbvie-offers-up-80-humira-discount-eu-tender-market-to-hold-off-biosims-report

Patents prevent such competition, which is problematic when 43% of all issued patents challenged in court are ultimately found to be invalid,[5] albeit at great expense due to the high costs of patent litigation. These include "secondary" drug patents that are often characterized as "weak" or "less solid" even by the companies obtaining them.[6]

Any delay in the introduction of generic and biosimilar competition can have significant economic impact on patients and payors. For some, this is the difference between being able to afford a treatment and not being able to afford a treatment.

INTER PARTES REVIEW ELIMINATES INVALID DRUG PATENTS, LOWERING PRICES

When Congress passed the America Invents Act ("AIA"), a core motivating goal was "to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs."[7] The *Inter Partes Review* process ("IPR") created by the AIA fulfills that goal. This quick, efficient, and less expensive means of challenging potentially erroneously granted pharmaceutical patents is especially important to speed up the entry of competition and reduce drug costs for American patients and payors.

Although IPR is a comparatively new process, it has led to significant price savings in several instances:

- Competition for the prostate-cancer drug Zytiga was being held up by an invalid patent leading to high drug prices. After a successful IPR and district court challenge, generics entered at prices ranging $3-$20 per dose compared to $87 for the brand.
- Another example is Lantus, a biologic that many diabetes patients need to regularly inject to survive. Sanofi's remaining patents on the active ingredient insulin glargine were found to be invalid in 2019. However, competition was still held up due to Sanofi's patents on the injector, SoloStar, used to deliver the insulin glargine. This injector was strikingly similar to other injectors on the market before, and the PTAB found any changes to be obvious and therefore erroneously granted. Mylan received approval for and announced plans to launch a generic glargine injector pen at a list price of $147.98 for five pens compared to $425.31 for the Lantus SoloStar.
- In yet another example, prices for an important drug used to treat opioid addiction, Suboxone, fell by about 50% compared to its peak brand price after a successful IPR challenge combined with other litigation.

DISCRETIONARY DENIALS ALLOW ERRONEOUS PATENTS TO STAND, HARMING PATIENT CONSUMERS

The current trend to deny institution of otherwise meritorious IPR petitions is alarming and can deprive Americans of the vital price reductions that come with generic and biosimilar competition. These non-substantive denials have the potential to delay competition, resulting in significant cost to American patients and payors. As the Request for Comments notes, discretionary denials only come into play "in cases where a petitioner has satisfied the institution standard" for inter partes review, namely showing

[5] http://texaslawreview.org/wp-content/uploads/2015/08/AllisonEtAl-92-7.pdf
[6] C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 Science 1386, 1387 (2013); Competition Dir.-Gen., European Comm'n, *Pharmaceutical Sector Inquiry: Final Report* para. 501, at 191 (2009).
[7] H.R. REP. 112-98, 40.

that the petitioner has shown a "reasonable likelihood" that at least one challenged patent claim is invalid.[8] In other words, the effect of a discretionary denial is to let stand a patent that is reasonably likely to be in error.

The harm of erroneous patents is well-established: raising drug prices and making medicines unaffordable. To discretionarily deny an IPR petition, then, the USPTO must justify that the harm of allowing a likely-invalid patent to stand is tolerable.

SERIAL IPR PETITIONS ON DRUG PATENTS ARE OFTEN JUSTIFIED

The USPTO first inquires as to the use of discretionary denials when multiple IPR petitions are filed on a patent. Yet these "serial IPR petitions" are often justifiable in view of procedural limitations, and there should be no blanket rule against them. Drug patent challenges are often so complicated that petitioners need to file multiple petitions at the same time because of the short word count limits on a single IPR petition. The USPTO's Trial Practice Guide Update says this may be allowed "when the patent owner has asserted a large number of claims in litigation."

Nevertheless, the Board has discretionarily denied multiple-IPR petitions that were used precisely to present full challenges to patents in view of the word limits:

- In *Mylan Pharmaceuticals v. Sanofi-Aventis*, IPR2019-01658, patents on the Lantus insulin injector were challenged as obvious. Due to the number of claims and prior art references, Mylan presented multiple IPR petitions to ensure that the Board had a full record of evidence despite the per-petition word count. Nevertheless, the Board discretionarily denied one, saying that the Trial Practice Guide language was inapplicable since litigation had not yet commenced.
- In *Nalox-1 Pharmaceuticals v. Opiant Pharmaceuticals*, IPR2019-00695, -00696, the petitioner filed multiple IPR petitions to ensure that the Board had a full record of prior art references available to it. Nevertheless, the Board denied all but one of the petitions, despite the petitioner's arguments that the additional prior art in the other petitions might be needed to overcome a possible deficiency in the sole granted petition. The Board's final written decision in that granted petition in fact relied on that deficiency to uphold the patent, leaving a glaring question of whether the denied petitions were in fact necessary to give full consideration to the patent's validity. Narcan costs $126 for two doses and is only expensive because of the injector patent that was challenged. The active ingredient, Naloxone, is available for about $30 as a generic. Thus, had the *Nalox-1* IPR been successful, patients could have saved a great deal of money.

Additionally, the USPTO asks whether one party's IPR petition should be discretionarily denied in view of an unrelated party's earlier IPR petition on the same patent. It should not, because there is no reason to believe that the earlier petitioner's challenge was complete or sufficiently effective. One can imagine, for example, a patent holder suing a small firm first, who might lack the resources to do a comprehensive prior art search and file a strong IPR petition. Later alleged infringers of the patent

[8] 35 U.S.C. § 314(a).

should not be prevented from doing more comprehensive searches or filing stronger arguments in new IPR petitions.

Settlement of an IPR petition may also make a subsequent IPR petition appropriate. In *Pfenex v. GlaxoSmithKline Biologicals*, IPR2019-01478, the petitioner sought IPR after an unrelated party, Merck, had settled its previous IPR proceeding. The Board applied discretionary denial to Pfenex's petition on the grounds that Pfenex had unreasonably delayed in seeking IPR, since it only filed after Merck settled. This creates an unreasonable dilemma: Either petitioners like Pfenex must file duplicative and costly petitions immediately in parallel with others, or the patent becomes effectively immune to IPR challenge upon settlement. Neither choice advances the purpose of IPR to be a low-cost, efficient mechanism for early resolution of patent disputes.

PARALLEL LITIGATION SHOULD NOT BE A CAUSE TO DISCRETIONARILY DENY IPR

The USPTO next asks whether it should codify the *NHK-Fintiv* factors on discretionary denials of IPR petitions when parallel litigation on the challenged patents is pending. But the *NHK-Fintiv* factors, as applied by the USPTO so far, erroneously deny meritorious petitions too frequently and can be manipulated to insulate bad patents from review in either courts or IPR.

The *NHK-Fintiv* factors, in general terms, favor discretionary denial of an IPR petition when a court is set to hold trial on invalidity of the challenged patent in the near future. This has led patent holders to select district courts, such as the Eastern and Western Districts of Texas, that set unnaturally early trial dates that are subsequently delayed. Denying IPR petitions in view of parallel litigation would thus allow patent holders to escape early disposition of patent validity in any forum.

The USPTO has also used its discretionary authority to deny a petition because of the trial date of a completely different company. This denies the IPR petitioner valuable rights, since it cannot control the arguments or evidence in litigation in which it is not involved. In *Mylan Laboratories v. Janssen Pharmaceutica*, IPR2020-00440, the petitioner challenged a patent on the schizophrenia treatment paliperidone palmitate (Invega Sustenna), which currently costs $1,853 per injection dose. The Board discretionarily denied the petition, in part based on co-pending litigation between Teva and the patent holder, and despite Mylan's argument that Mylan was not involved in Teva's case. To be sure, there was also co-pending litigation against Mylan, but the Board nevertheless made clear that it could deny a petition for "being duplicative of the prior case even if the petition is brought by a different party."

SPECIFIC ANSWERS TO THE USPTO'S QUESTIONS

For the reasons above, we urge the PTO to not codify the policies and practices mentioned in the Request for Comments. Instead, we encourage the Office to unwind its recent efforts which have weakened IPR and made it harder to challenge invalid patents.

1. *Should the Office promulgate a rule with a case-specific analysis, such as generally outlined in General Plastic, Valve I, Valve II and their progeny, for deciding whether to institute a petition on claims that have previously been challenged in another petition?* **No. As noted above, serial**

petitions can serve important purposes for complex patent disputes where some parties are likely to settle or otherwise fail to prosecute IPR petitions fully. Codifying those precedents in rules would prevent the Board from flexibly distinguishing precedent where necessary to address novel and unexpected situations where serial IPR petitions could be appropriate.

2. *Alternatively, in deciding whether to institute a petition, should the Office (a) altogether disregard whether the claims have previously been challenged in another petition, or (b) altogether decline to institute if the claims have previously been challenged in another petition?* **No to both. While prior petitions may bear some relevance to whether to institute future ones, the proposal of (b) would deny IPR petitions based on potentially unrelated, incomplete prior ones, thereby preventing IPR from being an effective alternative to litigation.**
3. *Should the Office promulgate a rule with a case-specific analysis, such as generally outlined in the Consolidated Trial Practice Guide, for deciding whether to institute more than one petition filed at or about the same time on the same patent?* **No. Multiple petitions may be necessary for a variety of reasons as described above, and failure to grant them could deny the Board with sufficient evidence or the best arguments to consider with respect to any given patent, leading to incomplete or erroneous outcomes.**
4. *Alternatively, in deciding whether to institute more than one petition filed at or about the same time on the same patent, should the Office (a) altogether disregard the number of petitions filed, or (b) altogether decline to institute on more than one petition?* **The Office should institute enough petitions to ensure that a full record of prior art and arguments is available before it. Preliminary assessments of whether prior art is "duplicative" can easily turn out to be wrong. Furthermore, the Office should not use an unrelated third party's IPR proceeding as reason to deny a petition, since there is no guarantee that the unrelated third party will prosecute its challenge fully.**
5. *Should the Office promulgate a rule with a case-specific analysis, such as generally outlined in Fintiv and its progeny, for deciding whether to institute a petition on a patent that is or has been subject to other proceedings in a U.S. district court or the ITC?* **No. The *Fintiv* factors are insufficient and open to manipulation by forum shopping, so codifying those factors would render IPR less effective and improperly contrary to its congressional purpose. Furthermore, even if those factors are correct, codifying them would prevent the Board from further applying the case law method to refine those factors to adapt to new litigation strategies and factual situations.**
6. *Alternatively, in deciding whether to institute a petition on a patent that is or has been subject to other proceedings in district court or the ITC, should the Office (a) altogether disregard such other proceedings, or (b) altogether decline to institute if the patent that is or has been subject to such other proceedings, unless the district court or the ITC has indicated that it will stay the action?* **The Office should generally grant petitions even with co-pending litigation. The very purpose of IPR was to be a lower-cost alternative to litigation; denying IPR petitions in view of litigation subverts that very purpose.**