

2019-1147, -1148, -1323, -1324, -1325

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2019-1147

BTG INTERNATIONAL LIMITED, JANSSEN
BIOTECH, INC., JANSSEN ONCOLOGY, INC.,
JANSSEN RESEARCH & DEVELOPMENT, LLC,
Plaintiffs-Appellants

v.

AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF
NEW YORK, LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S
LABORATORIES, LTD., WOCKHARDT BIO AG, WOCKHARDT USA LLC,
WOCKHARDT LTD., MYLAN PHARMACEUTICALS INC., MYLAN INC.,
WEST-WARD PHARMACEUTICALS CORP., NKA HIKMA
PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS LLC,
TEVA PHARMACEUTICALS USA, INC.,
Defendants-Appellees

PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL
COMPANIES, INC., RISING PHARMACEUTICALS, INC.,
Defendants

Appeals from the United States District Court for the District of New Jersey in
Nos. 2:15-cv-05909-KM-JBC, 2:16-cv-02449-KM-JBC, and
2:17-cv-06435-KM-JBC, Judge Kevin McNulty.

(Caption continued on next page)

2019-1148

BTG INTERNATIONAL LIMITED, JANSSEN
BIOTECH, INC., JANSSEN ONCOLOGY, INC.,
JANSSEN RESEARCH & DEVELOPMENT, LLC,
Plaintiffs-Appellants

v.

AMERIGEN PHARMACEUTICALS, INC.,
AMERIGEN PHARMACEUTICALS LIMITED,
Defendants-Appellees

Appeal from the United States District Court for the District of New Jersey
in No. 2:16-cv-02449-KM-JBC, Judge Kevin McNulty.

2019-1323

JANSSEN ONCOLOGY, INC.,

Appellant

v.

AMERIGEN PHARMACEUTICALS LIMITED,
ARGENTUM PHARMACEUTICALS LLC,

Appellees

Appeal from the United States Patent and Trademark Office, Patent Trial
and Appeal Board in Nos. IPR2016-00286 and IPR2016-01317.

(Caption continued on next page)

2019-1324

JANSSEN ONCOLOGY, INC.,

Appellant

v.

MYLAN PHARMACEUTICALS INC., AMNEAL
PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS
OF NEW YORK, LLC, DR. REDDY'S LABORATORIES, INC.,
DR. REDDY'S LABORATORIES, LTD., TEVA PHARMACEUTICALS USA,
INC., WEST-WARD PHARMACEUTICAL CORPORATION, HIKMA
PHARMACEUTICALS LLC,

Appellees

Appeal from the United States Patent and Trademark Office, Patent Trial and
Appeal Board in Nos. IPR2016-01332 and IPR2017-00853.

2019-1325

JANSSEN ONCOLOGY, INC.,

Appellant

v.

WOCKHARDT BIO AG,

Appellee

Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board in No. IPR2016-01582.

**INVITED BRIEF FOR THE DIRECTOR – U.S. PATENT AND
TRADEMARK OFFICE AS AMICUS CURIAE IN SUPPORT OF
NEITHER PARTY**

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February 1, 2019

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STATEMENT OF INTEREST

The Director respectfully submits this amicus brief pursuant to Fed. R. App. P. 29(a) and this Court's Orders of November 20, 2018 (ECF No. 68), December 12, 2018 (ECF No. 83), and December 20, 2018 (ECF No. 86).

The Director's brief takes no position on the merits of this case.

SUMMARY

The Director of the U.S. Patent and Trademark Office submits this briefing in response to the Court's invitation dated November 20, 2018, ECF No. 68, requesting amicus participation by the USPTO on the following questions:

1. Whether a petitioner is estopped from challenging claims in district court under 35 U.S.C. § 315(e)(2) based on a ground that it brought in an inter partes review, which resulted in a final written decision holding the claims unpatentable but which has a pending request for rehearing.

2. Whether a decision is a "final written decision" under 35 U.S.C. § 315(e)(2) if the period for rehearing under 37 C.F.R. § 42.71(d) has not yet expired.

3. Whether a PTAB decision on the pending requests for rehearing could moot the estoppel issue.

4. Whether a district court can stay a case pending the outcome of a request for rehearing of a final written decision and/or appeal from a final written decision.

The first question has two parts: (a) whether "estoppel" under § 315(e)(2) attaches to a successful petitioner, and (b) whether the estoppel attaches (i) when the final written decision issues or (ii) only after any rehearing request has been addressed. The plain language of the statute answers both subparts, and its drafting history quiets any doubt. As to the successful-petitioner question, the plain language makes no distinction between successful and unsuccessful petitioners, in stark contrast to the statute's inter partes reexamination predecessor. Likewise, the plain language requires estoppel to attach when the proceedings result in a final

written decision, regardless of whether a rehearing request remains outstanding; this is again in contrast to the inter partes reexamination predecessor statute, which delays application of estoppel until all appeals have been exhausted. Moreover, the answer to the second subpart flows logically from the answer to the first—if the estoppel is not outcome dependent, then there is no need to wait beyond issuance of a final written decision to attach it.

The answer to the second question is not implicated under the facts of this case because BTG's rehearing petitions were timely filed before the district court trial on invalidity and were pending at the time of the district court's decision. If reached, the answer to the first question resolves this question as well: estoppel attaches regardless of whether a rehearing request remains outstanding.

As to the third question, estoppel attaches under section 315(e)(2) as soon as the proceedings result in a written decision as to the patentability of the challenged claims. That remains true even if a party petitions for rehearing. Accordingly, the Board's decision to deny the petitions for rehearing here did not affect the application of section 315(e)(2) to the district court proceedings.

As to question four, a district court has considerable discretion to stay proceedings under established case law and nothing in § 315(e)(2) limits that discretion.

DETAILED RESPONSE TO ORDER

As an initial matter, the USPTO notes that if the Court were to affirm the PTAB's findings of unpatentability in the proceedings below, it would not necessarily have to fully resolve the questions posed in the Court's order. *See infra* p. 17 n.6. Subject to that caveat, the USPTO's answers to the Court's questions are set forth below.

(1) Whether a petitioner is estopped from challenging claims in district court under 35 U.S.C. § 315(e)(2) based on a ground that it brought in an inter partes review, which resulted in a final written decision holding the claims unpatentable but which has a pending request for rehearing.

This first question can be divided into two separate and distinct questions:

(a) whether section 315(e)(2) bars a successful inter partes review petitioner from making the same arguments in district court that it prevailed on in the inter partes review, and (b) whether the operation of the 35 U.S.C. § 315(e)(2) estoppel is affected by the pendency of an administrative rehearing request. The USPTO addresses those questions in turn.

a. Section 315(e)(2) applies to both successful and unsuccessful petitioners

On its face, the text of § 315(e)(2) is unambiguous and draws no distinction between successful and unsuccessful petitioners:

(e) **Estoppel.**—

(2) **Civil actions and other proceedings.**—*The petitioner* in an inter partes review of a claim in a patent under this chapter *that results in a final written decision under section 318(a)*, or the real party in interest or privy of the petitioner, may not assert either in a civil action arising in whole or in part under section 1338 of title 28 or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 that the claim is invalid on any ground that *the petitioner* raised or reasonably could have raised during that inter partes review.

35 U.S.C. § 315(e)(2) (emphasis added). By its terms, the § 315(e)(2) bar extends to any petitioner—successful or not—in an inter partes review “that results in a final written decision under § 318(a).” If the petitioner has pursued an inter partes review that resulted in a final written decision, the petitioner may not assert in district court or in the ITC any invalidity ground that was or reasonably could have been raised during the inter partes review, regardless of the *actual* outcome of that decision.

The USPTO acknowledges that the plain language, as explained above, leads to the counterintuitive result that a district court would not be able to consider invalidity arguments the Board found persuasive. But the drafting history of this provision confirms the natural meaning of this text. Prior to the creation of inter partes review in the America Invents Act (AIA) in 2011, Congress provided a similar mechanism for administrative review of issued patents in the form of inter partes reexaminations. Inter partes reexamination decisions, like IPR decisions,

were given preclusive effect in infringement litigation. But the preclusionary provision for inter partes reexaminations, pre-AIA § 315(c), was expressly confined to cases in which patent claims had been finally determined to be “valid and patentable”:

A third party requester whose request for an inter partes reexamination results in an order under section 313 [35 U.S.C. § 313] is estopped from asserting at a later time, in any civil action arising in whole or in part under section 1338 of title 28, the invalidity of any claim finally determined to be valid and patentable on any ground which the third party requester raised or could have raised during the inter partes reexamination proceedings.

35 U.S.C. § 315(c) (pre-AIA) (2011) (“Civil Action”) (emphasis added).

In other words, only unsuccessful inter partes reexamination requesters were barred from bringing the previously addressed or addressable challenges in district court. Congress did not carry forward the outcome-determinative “determined to be valid and patentable” language when it wrote § 315(e)(2). Rather, Congress replaced it with language that is indifferent to the outcome: that petitioner is estopped when the inter partes review “results in a final written decision”—win or lose. 35 U.S.C. § 315(e)(2). In short, Congress deleted the precise words that the defendants now seek to add back into the statute, but the best indication of Congress’s intent is the change in the statutory text itself. *Stone v. INS*, 514 U.S. 386, 397 (1995) (“When Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect.”); *Bausch & Lomb, Inc. v.*

United States, 148 F.3d 1363, 1367 (Fed. Cir. 1998) (“A change in the language of a statute is generally construed to import a change in meaning....”) (citation omitted).

Moreover, the heading of § 315(e), “Estoppel,” does not evidence legislative intent to incorporate common law collateral estoppel principles (and thereby an unspoken limitation to unsuccessful petitioners) into § 315(e)(2). That argument places too much weight on what is, in the end, simply a broad subsection heading. Though “statutory titles and section headings ‘are tools available for the resolution of a doubt about the meaning of a statute,’” the subchapter heading standing alone “cannot substitute for the operative text of the statute” itself. *Florida Dept. of Revenue v. Piccadilly Cafeterias, Inc.*, 554 U.S. 33, 47 (2008) (citation omitted); *Pennsylvania Dept. of Corrections v. Yeskey*, 524 U.S. 206, 212 (1998) (“[T]he title of a statute . . . cannot limit the plain meaning of the text.”) (citation omitted); *Bhd. of R.R. Trainmen v. Baltimore & Ohio R.R. Co.*, 331 U.S. 519, 528 (1947) (the headings of statutory provisions are “not meant to take the place of the detailed provisions of the text”).¹

¹ Indeed, the text of § 315(e)(2) cannot be reconciled with common law collateral estoppel because it estops petitioners on grounds that they raised or “reasonably could have raised”; collateral estoppel applies only to grounds that were “actually litigated and determined.” *B&B Hardware, Inc. v. Hargis Indus., Inc.*, ___ U.S. ___, 135 S. Ct. 1293, 1303 (2015), quoting Restatement (Second) of Judgments §27, p. 250 (1980).

The operative statutory text here is “may not assert,” which makes no distinction between successful and unsuccessful petitioners. The argument that “may not assert” would not prevent a petitioner from “maintaining” a previously-asserted defense proves too much—if “assert” could be read that way, then unsuccessful petitioners would likewise not be estopped. Moreover, when Congress sought to exclude a class of petitioners from the reach of § 315(e)(2), it did so expressly. *See* 35 U.S.C. § 317(a) (providing exception for petitioners in proceedings that were terminated prior to resulting in a final written decision). In view of the plain language of the operative text, the existence of an exception that does not aid successful petitioners, and the differences between § 315(e)(2) and its inter partes reexamination predecessor (pre-AIA § 315(c)), the provision must be read to apply to successful as well as unsuccessful petitioners. The bare use of the word “estoppel” in the subsection heading cannot create a distinction that is not supported by the statutory text, and ignores the intent reflected in § 317(a) and the change from pre-AIA § 315(c).²

The USPTO notes that the Board’s Trial Practice Guide does look to collateral estoppel principles, but only for determinations of privity. *See* 77 Fed. Reg. 48759 (Aug. 14, 2012).

² In the context of common law assignor estoppel, this Court has likewise made clear that common law notions of estoppel must give way to the plain language of the AIA. *See Arista Networks, Inc. v. Cisco Sys., Inc.*, 908 F.3d 792, 803 (Fed. Cir. 2018) (holding that the “plain language” of § 311(a) “delineates who may file an IPR petition” and that this plain language allows any “person who is

In any event, as the district court noted in *SiOnyx*, the application of § 315(e)(2) to successful petitioners, in many cases, has no “practical effect.”³ *SiOnyx, LLC v. Hamamatsu Photonics K.K.*, 330 F.Supp.3d 574, 600 (D. Mass. 2018). If this Court affirms the Board’s unpatentability determination, the challenged claims will be cancelled. 35 U.S.C. § 318(b). Those cancelled claims could no longer be asserted against the successful petitioners or any other party. Accordingly, any co-pending infringement proceeding would be resolved in the petitioner’s favor. Conversely, if the court reverses the Board’s unpatentability determination, defendants would then become “unsuccessful” petitioners and indisputably subject to estoppel. *SiOnyx*, 330 F. Supp. 3d at 600.⁴ Under this

not the owner of a patent” to file an inter partes review petition, including “an assignor, who is no longer the owner of a patent.”); *see also Johnson v. Whitehead*, 647 F.3d 120, 129 (4th Cir. 2011) (“While judicial preclusion rules ordinarily reflect the common law, agency preclusion rules are creatures of statute. Courts must thus refrain from imposing judge-made preclusion principles on agencies unless such a course is dictated by statute.”) (citing, *inter alia*, *Astoria Fed. Sav. & Loan Ass’n v. Solimino*, 501 U.S. 104, 108 (1991) and *FCC v. Schreiber*, 381 U.S. 279, 290-91 (1965)).

³ An administrative law judge at the ITC also applied estoppel to a successful petitioner. *Certain Hybrid Electric Vehicles and Components Thereof*, Inv. No. 337-TA-1042 (USITC Nov. 2, 2017). The case settled (2018 WL 3456237 (USITC Apr. 26, 2018)) after the Commission granted review of that decision. 2017 WL 6350515 (USITC Dec. 8, 2017).

⁴ Although some district court cases have stated that § 315(e)(2) estoppel applies to unsuccessful petitioners, they have done so without any examination of whether it also applies to successful petitioners. *See, e.g., Milwaukee Elec. Tool Corp. v. Snap-On, Inc.*, 271 F. Supp. 3d 990, 1027 (E.D. Wis. 2017). As such, they

reasoning, the *SiOnyx* district court estopped defendants from arguing the invalidity of claims on grounds that defendants had prevailed on at the Board, but before all appeals had been exhausted. *Id.*

Contrary to the district court's suggestion in this case, the USPTO's reading of § 315(e)(2) does not require a party "to stand mute" in an infringement proceeding simply because it prevailed before the Board. As explained *infra*, successful petitioners may ask the district court to stay infringement litigation until the Board rehearing and appeals process has been completed and the patent itself has been cancelled. Although a stay of proceedings cannot be guaranteed, successful petitioners have strong arguments that a stay would be appropriate. These arguments include the fact that a final adjudication of the IPR could obviate the need for a trial, as well as (potentially) a post-trial amendment or judgment to account for cancellation of the patent.

b. Section 315(e)(2) estoppel attaches once the PTAB has issued a "final written decision" even if a party seeks rehearing of that decision

The second part of the Court's first amicus question is whether the filing of a rehearing request delays the onset of the § 315(e)(2) bar until a decision is made on the rehearing request. As a preliminary matter, the USPTO's answer to the first

are not persuasive authority as to whether § 315(e)(2) applies to successful petitioners.

half of the question points to the correct answer for the second half. Thus, if § 315(e)(2) applies only to unsuccessful petitioners, it might make sense to have it apply only after the agency has rendered a truly final decision—that is, disposed of any rehearing request. But because, as the USPTO has argued above, § 315(e)(2) does not distinguish between successful and unsuccessful petitioners, there is no reason to delay estoppel application until the rehearing request has been resolved. Even if the Board decides on a petitioner’s rehearing request that it erred and the petitioner’s invalidity arguments are in fact meritorious, the petitioner will still be precluded from contesting validity in district court on those grounds, so there is nothing to be gained from waiting to see whether the Board changes its decision.

More fundamentally, as a strictly textual matter, § 315(e)(2) applies to prevent petitioners from litigating in district court any invalidity claim raised in an inter partes review once that proceeding has “result[ed] in a final written decision under section 318(a).” In other words, up until the point at which the Board has rendered a decision on the patentability of any challenged patent claim, which it is required to do at the conclusion of trial, 35 U.S.C. § 318(a), petitioners may continue to assert invalidity defenses in co-pending litigation. But the estoppel

provisions under section 315(e)(2) attach once the IPR proceedings have “result[ed]” in a written decision by the Board.

This is true even though a rehearing request might be filed from a “final written decision.” While the filing of a rehearing request renders a “final written decision” non-final and, therefore, unappealable, *see ICC v. Brotherhood of Locomotive Engineers*, 482 U.S. 270, 284-85 (1987); 37 C.F.R. § 90.3(b), the statute nonetheless attaches estoppel as soon as the inter partes review has “result[ed] in” a decision. Thus, the question is not whether a “final written decision” is “final” for purposes of appellate review; the question is only whether, pursuant to § 318(a), a “final written decision” has issued. As with district court litigation, the initial judgment retains its preclusive effect even if additional filings render the decision non-appealable. *See, e.g.*, 18 James Wm. Moore, Moore’s Federal Practice § 131.30[2][c][iv], at 131-101 (3d ed. 1998).

Congress could have, but did not, use clear language to provide that the § 315(e)(2) bar applies only after final agency action, including resolution of any rehearing requests. For example, prior to the AIA, estoppel in inter partes reexamination attached only after the challenged claims had been “finally determined to be valid and patentable” after the conclusion of all judicial appeals. *See* 35 U.S.C. § 315(c) (2011); *Bettcher Indus. Inc. v. Bunzl U.S.A. Inc.*, 661 F.3d 629, 642-43 (Fed. Cir. 2011). Congress chose not to carry forward that aspect of

the inter partes reexamination statute, and instead, elected to have estoppel attach as soon as the inter partes review “results in a final written decision.” This change illustrates that Congress intended estoppel to attach regardless whether the Board’s decision would ultimately be subject to further review. Thus, especially when one considers that Congress made § 315(e)(2)’s bar indifferent to outcome, it can reasonably be inferred that Congress was more concerned with accelerating the effect of the bar than waiting for a final decision, either from the agency or the courts.

Tying estoppel to a decision that is required to ordinarily be reached by a date certain provides predictability and certainty, and is consistent with the AIA’s goal of providing a low-cost and speedy alternative to district court litigation. The AIA’s authors were particularly concerned about the timing of post-issuance proceedings, and the fact that under the pre-AIA system, “it typically takes three or four years before the PTO decides an inter partes reexamination,” and “the decision can then be appealed, which can make the process last from 5 to 8 years.” S. Rep. No. 111-18, at 55 (2009) (Minority Views of Sens. Kyl, Feingold, and Coburn). To address these concerns, Congress imposed a 12-month time limit for completion of AIA trials, *see* 35 U.S.C. § 316(a)(11), made estoppel effective against challenges in all other fora upon issuance of the Board’s “final written decision under section 318(a)” rather than upon exhaustion of Article III appeals,

see id. § 315(e), and eliminated internal agency appeals of post-issuance review decisions. *See* 157 Cong. Rec. S1376 (Mar. 8, 2011) (Sen. Kyl) (noting that “the AIA’s eliminat[ion of] administrative appeals” will “substantially accelerate the resolution of inter partes cases”).

By contrast, if estoppel did not attach until the resolution of all requests for rehearing, neither parties nor district courts would be able to readily predict when estoppel might attach. Neither the statute nor the regulations impose a timeframe upon the Board for issuing a rehearing decision. While the Board endeavors to decide a request within two months of filing, extenuating factors can prevent the Board from meeting this goal as illustrated by the 11-month pendency of the rehearing requests in this case. This uncertainty might discourage district courts from staying infringement actions pending decisions at the Board,⁵ and would

⁵ Trial courts have emphasized that an important factor in deciding whether to stay a civil action is that, upon conclusion of the Board proceeding, “the defendant will be estopped from challenging the validity of the claims on any ground that was, or could reasonably have been, asserted in the inter partes proceeding.” *NFC Tech. LLC v. HTC Am., Inc.*, Case No. 2:13-CV-1058-WCB, 2015 WL 1069111, *4 (E.D. Tex. Mar. 11, 2015) (Bryson, J., sitting by designation) (citing § 315(e)(2)). Courts evaluating stays of litigation have thus relied on the fact that the inter partes review machinery allows them to know with reasonable certainty when the USPTO will institute review, *see Oil-Dri Corp. v. Nestle Purina Petcare Co.*, Case No. 15-cv-1067, 2015 WL 13650951, at *1 (N.D. Ill. May 5, 2015), and even to predict a date certain by which the Board will issue a final written decision and the § 315(e)(2) estoppel will take effect. *See Milwaukee Elec. Tool Corp. v. Hilti, Inc.*, 138 F. Supp. 3d. 1032, 1035 (E.D. Wisc. 2015) (granting a stay while noting that “[u]nder the USPTO’s statutory schedule, final written decisions on the IPRs are expected by July 31, 2016” at which point the defendants “will be bound

drive up the cost of litigation by keeping otherwise estopped invalidity arguments in play.

The USPTO's view on § 315(e)(2) estoppel here also reflects the reading the Office has given to the sister administrative statutory bar provision at § 315(e)(1). Section 315(e)(1) provides that “[t]he petitioner in an inter partes review . . . that results in a final written decision under section 318(a) . . . may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that inter partes review.” The Board has applied the § 315(e)(1) bar based upon issuance of the final written decision, independent of any pending or possible rehearing request. *See, e.g., Facebook, Inc. v. Uniloc USA, Inc.*, IPR2017-01427, Paper 30 (PTAB May 29, 2018) (applying § 315(e)(1) bar based on final written decision in IPR2017-00225 during period for rehearing); *Apple Inc. v. Personalized Media Communications LLC*, 2018 WL 922376, at *2 (PTAB Feb. 15, 2018) (applying § 315(e)(1) bar based upon a separate final written decision for which a rehearing

by the estoppel provision [at] 35 U.S.C. § 315(e)(2)"); *see also Cypress Semiconductor Corp. v. GSI Tech., Inc.*, Case No. 13-cv-02013-JST, 2014 WL 5021100, *1 & 3 (N.D. Cal. Oct. 7, 2014) (relying on date certain for final written decision and related § 315(e) estoppel). Uncoupling the § 315(e)(2) estoppel from the “final written decision” under section 318(a) — an event that reliably occurs 12 months after institution — would eliminate certainty as to when the estoppel will take effect, and would inevitably affect district judges’ decisions whether to grant a stay of litigation pending completion of inter partes review.

request had been filed and was “being determined concurrently”); *Valve Corp. v. Ironburg Inventions Ltd.*, 2018 WL 575390, at *1 n.4 & *4 (PTAB Jan. 25, 2018) (applying § 315(e)(1) bar based on separate final written decision with pending rehearing request); *see also Emerson Elec. Co. v. IP Co., LLC*, 2017 WL 2390705, at *1-3 (PTAB May 31, 2017) (precluding institution based on separate final written decision that was on appeal). At least one district court has recognized that “estoppel attaches when the [Board] issues a final written decision under section 318(a),” despite the Board’s issuance of a subsequent decision denying rehearing. *See Verinata Health, Inc. v. Ariosa Diagnostics, Inc.*, Case No. 12-cv-05501-SI, 2017 WL 235048, at *5 (N.D. Cal. Jan. 19, 2017); *see also SiOynx*, 330 F. Supp. 3d at 600-01 (rejecting argument that estoppel should not attach in view of pending judicial appeal).

In short, not only does the plain language of the statute provide that estoppel attaches upon decision issuance, but there is also no good reason that Congress would have wanted a petitioner to be able to indefinitely toll the application of the § 315(e)(2) bar by simply filing a rehearing request.

(2) Whether a decision is a “final written decision” under 35 U.S.C. § 315(e)(2) if the period for rehearing under 37 C.F.R. § 42.71(d) has not yet expired.

The final written decisions in the underlying inter partes reviews here all issued on January 17, 2018. *See* Appx2. Appellant Janssen timely filed requests for

rehearing in all three proceedings in February, 2018; the Board denied those rehearing requests on December 3, 2018. *See BTG Br.* at 1. Thus, requests for rehearing were pending when the district court conducted its bench trial between July 23, 2018, and August 2, 2018 (Appx3), and when the court addressed the estoppel issue in its October 31, 2018 decision.

Because the rehearing requests here were filed before the district court trial at which estoppel should have applied, question two is not presented by the facts of this case. However, if reached, the USPTO's answer to question one would largely answer question two. While the USPTO regulations provide 30 days to file a request for rehearing on the final written decision (37 C.F.R. § 42.71(d)(2)) and reset the period for appeal upon refile of a timely request for rehearing (37 C.F.R. § 90.3(b)(1)), the statute does not condition estoppel attachment on exhausting any rehearing remedy. Thus, § 315(e)(2)'s bar attaches once a final written decision has been issued and the possibility of a rehearing request does not alter or forestall that result.

(3) Whether a PTAB decision on the pending requests for rehearing could moot the estoppel issue.

As explained above, estoppel attaches under § 315(e)(2) as soon as the IPR proceeding results in a written decision as to the patentability of the challenged claims. That remains true even if a party petitions for rehearing. Accordingly, the Board's decision to deny the petitions for rehearing did not affect the application of

§ 315(e)(2) to the district court proceedings. Of course, now that the appeals from the district court actions have been consolidated with the appeals from the inter partes reviews, if this Court upholds the Board's unpatentability findings, and all possible avenues of review of those decisions are exhausted, the estoppel issue need not be addressed.⁶

(4) Whether a district court can stay a case pending the outcome of a request for rehearing of a final written decision and/or appeal from a final written decision.

Yes, district courts can stay a case pending the outcome of a request for rehearing of a final written decision and/or appeal from a final written decision. District courts have broad discretion to manage their dockets, including staying proceedings to accommodate case management considerations. *See, e.g., Clinton v. Jones*, 520 U.S. 681, 706 (1997) (“[A] District Court has broad discretion to stay proceedings as an incident to its power to control its own docket.”). And district courts have frequently stayed litigation pending the completion of IPR proceedings or appeals. *See, e.g., Depomed, Inc. v. Purdue Pharma L.P.*, 2016 WL 50505, at *2

⁶ The USPTO acknowledges that BTG has argued that even if the patents are finally held invalid, it would still be entitled to damages based on the district court's failure to issue a 35 U.S.C. § 271(e)(4)(a) order to the FDA that would have prolonged BTG's exclusivity. This argument appears to fly in the face of *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1341-44 (Fed. Cir. 2013), which makes clear that past damages are not available for patents that have been finally held invalid.

(D.N.J. 2016) (“A stay of Depomed’s infringement action pending Purdue’s IPR appeals would not be an unusual result.”).

The Hatch-Waxman Act creates no exception to these principles. Indeed, at least one court has stayed a Hatch-Waxman action until the USPTO issues a final written decision in the IPR proceedings. *Eli Lilly & Co. v. Accord Healthcare Inc.*, 2015 WL 8675158, at *2 (S.D. Ind. Dec. 11, 2015); *see also Abbott Labs. v. Matrix Labs., Inc.*, 2009 WL 3719214, at *3 (N.D. Ill. Nov. 5, 2009) (rejecting arguments that Hatch-Waxman precludes a stay of ANDA litigation). A district court is therefore free to stay an infringement action to await the completion of administrative proceedings on a related inter partes review petition.

CONCLUSION

If this Court addresses BTG's estoppel challenges, the Court should interpret the § 315(e)(2) estoppel to apply to both successful and unsuccessful petitioners, and to attach when the IPR proceeding results in a written decision regardless of any pending or possible request for rehearing.

February 1, 2019

Respectfully submitted,

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RULE 32(a)(7)(C) CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7), the undersigned certifies that the foregoing **INVITED BRIEF FOR THE DIRECTOR – U.S. PATENT AND TRADEMARK OFFICE AS AMICUS CURIAE IN SUPPORT OF NEITHER PARTY** complies with the type-volume limitation required by the Court’s rule. The total number of words in the foregoing brief, excluding the parts exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b), is 4,580 as calculated using the Word® software program.

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CERTIFICATE OF SERVICE

I hereby certify that on February 1, 2019, the foregoing **INVITED BRIEF FOR THE DIRECTOR – U.S. PATENT AND TRADEMARK OFFICE AS AMICUS CURIAE IN SUPPORT OF NEITHER PARTY** was electronically filed using the Court’s CM/ECF filing system. Counsel of record was electronically served by and through the Court’s CM/ECF filing system pursuant to Fed. Cir. R. 25(e).

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