UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Regeneron Pharmaceuticals, Inc.,
Petitioner,

v.

Novartis Pharma AG,
Novartis Technology LLC,
Novartis Pharmaceuticals Corporation,
Patent Owner

Case IPR2020-01317
U.S. Patent No. 9,220,631

PETITIONER'S REQUEST FOR REHEARING

PURSUANT TO 37 C.F.R. § 42.71(d)

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I. STATEMENT OF THE PRECISE RELIEF REQUESTED

Regeneron Pharmaceuticals, Inc. ("Regeneron") filed its *inter partes* review petition only 27 days after being accused of infringement of U.S. Patent No. 9,220,631 ("the 631 patent") in complaints filed in the International Trade Commission (ITC) and in district court by Patent Owner Novartis. By statute (28 U.S.C. § 1659), the district court proceeding was stayed in favor of the ITC investigation. While the ITC investigation is moving forward, the ITC's final determination on the validity of the 631 patent will have no preclusive effect and will not prevent Patent Owner from proceeding in district court.

In its Patent Owner Preliminary Response (Paper 10), Novartis argued, *inter alia*, that the Board should exercise its discretion pursuant to 35 U.S.C. § 314(a) and deny institution of trial based on the pending ITC investigation. Novartis did not argue that institution should be denied based on the stayed district court case. Regeneron asked for and was granted permission to file a reply brief (Paper 13), and Novartis filed a sur-reply (Paper 14). As Regeneron explained, the facts here showed that Regeneron: (a) filed the instant petition before the ITC had even instituted an investigation based on Patent Owner's complaint; (b) challenged every claim of the 631 patent; and (c) stipulated that it would not pursue any invalidity arguments in the ITC that would be the subject of an IPR trial. *See* Paper 13 at 11-13. In short, these facts presented a clear case for instituting trial.

Nonetheless, on January 15, 2021 the Board relied on *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB May 13, 2020) ("*Fintiv*") and exercised its "discretion under 35 U.S.C. § 314(a) to deny institution" based solely on the pending ITC investigation. Paper 15 at 1. Regeneron now requests rehearing of the Board's institution decision. The denial of institution here demonstrates that the Board has created a nearly *per se* rule that IPR trials are largely off-limits to ITC respondents. That outcome cannot be what Congress intended. It is an abuse of discretion for the Board to deny institution based on parallel proceedings before the ITC, which undisputedly cannot issue findings or render decisions on patent validity that have preclusive effect. The Board's denial of institution in these circumstances is at odds with Congress's intent that IPR proceedings "serve as a less-expensive alternative to courtroom litigation and provide additional access to the expertise of the Patent Office on questions of patentability." *See* 157 Cong. Rec. S1352 (daily ed. Mar. 8, 2011) (statement of Sen. Udall).

Regeneron will ask for Precedential Opinion Panel ("POP") review of this request for rehearing, and requests that the POP hold that *Fintiv* should not be the basis for denying institution of IPRs when there is a parallel ITC investigation.[1]

[1] Regeneron notes that this issue – reliance on the *Fintiv* factors as a basis to discretionarily deny IPRs based on a parallel ITC investigation – is also before the

II. LEGAL STANDARD

Pursuant to 37 C.F.R. § 42.71(d), a "party dissatisfied with a decision may file a single request for rehearing." The request must "specifically identify all matters the party believes the Board misapprehended or overlooked…." *Id.* Institution decisions are reviewed on rehearing "for an abuse of discretion." 37 C.F.R. § 42.71(c). "An abuse of discretion occurs when a 'decision [i]s based on an erroneous conclusion of law or clearly erroneous factual findings, or … a clear error of judgment.'" *Apple Inc. v. DSS Tech. Mgmt., Inc.*, IPR2015-00369, Paper 14 at 3 (PTAB Aug. 12, 2015) (citation omitted).

III. STATEMENT OF REASONS FOR RELIEF REQUESTED

The Board denied institution, finding that based on its "holistic review of all the *Fintiv* factors, the weight of the evidence sufficiently tips the balance in favor of exercising our discretion to deny institution under § 314(a)." Paper 15 at 24. Regeneron recognizes that, because it is a precedential opinion, the Board is bound to follow and apply *Fintiv* when a question arises regarding the status of parallel litigation. Regeneron asserts, however, that application of the *Fintiv* factors when

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POP in *Garmin Int'l, Inc. v. Koninklijke Philips N.V.*, IPR2020-00754. *See* November 19, 2020 POP request by petitioners.

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