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To: [Precedential Opinion Panel Request](#)
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Subject: Precedential Opinion Panel Request - IPR2020-01317
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Attachments: [Paper 16. 2021-02-12, Petitioner's Request for Rehearing.pdf](#)

Dear Board:

I write on behalf of Petitioner Regeneron Pharmaceuticals, Inc. (“Regeneron”) to request Precedential Opinion Panel (“POP”) review of the Board’s decision in *Regeneron Pharma., Inc. v. Novartis Pharma AG, et al.*, IPR2020-01317, Paper 15 (PTAB January 15, 2021), denying institution of *inter partes* review under 35 U.S.C. § 314(a) (“Institution Decision”). Regeneron has concurrently filed a Request for Rehearing of the Institution Decision pursuant to 37 C.F.R. § 42.71(d), a copy of which is attached. Regeneron respectfully requests that, for the reasons set forth in its Request for Rehearing and as further explained below, POP intervention is necessary.

BASIS FOR POP REVIEW

Based on my professional judgment, I believe this case requires an answer to one or more precedent-setting questions of exceptional importance: specifically, whether the Board’s decision in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB March 20, 2020) (precedential) should *ipso facto* be followed to discretionarily deny institution of IPRs under 35 U.S.C. § 314(a) when there are parallel proceedings before the United States International Trade Commission (“ITC”). The signature of an attorney of record for Regeneron is found at the end of this request. The explanation of why this is a matter of exceptional importance is set forth below.

In the instant proceeding, Patent Owner filed complaints for patent infringement and violation of Section 337 of the Unfair Trade Practices Act in district court and at the ITC, respectively. Less than one month later, and before the ITC’s investigation of Regeneron was even instituted, Regeneron filed petitions for *inter partes* review of the asserted patent (IPR2020-01317 and IPR2020-01318). Regeneron moved to dismiss the latter petition, which the Board granted. As to the former, the Board applied the *Fintiv* factors and exercised its discretion to deny institution without considering the merits of the petition. See Institution Decision at 23-24.

Regeneron notes that this same issue has been raised to the POP by petitioners Garmin International, Inc., Garmin USA, Inc., Garmin LTD. (“Garmin”) and Fitbit, Inc. in *Garmin International, Inc., et al. v. Koninklijke Philips N.V.*, IPR2020-00754, Precedential Opinion Panel Request (PTAB November 19, 2020) (“hereinafter, “Garmin POP Request”). Regeneron agrees with the analysis in Garmin’s POP Request, and does not repeat it, but provides additional

analysis herein. To the extent that the POP determines that Garmin's POP Request has merit, Regeneron respectfully requests that it reach the same conclusion as to the instant request.

First, Garmin's analysis of the six *Fintiv* factors, and why they should not be applicable to IPR proceedings involving parallel ITC investigations, *id.* at 1-2, applies with equal or even more force as to Regeneron's rehearing request. As Garmin argued, reliance on the *Fintiv* factors to deny institution amounts to effectively a *de facto* rule against instituting IPRs when there is a parallel ITC investigation. *Id.* Indeed, here the Board determined that **every** *Fintiv* factor weighed against institution. Institution Decision at 11-24. This was so even though Regeneron filed its IPR petitions within a month of being served with the ITC and district court complaints and before the ITC's investigation was even instituted. As Regeneron noted, with respect to factors 2 and 3, the only way for a Petitioner to act more expeditiously is to file the petitions **before** being sued, which is plainly contrary to 35 U.S.C. § 315(b) (giving petitioners up to a year after being served with a complaint to file a petition). *See* Institution Decision at 14-15 (acknowledging Regeneron's argument but finding that factor 2 weighed against institution). In addition, although not required, Regeneron stipulated that it would not pursue the grounds asserted in its petitions before the ITC if the Board instituted trial. That stipulation should have been enough to alleviate any concerns about the Board and the ITC issuing duplicative or inconsistent rulings. The Board nonetheless found factor 4 weighed against institution, erroneously determining that the ITC and Board would have to decide "substantially the same arguments," and that Regeneron could press the same arguments later in district court. *Id.* at 21-22. This latter rationale is plainly contradicted by the estoppel provisions of 35 U.S.C. § 315(e)(2).

Second, as fully set forth in Regeneron's Request for Rehearing, the POP should reject application of the *Fintiv* factors to deny institution when there are parallel ITC proceedings because doing so is clearly against Congressional intent. *See, e.g.*, 157 Cong. Rec. S1352 (daily ed. Mar. 8, 2011) (statement of Sen. Udall) ("Inter partes ... proceedings are intended to serve as a less-expensive alternative to courtroom litigation and provide additional access to the expertise of the Patent Office on questions of patentability."); Request for Rehearing at 4-11. In a post-*Fintiv* decision, the ITC itself recognized that the Board is the "lead agency in assessing the patentability, or validity, of proposed or issued claims." *Certain Unmanned Aerial Vehicles and Components Thereof*, Inv. No. 337-TA-1133, Comm'n Op. at 37 (Sept. 8, 2020). Congress's preference is further confirmed by the fact that it gave Board findings of invalidity (subject to appellate review) preclusive effect, 35 U.S.C. § 318(b), but expressly did not give preclusive effect to ITC invalidity findings, even when those are affirmed by the Federal Circuit. *Texas Instruments v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1568-69 (Fed. Cir. 1996); *see* Garmin POP Request at 3 ("There simply is no legitimate reason the PTAB should be deferring to a tribunal [the ITC] that lacks the ability to cancel claims.").

The lack of preclusive effect given to ITC invalidity findings allows patent owners to engage in costly serial litigation by asserting in district court patents found invalid by the ITC, thereby

allowing multiple bites of the apple against defendants. Here, Patent Owner has already indicated its intention to proceed in district court after completion of the ITC investigation. Institution Decision at 12 (“Patent Owner notes the NDNY Patent Litigation has been stayed, but will proceed after the ITC Investigation is complete.”). The Board should not have denied institution here knowing that Patent Owner intended to do so, thereby exposing Regeneron to the type of “unnecessary and counterproductive litigation costs” that Congress intended IPRs to prevent. *See* H.R. Rep. 112-98, at 69 (2011). For at least this reason, the Board’s reliance on the statement in *Fintiv* that ““as a practical matter, it is difficult to maintain a district court proceeding on patent claims determined to be invalid at the ITC,”” Institution Decision at 23 (quoting *Fintiv* at 9), is misplaced. Neither the Board panel here, nor the panel in *Fintiv*, provided any explanation supporting this statement. To the contrary, as Regeneron explained, it is not uncommon for patent owners to press forward with district court cases even following ITC invalidity rulings. Paper 13 at 10-11; Request for Rehearing at 8-10; Garmin POP Request at 3 (listing cases and concluding that “district court proceedings are routinely maintained on patent claims determined to be invalid or not infringed at the ITC.”).

Third, the *Fintiv* factors, and the discretionary denial analysis under § 314 more broadly, have been inconsistently applied across Institution Decisions addressing parallel ITC investigations. Such inconsistencies erode confidence in the IPR process and leave participants guessing as to which arguments Board panels do or do not find persuasive in their institution decision outcomes.

Here, Regeneron filed its petitions on July 16, 2020. Less than two months prior, the Board in *3Shape A/S v. Align Tech., Inc.*, IPR2020-00223, Paper 12 (PTAB May 26, 2020) instituted trial and rejected the argument that it should discretionarily deny institution in view of a parallel ITC proceeding. In particular, the *3Shape* panel emphasized the fact that “the ITC does not have the power to cancel a patent claim, even if that claim is demonstrated to be invalid. Also, the burden of proof in demonstrating that a patent claim is invalid differs between the ITC and an *inter partes* review.” *Id.* at 32-33. The Board’s decision in *3Shape* was not an outlier. Leading up to the time that Regeneron filed its petitions and even shortly thereafter, there were multiple examples of other Board panels, both prior to and after *Fintiv*, addressing this same issue and rejecting the call to deny institution because of a parallel ITC investigation. *See, e.g., Nichia Corp. v. Lighting Sci. Group Corp.*, IPR2019-01259, Paper 21 at 27-28 (PTAB Jan. 15, 2020) (finding that “the ITC does not have the authority to invalidate a patent in a way that is applicable to other forums, and thus ITC decisions do not preempt issues addressed in an *inter partes* review proceeding”). The clear trend by Board panels not to deny institution in view of parallel ITC investigations continued after *Fintiv*. *See Intel Corp. v. Tela Innovations, Inc.*, IPR2019-01636, Paper 16 at 23-24 (PTAB March 31, 2020) (“[W]e do not find the ITC Proceeding weighs in favor of denying institution...”); *Samsung Elec. Co., Ltd. v. Dynamics, Inc.*, IPR2020-00504, Paper 11 (PTAB August 12, 2020) (instituting trial and rejecting argument that the *Fintiv* factors supported discretionary denial under § 314(a)).

Thus, at the time that Regeneron filed its petitions, it had no basis to believe that the Board would deny institution because of the parallel ITC investigation. Indeed, *Nichia*, which was prior to *Fintiv*, and *3Shape* and *Intel*, both post-*Fintiv*, highlighted the importance of the lack of preclusive effect of ITC invalidity holdings as compared to Board decisions. Yet, by the time of the Board decision here (and even earlier, as shown by the outcome in *Garmin*), Board panels had apparently determined that this fact was no longer of import in considering the *Fintiv* factors in view of parallel ITC investigations. As explained above, this is (1) against Congressional intent, and (2) a stark example of how Board panels are inconsistently analyzing and applying the *Fintiv* factors when there is a parallel ITC investigation. See also *Garmin* POP Request at 3-4 (“The POP should intervene to protect the integrity of the system by providing clarity to the panels to avoid inconsistent decisions on nearly identical facts.”).

CONCLUSION

For the reasons expressed herein, in Regeneron’s Rehearing Request, and in Garmin’s POP Request, Regeneron respectfully requests that the POP direct Board panels to cease reliance on the *Fintiv* factors as justification for denying institution of IPR trials when there is a parallel ITC investigation. In doing so, the POP should also review the Institution Decision here and institute trial in this IPR.

Respectfully submitted,

/Brian E. Ferguson/

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