**2017-109**

# United States Court of Appeals for the Federal Circuit

IN RE: VERINATA HEALTH, INC., ILLUMINA, INC.,

*Petitioners*.

*On Petition for Writ of Mandamus to the United States District Court for the Northern District of California in No. 3:12-cv-05501-SI, Judge Susan Y. Illston.*

**BRIEF OF BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) AS *AMICI CURIAE* IN SUPPORT OF PETITION**

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February 9, 2017

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**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

In re: Verinata Health, Inc.

Case No. 2017-109

**CERTIFICATE OF INTEREST**

Counsel for the:
☐ (petitioner) ☐ (appellant) ☐ (respondent) ☐ (appellee) ☒ (amicus) ☐ (name of party)

Biotechnology Innovation Organization ("BIO")
Pharmaceutical Research and Manufacturers of America ("PhRMA")

certifies the following (use "None" if applicable; use extra sheets if necessary):

| 1. Full Name of Party Represented by me | 2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is: | 3. Parent corporations and publicly held Companies that own 10 % or more of stock in the party |
|---|---|---|
| Biotechnology Innovation Organization | None | None |
| Pharmaceutical Research and Manufacturers of America | None | None |
| | | |

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (**and who have not or will not enter an appearance in this case**) are:

Nathan Nobu Lowenstein
Kenneth Weatherwax
Jonathan H. Steinberg, *of counsel*
Lowenstein & Weatherwax LLP

February 9, 2017
Date

/s/ Kenneth Weatherwax
Signature of counsel

Please Note: All questions must be answered

Kenneth Weatherwax
Printed name of counsel

cc:

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## STATEMENT OF INTEREST OF *AMICI CURIAE*

The Biotechnology Innovation Organization (BIO) is the world's largest biotechnology trade association, with over 1,100 members worldwide involved in research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products. The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's member companies are dedicated to discovering medicines enabling patients to lead longer, healthier, and more productive lives. BIO and PhRMA are concerned that the development and commercialization of a range of life science technologies will be impeded if this Court does not address the mounting uncertainty concerning the scope of *inter partes* review estoppel under 35 U.S.C. § 315(e)(2).[1]

All parties have consented to the filing of this brief on February 9, 2017.

[1] *Amici* have no direct stake in the result of this appeal. No counsel for a party authored this brief in whole or in part, and no such counsel or party, nor any person other than *amici curiae* or their counsel, made a monetary contribution intended to fund preparation or submission of this brief. This brief is solely the work of BIO and PhRMA and their counsel; it reflects *amici's* consensus view but not necessarily the view of any of their individual members. *Amici* are contemporaneously moving for leave (to the extent required) to file this brief.

## ARGUMENT

This Petition provides an opportunity for this Court to answer a critical question that is creating mounting confusion about the scope of *inter partes* review (IPR) estoppel. The Court should grant the writ and clarify that *Shaw Industries Group, Inc. v. Automated Creel Systems, Inc.*, 817 F.3d 1293 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 374 (2016), did ***not*** restrict the scope of § 315(e) estoppel in IPRs to grounds that were both raised in a petition and instituted and bar all other estoppel as to all other grounds. Instead, *Shaw* stands, at most, for the proposition that estoppel does not apply to grounds that were raised in the petition but that the Patent Trial and Appeal Board (PTAB) declined to institute for non-substantive reasons such as redundancy. *Shaw* does ***not*** stand, as the district court here and courts elsewhere have incorrectly suggested, for the much broader proposition that IPR estoppel does not apply to unraised grounds in the IPR petition. Nor can *Shaw* be understood to bar estoppel for grounds that were raised and denied institution on their merits—a point on which *Shaw* was silent.[2]

Congress, in closely scrutinized provisions of the America Invents Act, extended IPR estoppel to "any ground that the petitioner raised ***or reasonably***

[2] *Shaw* considered a PTAB denial of certain grounds as "redundant" because the PTAB deemed the instituted grounds sufficient and made no "substantive determinations" regarding those grounds. *Shaw*, 817 F.3d at 1297. Thus, *Shaw* did not involve a PTAB decision that denied institution of "redundant" grounds in the sense that they are substantively duplicative.

***could have raised*** during" an IPR. 35 U.S.C. § 315(e). Whether grounds absent from an IPR petition may be subject to "could have raised" estoppel is a question that affects most cases involving patents that have survived IPR. The answer spells the difference between estoppel making IPRs meaningful substitutes for litigation of common patentability issues—consistent with the statutory language, the legislative history, the PTAB's prior decisions, and the public's expectations—and a meager estoppel that barely diminishes (let alone substitutes entirely for) subsequent invalidity litigation and perversely encourages piecemeal harassment of patent owners.

The scope of *Shaw*'s precedential effect has sorely puzzled courts and spurred pleas for this Court's guidance. *See, e.g., Intellectual Ventures I LLC v. Toshiba Corp.*, 2017 U.S. Dist. LEXIS 3800, at *3-4, 2017 WL 107980 (D. Del. Jan. 11, 2017) (Robinson, J.), (denying reconsideration on question of scope of *Shaw*, expressing uncertainty about correct answer, and voicing hope that this Court will "clarify the issue for future judges"), *reaffirming result in* 2016 U.S. Dist. LEXIS 174699 (D. Del. Dec. 19, 2016); *Verinata Health, Inc. v. Ariosa Diagnostics, Inc.*, 2017 U.S. Dist. LEXIS 7728, at *7-8 & n.4 (N.D. Cal. Dec. 19, 2016) (Illston, J.) (holding that "*Shaw* dictates" that if "the PTAB did not institute on [a] ground . . . , therefore, defendants are not estopped from raising the same invalidity argument in this litigation").

This confusion also clashes with other tribunals' views. The PTAB's pre-*Shaw* decision in *Apotex Inc. v. Wyeth LLC*, IPR2015-00873, Paper 8, 2015 Pat. App. LEXIS 12730, 2015 WL 5523393 (P.T.A.B., Sep. 16, 2015), interpreted the same statutory estoppel language the same way as *Shaw*, as to the same sort of grounds confronted by *Shaw*—*i.e.*, grounds petitioned, but non-substantively denied as redundant—yet had no difficulty simultaneously holding that such estoppel ***does apply*** to grounds that were never raised in the petition, but reasonably could have been. The district court concluded that *Shaw*'s rationale sweepingly precludes estoppel as to grounds not actually instituted, even though such grounds were not before the *Shaw* Court. 2017 U.S. Dist. LEXIS 7728, at *7-8; *see also Intellectual Ventures I*, 2017 U.S. Dist. LEXIS 3800, at *2-3. In *Apotex*, the PTAB used a similar rationale as *Shaw*, yet reached the opposite conclusion from the district court; for the PTAB had no difficulty simultaneously also applying estoppel to issues that never were, but reasonably could have been, raised in the IPR.

Even if *Shaw*'s rationale were truly in tension with estoppel of unpetitioned, uninstituted grounds, *Shaw* would still not be entitled to the broad effect the district courts suggest. Because *Shaw* "did not confront and decide the same issue, it is not precedent on the question before us." *See Special Devices, Inc. v. OEA, Inc.*, 269 F.3d 1340, 1346 (Fed. Cir. 2001). In *Shaw*, estoppel of unpetitioned grounds was

raised by neither the facts nor the parties, and resolution of the question was not necessary for its denial of relief. Indeed, Judge Reyna, on *Shaw*'s panel, pointedly observed that the estoppel question was not properly before the Court at all.

No matter how courts ultimately resolve the exact contours of § 315(e) estoppel, there is no basis on which to extend *Shaw* beyond its facts. Yet district courts are doing just that, thereby eviscerating the broad IPR estoppel that Congress provided for and on which the public relied. To dispel this confusion and restore IPR estoppel to its proper scope, the petition for writ of mandamus should be granted.

*Amici* expresses no view on any matters not expressly addressed herein.[3]

## The AIA Was Commonly Understood To Provide For Broad IPR Estoppel That Could And Did Extend To Unpetitioned Grounds.

Many stakeholders—*amici* among them—participated in the years-long Congressional negotiations in which these estoppel provisions and other IPR provisions were carefully debated before they became law. The associated

[3] For example, *amici* express no view in this brief concerning other issues in the district court case, such as how estoppel applies to parties who become IPR real-parties-in-interest post-institution, or other matters suggested in the Petition, such as the ability of district courts to review substantive noninstitution decisions as part of their estoppel determinations. Pet. at 21.

legislative history is extensive. Coupled to the statutory language, it shows clearly Congress's intent that the AIA's estoppel provisions were to have broad scope.[4]

Congress went on record to repeatedly emphasize that IPRs were to be a "complete alternative" or "substitute" for litigating the most common types of prior art validity disputes, namely those based on patents and printed publications. Parties wishing to challenge validity could do so either in litigation or in an IPR, and in IPR such challenges were to be quick, efficient, and inexpensive. Congress wanted to protect patent owners from serial and harassing challenges, however. Accordingly, if an IPR final decision upheld some of the challenged claims, it was Congress's clear intent that ***any*** grounds the petitioner reasonably could have presented to the PTAB could not thereafter be raised in a renewed attack in court. That intent is captured in 35 U.S.C. § 315(e)(2)'s language, which precludes petitioners, after a final written decision, from raising in district court any ground IPR petitioners either "raised" or "reasonably could have raised" during IPR.

When the AIA was enacted in 2011, Senator Grassley, "a central figure" in the AIA's passage, *Synopsys, Inc. v. Mentor Graphics Corp.*, 814 F.3d 1309, 1327

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[4] Some of this legislative history is discussed in the Petition. Pet. at 15-16. *See also SAS Inst., Inc. v. ComplementSoft, LLC*, 825 F.3d 1341, 1353-60 (Fed. Cir. 2016) (Newman, J., concurring-in-part and dissenting-in-part); *Synopsys, Inc. v. Mentor Graphics Corp.*, 814 F.3d 1309, 1324-39 (Fed. Cir. 2016) (Newman, J., dissenting), which did not directly involve the scope of IPR estoppel, but in which Judge Newman's separate opinions collect much relevant legislative history.

(Fed. Cir. 2016) (Newman, J., dissenting), summarized his understanding that "if an inter partes review is instituted while litigation is pending, that review will ***completely substitute*** for at least the patents-and-printed-publications portion of the civil litigation." 157 Cong. Rec. S1376 (daily ed. March 8, 2011) (statement of Sen. Grassley).[5] He explained that IPR would be an "alternative" to court litigation on these issues, and the IPR provisions would "significantly reduce the ability to use post-grant procedures for abusive serial challenges to patents." 157 Cong. Rec. S952 (daily ed. Feb. 28, 2011) (statement of Sen. Grassley on S.23).

Throughout the multi-year legislative process, USPTO directors testified before Congress about the pending bills that would eventually become the AIA, consistently expressing their understanding that IPRs would create broad, significant estoppel. Director Dudas testified that

> ***the estoppel needs to be quite strong*** that says on the second window ***any issue that you raised or could have raised you*** can bring up no place else. That second window, from the administration's position, is ***intended to allow nothing—a complete alternative to litigation***.

*Patent Reform: The Future of American Innovation: Hearing Before the Senate Comm. on the Judiciary*, 110th Cong. 13 (2007). Likewise, Director Kappos emphasized that, "[t]hose estoppel provisions mean that your patent is ***largely unchallengeable*** by the same party." America Invents Act: Hearing on H.R. 1249

[5] All emphasis in this brief is added unless otherwise noted.

Before the House Comm. on the Judiciary, 112th Cong. 52-53 (2011). Therefore, "there are significant advantages for patentees who successfully go through the post-grant system—in this case inter partes review—***because of those estoppel provisions***." *Id.*

Further proof that the "reasonably could have raised" language of § 315(e) was widely understood to have broad scope is the outcry when that language appeared in the enacted post-grant review provision, 35 U.S.C. § 325(e)(2). The House Judiciary Committee subsequently stated that the inclusion of this estoppel language—perhaps by mistake—in § 325(e)(2) would derail the PGR system, because the inclusion of that broad, powerful language would preclude later validity challenges:

> [T]he preservation of a civil-litigation could-have-raised estoppel following post-grant review threatens to fatally undermine the new proceeding. . . . ***Applying a litigation could-have-raised estoppel to post-grant review thus would present petitioners with a daunting prospect: once such a review is instituted, the petitioner effectively would be barred from challenging the validity of the patent on any ground should he later be sued for its infringement*** . . . .

H.R. Rep. 114-235, at 44 (Jul. 29, 2015).[6] Thus, Congress understood the "reasonably could have raised" language to be a decisive limitation upon later

[6] Available at http://patentdocs.typepad.com/files/crpt-114hrpt235.pdf.

court challenges.[7]

Like Congress, the public, including *amici* and their members, believed these estoppel provisions to be broad. For example, two commentators stated that "[i]t is, however, clear that as long as a prior art reference was available to the petitioner, the PTAB would consider any ground of invalidity involving that prior art as 'reasonably could have [been] raised' in the earlier petition." Barbara McCurdy and Arpita Bhattacharyya, "Recent Decisions Shed Some Light On Scope Of AIA Estoppel," Law360, Jul. 16, 2015;[8] *see also* Ryan Davis, "AIA Estoppel Provision Not As Restricted As Many Expected," Law360, Jan. 26, 2017 ("the [estoppel] provision . . . suggested to many observers that petitioners would have one chance in the inter partes review petition to make all their arguments that the patent is invalid as obvious or anticipated, and that by challenging the patent, they would forfeit the chance to make that case later.").[9] However, courts are now

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[7] Conversely, in transitional "covered business method" proceedings, Congress elected to exclude the "could have raised" language, and to limit estoppel only to grounds ***actually raised***. America Invents Act § 18(a)(1)(D). Congress was clearly mindful of its different calibration of estoppel effects in various post-grant proceedings. This Court should ensure respect for Congress's intent.

[8] https://www.law360.com/articles/676056/recent-decisions-shed-some-light-on-scope-of-aia-estoppel.

[9] https://www.law360.com/articles/884773/aia-estoppel-provision-not-as-restricted-as-many-expected.

mistakenly concluding that the scope of IPR estoppel that Congress intended is foreclosed. Guidance is urgently needed.

**<u>*Shaw*'s Precedential Effect Is Narrow At Best.</u>**

*Shaw*'s reasoning and precedential effect do not apply as broadly as the courts interpreting *Shaw* have found. In this context, it is helpful to compare the PTAB's decisions interpreting the scope of estoppel under § 315(e)(1), which applies to proceedings before the PTO and contains "could have raised" language identical to § 315(e)(2). The Board has consistently interpreted this language to mean estoppel applies to grounds that reasonably could have been, but were not, raised ***in the petition***. *See Dell Inc. v. Elecs. & Telecomm'ns Res. Inst.*, IPR2015-00549, Paper 10, at 4-6 (P.T.A.B. March 26, 2015) (representative decision) (consulting AIA legislative history to conclude that estopped "could have raised" grounds include prior art a skilled searcher conducting a reasonable search reasonably could be expected to discover). The PTAB has applied such estoppel not only as to grounds that used the same references as those on which review was instituted in the first IPR, but also to grounds that used references that had been raised in the first IPR but ***denied*** institution on the merits. *Id.*[10]

[10] Moreover, the PTAB has continued to adhere to its broad view of § 315(e)(1) estoppel. *See, e.g., Johns Manville Corp. v. Knauf Insulation, Inc.*, IPR2016-00130, Paper 29, at 1-2 (P.T.A.B. Feb.6, 2017) (interpreting § 315(e)(1) to estop grounds based on references not raised in first IPR but "were in the possession of Petitioner at the time . . . and thus under § 315(e)(1) 'reasonably could have [been] raised during that [IPR]").

In particular, in *Apotex Inc. v. Wyeth LLC*, IPR2015-00873, Paper 8, 2015 Pat. App. LEXIS 12730, 2015 WL 5523393 (P.T.A.B., Sep. 16, 2015), the PTAB addressed not only grounds that had not been raised in the first petition but reasonably could have been, but also grounds that had been raised in an earlier petition, but were denied for non-substantive reasons based on redundancy. *Id.* at 7. First, consistent with *Dell*, the PTAB concluded that the grounds that were not raised in the first IPR petition were estopped. *Id.* at 8-9. The PTAB explained that "the record demonstrates that Petitioner was aware of the prior art references asserted in [the estopped ground] when it filed the [first] IPR," *id.* at 6, and that "[w]hat a petitioner 'could have raised' was ***broadly described*** in the legislative history of the America Invents Act . . . to include 'prior art which a skilled searcher conducting a diligent search reasonably could have been expected to discover.'" *Id.*

Next, *Apotex* addressed the type of ground later featured in *Shaw*: grounds that had been petitioned in the first IPR, but been denied institution for non-substantive reasons as redundant. The PTAB concluded that such grounds were ***not*** estopped:

> [G]rounds raised during the preliminary proceeding, but not made part of the instituted trial, are not raised "during" an *inter partes* review and cannot be the basis for estoppel under 35 U.S.C. § 315(e)(1). ***Nor are such grounds ones that "reasonably could have been raised***

> ***during" the review***, because once denied, the Board's decision on institution ***prevents*** Petitioner from raising that ground during the trial**.** Ground 1 in the instant Petition was never raised during the '115 IPR, because the Board denied institution of Ground 6 as redundant, and Petitioner could not have raised Ground 6 again once institution was denied as to that ground.

*Id.* (citation omitted).

The PTAB perceived no conflict between its conclusion that unpetitioned grounds ***are*** estopped, and its simultaneous conclusion that grounds denied institution for non-substantive reasons are ***not*** estopped. The PTAB evidently reasoned that, if a ground could have been raised during the first IPR but petitioner never even tried to raise it, there was no reason to conclude that it could not have been raised, so it was estopped. In contrast, a petitioned ground denied institution for non-substantive reasons is different: such a ground is not only never addressed on the merits, but it could not possibly be raised during the IPR trial, because the PTAB itself prevented both from occurring, and so estoppel should not attach to the ground in later cases. *See id.* at 5-9. The important point is that the PTAB saw no conflict between these two conclusions.

Then came this Court's turn. In *Shaw*, this Court addressed the identical estoppel language in § 325(a)(2). 817 F.3d at 1300. The facts featured only grounds that were petitioned and been denied for non-substantive reasons as

redundant. The petition for mandamus asked, in the alternative, that the Court order the PTO to institute an IPR on the "redundant" grounds, on the basis that a district court might later estop such grounds. This Court concluded that mandamus was unwarranted because the petitioned but redundant claims did not seem to be subject to estoppel. *See id.*

There is essentially no difference between the reasoning of this Court in *Shaw* as to petitioned but denied-as-redundant grounds and the PTAB's earlier reasoning in *Apotex* as to such grounds. Both cases rely on essentially the same reasoning: that the petitioned but denied-as-redundant grounds cannot be raised "during" the IPR trial following the institution decision, because the PTAB has refused to reach those grounds' merits or allow review based on them.[11] *Compare Apotex*, Paper 8, at 7, 2015 Pat. App. LEXIS 12730, at *10-11, *with Shaw*, 817 F.3d at 1300.

[11] To be clear, *amici* do not endorse *Shaw's* or *Apotex's* reasoning. *Shaw's* theory of IPR estoppel rests on the proposition that the only grounds that a Petitioner "could have raised *during* that inter partes review" are those that have been instituted because an IPR does not begin until institution. *Shaw*, 817 F.3d at 1300. *Shaw*, however, did not mention § 311(b) which makes clear that the petition is a part of the "inter partes review": "A petitioner ***in an inter partes review may request*** to cancel as unpatentable 1 or more claims of a patent only on a ground that ***could be raised*** under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications." Thus, § 311(b) makes clear that the request is a part of the inter partes review and that the grounds a Petitioner "could have raised" refers to grounds that comply with § 311(b)'s limitations.

*Shaw* neither confronted nor discussed whether ***unpetitioned*** claims are estopped. Contrary to later courts' conclusions, *Shaw* is not precedent for doing so. First, the PTAB's reasoning and holdings in *Apotex* amply demonstrate that the logic of *Shaw* ***need not*** be extended to requiring denial of estoppel as to unpetitioned grounds. In *Apotex*, the PTAB ***denied*** estoppel to petitioned but denied-as-redundant grounds, and ***applied*** estoppel to unpetitioned grounds, and saw no conflict between the two.

Second, *Shaw*'s statements regarding the scope of estoppel should not be interpreted broadly to bind beyond their facts. Judge Reyna, who "fully join[ed] the panel opinion" in *Shaw*, nevertheless wrote that the question of estoppel was not even properly before the Court:

> Whether estoppel applies, however, is not for the Board or the PTO to decide. Nor is it for us to decide in the first instance . . . because the issue is not properly before us. Instead, whether the "redundant" grounds are subject to estoppel must be determined in the first instance by the district court . . . .

*Shaw*, 817 F.3d at 1305 (Reyna, J., concurring)

Judge Reyna was correct. In *Shaw*, the lower tribunal had never considered estoppel. On appeal, the parties barely briefed the issue. Petitioner argued that the PTAB should grant a writ of mandamus to reinstitute its redundant grounds and, in the alternative, that estoppel should not apply. *Compare* Shaw Appeal Opening

Brief, 15-1116, Dkt. #24 at 75-76 (arguing Shaw should not be estopped from raising redundant grounds in court) with Shaw Petition For Mandamus, 15-1116, Dkt. #35 at 4 (containing only one reference to possibility of estoppel). Cross-Appellant Automated Creel did not address estoppel at all. Reply Brief for Cross-Appellant Automated Creel Systems, Inc., 15-1116, Dkt. #53. The PTO Director addressed this issue for only two pages, addressing neither the legislative history nor the AIA's structure. Brief for Intervenor PTO Director at 37-39, 15-1116, Dkt. #46.

On this cursory record, it is hardly surprising that the *Shaw* panel made only a cursory analysis of the estoppel issue. It addressed none of the earlier decisions on the issue, such as the PTAB's decisions in *Apotex* or *Dell*. And it did not even mention the legislative history. These are not the ingredients of a precedent that binds beyond its facts. *See, e.g.*, *Orenshteyn v. Citrix Sys.*, 691 F.3d 1356, 1360 (Fed. Cir. 2012) ("Generally, when an issue is not discussed in a decision, that decision is not binding precedent."); *BMC Resources, Inc. v. Paymentech L.P.*, 498 F.3d 1373 (Fed. Cir. 2007) (declining to apply earlier panel's published holding because it had been reached "without any analysis of the issues presented relating to" the new issue present in *BMC*); *Nat'l Cable Television Ass'n v. Am. Cinema Editors, Inc.*, 937 F.2d 1572, 1581 (Fed. Cir. 1991) ("When an issue is not argued

or is ignored in a decision, such decision is not precedent to be followed in a subsequent case in which the issue arises.").

Additionally, this cursory estoppel ruling was in the context of a mandamus ***denial***. The *Shaw* panel was silent as to whether it still had discretion to deny mandamus relief even were its view of estoppel law exactly the opposite. To the extent that the *Shaw* panel had such discretion, its estoppel reasoning should be considered dicta. *See Kollsman v. Los Angeles*, 737 F.2d 830, 833 n.5 (9th Cir. 1984) ("Our earlier refusal to grant a writ of mandamus requiring the district court to abstain does not preclude us from now holding that the district court should have abstained. . . . [W]e apply a more stringent standard of review under our mandamus jurisdiction than when reviewing on direct appeal a district court's order under the abuse of discretion standard.").

Finally, mistaking *Shaw* to be binding precedent that IPR estoppel is limited to grounds actually instituted has extreme and unfortunate results. Such a rule eviscerates the IPR regime Congress established, where IPRs were to be "complete alternative[s]" or "complete[] substitute[s]" to litigation, and incentivizes petitioners to intentionally withhold grounds from their petitions for a later second attack if their first does not succeed. *Shaw* compels no such conclusion, and should at most be limited to its facts.

The Petition for a writ of mandamus should be granted.

Respectfully submitted:

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# ADDENDUM
# PURSUANT TO F.R.A.P. 32.1

## ADDENDUM PURSUANT TO F.R.A.P. 32.1(B)

List of unpublished decisions cited in Brief Of Biotechnology Innovation Organization (BIO) As *Amicus Curiae* In Support Of Petition:

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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APOTEX INC.,
Petitioner,

v.

WYETH LLC,
Patent Owner.

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Case IPR2015-00873
Patent 7,879,828 B2

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Before JACQUELINE WRIGHT BONILLA, CHRISTOPHER L. CRUMBLEY, and JO-ANNE M. KOKOSKI, *Administrative Patent Judges.*

KOKOSKI, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
*37 C.F.R. § 42.108*

# I. INTRODUCTION

Apotex Inc. ("Petitioner") filed a Petition ("Pet.") to institute an *inter partes* review of claims 1–23 of U.S. Patent No. 7,879,828 B2 ("the '828 patent," Ex. 1001). Paper 1. Wyeth LLC ("Patent Owner") filed a Preliminary Response ("Prelim. Resp."). Paper 6. We have jurisdiction under 35 U.S.C. § 314.

Upon consideration of the Petition, the Preliminary Response, and the evidence of record, we determine that Petitioner has not established a reasonable likelihood of prevailing with respect to claims 1–23 of the '828 patent. Accordingly, we deny the Petition and do not institute an *inter partes* review.

## *A. Related Proceedings*

The parties indicate that the '828 patent is involved in at least four pending district court actions. Pet. 4; Paper 5, 3. Petitioner states that it is not a party to any of the pending actions. Pet. 4. The '828 patent was the subject of IPR2014-00115 ("the '115 IPR"), also filed by Petitioner, a proceeding in which a Final Written Decision ("the '115 Final Decision," Ex. 2002) issued on April 20, 2015 (*Apotex Inc. v. Wyeth LLC*, Case IPR2014-00115, slip op. at 26 (PTAB April 20, 2015) (Paper 94)), and IPR2014-01259, in which institution was denied on February 13, 2015 (*Initiative for Responsibility in Drug Pricing LLC v. Wyeth LLC*, Case IPR2014-01259, slip op. at 7 (PTAB Feb. 13, 2015) (Paper 8)).

## *B. The '828 Patent*

The '828 patent, titled "Tigecycline Compositions and Methods of Preparation," is directed to compositions comprising tigecycline, a suitable carbohydrate, and an acid or buffer. Ex. 1001, 1:8–11. Tigecycline, a

chemical analog of minocycline, is a tetracycline antibiotic used to treat drug-resistant bacteria. *Id*. at 1:22–25. Due to poor oral bioavailability, tigecycline typically is formulated as an intravenous solution that is prepared from a lyophilized tigecycline powder immediately prior to administration. *Id*. at 1:45–50. In solution, tigecycline undergoes oxidation at slightly basic pH, causing the tigecycline to degrade relatively rapidly. *Id.* at 2:24–26, 33–40. When the pH of the solution is lowered, however, oxidative degradation decreases, and degradation by epimerization predominates. *Id*. at 2:43–49. The tigecycline epimer lacks antibacterial effect, and is, thus, an undesirable degradation product. *Id*. at 3:19–22. According to the '828 patent, the claimed compositions reduce tigecycline degradation, because the acidic pH of the solution comprising tigecycline and a suitable carbohydrate minimizes oxidative degradation, while the carbohydrate stabilizes the tigecycline against epimerization in the acidic solution. *Id.* at 4:49–59.

The Specification discloses various embodiments, such as compositions comprising tigecycline, lactose, and hydrochloric acid, at pH values between 3.0 and 7.0. *Id.* at 7:63–10:35, 11:15–12:53. The Specification further discloses embodiments where the molar ratio of tigecycline to lactose varies between 1:0.24 and 1:4.87. *Id*. at 13:40–14:33.

*C. Illustrative Claim*

Petitioner challenges claims 1–23 of the '828 patent. Claims 1 and 12 are independent claims. Claim 1 is illustrative, and reads as follows:

> 1. A composition comprising tigecycline, lactose, and an acid selected from hydrochloric acid and gentisic acid, wherein the molar ratio of tigecycline to lactose is between about 1:0.2 and about 1:5 and the pH of the composition in a solution is between about 3.0 and about 7.0.

*D. The Prior Art*

Petitioner applies the following references in its asserted grounds:

| Name | Description | Date | Exhibit No. |
|---|---|---|---|
| CN ’550 | Chinese Patent Publication No. 1390550A | Jan. 15, 2003 | 1003<br>1004 (English translation) |
| Kirsch et al. | *Development of a Lyophilized Formulation for (R, R)- Formoterol (L)-Tartrate*, DRUG DEVEL. & INDUS. PHARM. 27(1):89–96 | 2001 | 1007 |
| Herman et al. | *The Effect of Bulking Agent on the Solid-State Stability of Freeze-Dried Methylprednisolone Sodium Succinate*, PHARM. RES. 11(10):1467–1473 | 1994 | 1006 |
| Pawelczyk et al. | *Kinetics of Drug Decomposition. Part 74. Kinetics of Degradation of Minocycline in Aqueous Solution*, POL. J. PHARMACOL. PHARMA. 34:409-421 | 1982 | 1008 |
| Remmers et al. | *Some Observations on the Kinetics of the C·4 Epimerization of Tetracycline*, J. PHARMA. SCI. 52(8):752–756 | 1963 | 1009 |

*E. The Asserted Grounds of Unpatentability*

Petitioner challenges the patentability of claims 1–23 of the ’828 patent on the following grounds:

| References | Basis | Claims challenged |
|---|---|---|
| CN ’550, Kirsch, and Herman | § 103(a) | 1–3, 6–9, 12, 13, 18, 19 |
| CN ’550, Kirsch, Herman, Pawelczyk, and Remmers | § 103(a) | 4, 5, 10, 11, 14–17, 20–23 |

## II. ANALYSIS

### *A. Claim Interpretation*

We interpret claims of an unexpired patent using the “broadest reasonable construction in light of the specification of the patent in which [the claims] appear[].” 37 C.F.R. § 42.100(b). For purposes of this Decision, based on the record before us, we determine that none of the claim terms requires an explicit construction.

### *B. 35 U.S.C. § 315(e)(1)*

Patent Owner contends that Petitioner is estopped, by 35 U.S.C. § 315(e)(1), from requesting *inter partes* review because the asserted grounds are based on prior art that Petitioner “was aware of, cited, and relied on in the ’115 IPR,” and therefore “could have been raised in the ’115 IPR.” Prelim. Resp. 9–10. 35 U.S.C. § 315(e)(1) provides:

> (e) Estoppel.–
>
> (1) Proceedings before the Office.—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 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*.

(Emphasis added).

The preconditions for applying § 315(e)(1) estoppel are in place here because the Petitioner here and in the '115 IPR are the same, and the '115 IPR resulted in a final written decision. For the reasons that follow, we determine Petitioner could have raised its second asserted ground—obviousness of claims 4, 5, 10, 11, 14–17, and 20–23 over the combination of CN '550, Kirsch, Herman, Pawelczyk, and Remmers ("Ground 2")—in the '115 IPR.

What a petitioner "could have raised" was broadly described in the legislative history of the America Invents Act ("AIA") to include "prior art which a skilled searcher conducting a diligent search reasonably could have been expected to discover." 157 Cong. Rec. S1375 (daily ed. Mar. 8, 2011) (statement of Sen. Grassley). In this case, however, we do not need to determine what such a search may have uncovered, because the record demonstrates that Petitioner was aware of the prior art references asserted in Ground 2 when it filed the '115 IPR.

In the '115 IPR Petition (Ex. 2001), Petitioner challenged claims 1–23 of the '828 patent on seven obviousness grounds based on a number of different references, including CN '550, Kirsch, Herman, and Pawelczyk. Ex. 2001, 3. Although Remmers was not included in any of the asserted grounds, in a section of the '115 IPR Petition describing the chemistry and degradation of tetracycline antibiotics, Petitioner states:

> Remmers also discloses that C4 epimerization of tetracycline occurs at a pH from 2.4 to 6.0, and that the equilibrium concentration of the C4 epimer is a function of the pH of the solution. Remmers studied C4 epimerization of tetracycline at pH 2.4, 3.2, 4.0, 5.0 and 6.0, and concluded that the rate at which epimerization occurs is essentially identical at pH 3.2, 4.0 and 5.0.

*Id.* at 16 (citations omitted). Petitioner cites Remmers for the same teaching in the instant Petition. *See* Pet. 54 ("Remmers studied C4 epimerization of tetracycline at pH 2.4, 3.2, 4.0, 5.0, and 6.0, and determined the equilibrium concentrations of C4 epimer as a function of pH."). Petitioner, therefore, had knowledge of Remmers and what it discloses when it filed the '115 IPR.

Petitioner argues that it could not have raised Ground 2 in the '115 IPR. Pet. 3. Petitioner states:

> Ground 2 could not have been raised during the '115 IPR because in its Decision instituting IPR, the Board indicated that the then-presented grounds of unpatentability were redundant. However, to the extent Patent Owner has based its arguments on the theory that CN '550, Naggar, and Pawelczyk do not provide motivation because CN '550 does not expressly mention epimerization, it is clear that the present grounds are not cumulative. [Petitioner] could not have raised Ground 2 in the '115 IPR because of the Board's view at the time that such grounds were redundant with the ground upon which the '115 IPR was instituted.

*Id.* (citation omitted). It is unclear, however, how the Board's determination that several grounds in the '115 IPR Petition were redundant to the ground upon which trial was instituted in the '115 IPR is relevant to determining whether Petitioner could have raised Ground 2 in the '115 IPR Petition. Petitioner did not know, at the time it filed the '115 IPR Petition, that the Board would find the grounds proposed therein to be redundant. Petitioner cannot argue that it could not have raised Ground 2 in the '115 IPR Petition because the Board found different grounds to be redundant to each other, after Petitioner had already made the decision not to raise Ground 2 in its prior petition.

On this record, we determine that Ground 2 constitutes a ground that Petitioner could have raised in the '115 IPR. Petitioner was aware of, and cited, all of the Ground 2 prior art in the '115 IPR Petition, and therefore reasonably could have raised it during that proceeding. Accordingly, Petitioner is estopped under 35 U.S.C. § 315(e)(1) from asserting Ground 2 now.

Patent Owner also contends that Petitioner is estopped from asserting its first ground based on CN '550, Kirsch, and Herman ("Ground 1") in this proceeding. *See* Prelim. Resp. 9–16. Petitioner asserted Ground 1 in the '115 IPR Petition (where it was identified as Ground 6), and the Board found it to be redundant to the ground upon which trial was instituted. Ex. 2001, 51–55; Ex. 2003, 9. Because the Board did not reach the merits of the challenge presented in Ground 1 when deciding whether to institute a trial in the '115 IPR, we determine that Petitioner is not estopped from asserting Ground 1 in this proceeding.

As discussed above, the estoppel provisions of 35 U.S.C. § 315(e)(1) apply only to grounds that petitioner "raised or reasonably could have raised *during* [the] inter partes review." (emphasis added). An *inter partes* review does not begin until the Office decides to institute review; prior to that point, our Rules refer to a "preliminary proceeding" that begins with the filing of a petition and ends with a decision whether to institute trial. 37 C.F.R. § 42.2; *accord Intellectual Ventures II LLC v. JPMorgan Chase & Co.*, 781 F.3d 1372, 1376 (Fed. Cir. 2015) ("[The AIA] . . . suggests that a petition is a request for a [covered business method review] proceeding, not that the petition itself is part of the proceeding" and "the Director decides whether to 'institute,' or begin, a [] proceeding"). Therefore, grounds raised during the

preliminary proceeding, but not made part of the instituted trial, are not raised "during" an *inter partes* review and cannot be the basis for estoppel under 35 U.S.C. § 315(e)(1). Nor are such grounds ones that "reasonably could have been raised during" the review, because once denied, the Board's decision on institution prevents Petitioner from raising that ground during the trial. *See* 77 Fed. Reg. 48,680, 48,689 (Aug. 14, 2012) ("[a]ny claim or issue not included in the authorization for review is not part of the review").

Ground 1 in the instant Petition was never raised *during* the '115 IPR, because the Board denied institution of Ground 6 as redundant, and Petitioner could not have raised Ground 6 again once institution was denied as to that ground. Estoppel under 35 U.S.C. § 315(e)(1), therefore, does not bar Petitioner from maintaining a proceeding before the Office on Ground 1.

*C. 35 U.S.C. § 325(d)*

Patent Owner requests that the Board exercise its discretion under 35 U.S.C. § 325(d) and decline to institute *inter partes* review of the '828 patent because Petitioner "asserts both substantially the same art and substantially the same arguments as the Board considered in the '115 IPR proceeding." Prelim. Resp. 16. Specifically, Patent Owner contends the Petition "presents no new prior art, and asserts CN '550 and the secondary references for the same purposes it did in the '115 IPR." *Id.* at 20.

The permissive language of 35 U.S.C. § 325(d) does not prohibit instituting *inter partes* review based on arguments previously presented to the Office. *See* 35 U.S.C. § 325(d) ("In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director *may take into account* whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were

presented to the Office.") (emphasis added). While we are mindful of the burden on Patent Owner and the Office to rehear the same or substantially the same arguments that have been considered by the Office in other proceedings, we note that we did not reach the merits of Petitioner's arguments with respect to Ground 1 when considering the '115 IPR. Therefore, we do not exercise our authority to decline an *inter partes* review of the '828 patent under § 325(d).

*D. Obviousness over CN '550, Kirsch, and Herman*

Petitioner contends that claims 1–3, 6–9, 12, 13, 18, and 19 would have been obvious under 35 U.S.C. § 103(a) over the combination of CN '550, Kirsch, and Herman. Pet. 32–51. Petitioner relies on a Declaration by Raj Suryanarayanan, Ph.D. (Ex. 1002) in support of its contentions.

Petitioner contends that CN '550 describes all of the limitations of independent claims 1 and 12, except that it discloses minocycline, not tigecycline. Pet. 41–42. Petitioner contends that "[i]t was known in the art that tetracyclines, including minocycline and tigecycline, oxidize in neutral or basic solutions and epimerize in acidic solutions," and, "[a]lthough they proceed along two different pathways, oxidation and epimerization present the same ultimate problem: they reduce the amount of tetracycline present to exert its desired antibiotic effect." *Id.* at 39. Petitioner further contends that "[a] person of ordinary skill in the art would have found motivation to use lactose to improve the stability of a lyophilized tigecycline composition against degradation caused by oxygen, water, heat, and light as taught by CN '550," because "[d]egradation of tigecycline caused by oxygen, water, and heat were also problems with the original, unstable tigecycline formulation." *Id.* at 40.

It is in this context that Petitioner contends that a person having ordinary skill in the art would have found reason to substitute tigecycline for minocycline in the CN '550 compositions because it was known to work where other antibiotics failed, and that it was active against specific viruses that show tetracycline resistance. Pet. 41–42. Petitioner cites Dr. Suryanarayanan's testimony in support of this contention:

> A person of ordinary skill in the art in 2005 would find reason to substitute tigecycline for its known chemical analog minocycline in the lyophilized formulation of CN '550. Ex. 1001, 1:23–24. Further, a person of ordinary skill in the art would have been motivated to substitute tigecycline for minocycline because it was known that tigecycline "has been shown to work other antibiotics have failed" and "it has been active against methicillin-resistant *Staphylococcus aureus*, penicillin-resistant *Streptococcus pneumoniae*, vancomycin resistant enterococci…and against organisms carrying either of the two major forms of tetracycline resistance: efflux and ribosomal protection". *Id.* at 1:23–44.

Ex. 1002 ¶ 73.

Dr. Suryanarayanan does not explain, however, why the knowledge that tigecycline is effective "where other antibiotics have failed" would lead a person having ordinary skill in the art to substitute tigecycline for minocycline in the compositions disclosed in CN '550, a reference addressing the stability of lyophilized minocycline compounds. Neither Petitioner nor Dr. Suryanarayanan provides information demonstrating that a person of ordinary skill in the art would correlate the therapeutic effectiveness of tigecycline as an antibiotic to the properties of tigecycline that must be considered when preparing a lyophilized formulation of tigecycline. Moreover, Petitioner does not provide adequate evidence or explanation why a person having ordinary skill in the art reasonably would

have expected that the substitution of tigecycline for minocycline in the CN '550 compositions would have resulted in a stabilized tigecycline composition. Petitioner, therefore, has not provided sufficient rationale to explain why a person having ordinary skill in the art would have substituted tigecycline for minocycline in the CN '550 compositions.[1]

None of CN '550, Kirsch, or Herman discloses or discusses tigecycline, and CN '550 does not include any examples in which the disclosed minocycline compositions are stabilized with lactose. Prelim. Resp. 26. Petitioner does not adequately explain why a person having ordinary skill in the art, reading such references, would have had reason to use tigecycline in the compositions described by CN '550 when the references themselves lack any teaching or suggestion about the use or specific chemistry of tigecycline in particular. Petitioner, relying on Dr. Suryanarayanan's testimony, argues that "[a] person of ordinary skill in the art would recognize [that the] technique for stabilizing minocycline disclosed in CN '550 by using lactose, would improve a composition containing the similar antibiotic tigecycline," and "would be encouraged by Herman and Kirsch to select lactose rather than mannitol as a lyophilization excipient for minocycline and tigecycline in order to reduce the amount of residual water in the solid cake that comes into contact with the active pharmaceutical ingredient." Pet. 42 (citing Ex. 1002 ¶¶ 73–74), 48 (citing Ex. 1002 ¶ 88).

[1] Petitioner made this argument in the '115 IPR, and our conclusions here are consistent with those set forth in the '115 Final Decision. *See* Ex. 2002, 12.

Dr. Suryanarayanan's statements regarding what a person skilled in the art would have understood about the stability of tigecycline and lactose in the CN '550 compositions, however, are not supported by sufficient objective evidence or analysis. Dr. Suryanarayanan simply states that the skilled artisan "would recognize" from CN '550 that lactose would stabilize tigecycline, and "would be encouraged" by Kirsch and Herman to use lactose, instead of the mannitol described in the CN '550 examples, in the CN '550 compositions, without providing adequate explanation as to why that would be the case. Dr. Suryanarayanan's unsupported and unexplained opinions are not persuasive.

Accordingly, we determine that the record before us does not establish a reasonable likelihood that Petitioner would prevail in showing claim 1 and claims 2, 3, and 6–9 that depend therefrom, and claim 12 and claims 13, 18, and 19 that depend therefrom, would have been obvious over the combination of CN '550, Kirsch, and Herman.

## III. CONCLUSION

For the foregoing reasons, we are not persuaded that Petitioner has demonstrated a reasonable likelihood that at least one of the challenged claims of the '828 patent is unpatentable based on the asserted grounds.

## IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied*.

PETITIONER:

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Paper 10
Entered: March 26, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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DELL INC., HEWLETT-PACKARD COMPANY, and NETAPP, INC.
Petitioner,

v.

ELECTRONICS AND TELECOMMUNICATIONS RESEARCH, INSTITUTE,
Patent Owner.

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Case IPR2015-00549
Patent 6,978,346 B2

Before BRIAN J. McNAMARA, MIRIAM L. QUINN, and GREGG I. ANDERSON, *Administrative Patent Judges.*

ANDERSON, *Administrative Patent Judge.*

# DECISION
Denial of Institution of *Inter Partes* Review and
Denial of Motion for Joinder
*37 C.F.R. § 42.108(b)*
*37 C.F.R. § 42.122(a) and (b)*

## I. INTRODUCTION

On January 8, 2015, Dell, Inc., Hewlett-Packard Company, and NetApp, Inc. ("collectively Petitioner") filed a Petition ("Pet.") for *inter partes* review of U.S. Patent No. 6,978,346 B2 (Ex. 1001, "the '346 patent"). Paper 1. Patent Owner waived a Preliminary Response and concurrently represented it did not oppose joinder. Paper 8. Petitioner filed a Motion for Joinder ("Mot.") to join this proceeding with *VMWare, Inc. v. Electronics and Telecommunications Research Institute*, Case IPR2014-00901 ("'901 IPR").[1] Paper 5. We entered a Decision on Institution ("Dec. Inst.," Paper 14) in the '901 IPR on December 11, 2014. '901 IPR, Paper 14. This case and the '901 IPR both involve the '346 patent.

The Petition for *inter partes* review and Motion for Joinder are denied.

## II. ANALYSIS

### *A. Denial of Petition for Inter Partes Review*

#### *1. Background*

The Petition asserts the asserted grounds are identical to those on which we instituted review in the '901 IPR. Pet. 1; Mot. 7. In the '901 IPR we instituted trial on the ground alleging that claims 1–9 were obvious under

[1] *International Business Machines Corporation v. Electronics and Telecommunications Research Institute*, Case IPR2014-00949 ("'949 IPR") was joined previously into the '901 IPR ('949 IPR, Paper 25) and all further filings in the joined proceeding are made in the '901 IPR. Petitioner seeks joinder with the resulting '901 IPR. Mot. 2 n. 1.

35 U.S.C. § 103 over Mylex[2] and Hathorn.[3] '901 IPR, Dec. Inst. 22. Hathorn and Mylex also were asserted in challenges against the '346 patent asserted in *Dell, Inc. v. Electronics and Telecommunications Research Institute*, Case IPR2013-00635 ("'635 IPR"). Petitioner in this case and in the '635 IPR are the same.

As relevant here,[4] the '635 Petition challenged claims of the '346 patent on the following grounds: (1) claims 1–3 and 8 as obvious under 35 U.S.C. § 103(a) over Weygant and Mylex ('635 IPR Pet. 20–23); (2) claims 4 and 9 as obvious under 35 U.S.C. § 103(a) over Weygant, Mylex, and Serviceguard[5] ('635 IPR Pet. 23–39); (3) claims 5–7 as obvious under 35 U.S.C. § 103(a) over Weygant, Mylex, and ANSI[6] ('635 IPR Pet. 39–45); (4) claims 1–3 and 5–8 as anticipated under 35 U.S.C. § 102(b) by Hathorn ('635 IPR Pet. 45–60). On March 20, 2014, we instituted trial on the ground that claims 1–3 and 5–8 were anticipated under 35 U.S.C. § 102(b) by Hathorn, denying all other grounds on the merits. '635 IPR, Dec. Inst. 23–24. On February 27, 2015, we entered a Final Written Decision ("Final Dec." Paper 39) finding that claims 1–3 and 5–8 of the '346 patent had not been shown to be unpatentable by a preponderance of the evidence. '635 IPR, Final Dec. 24.

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[2] *Storage Area Networks; Unclogging LANs and Improving Data Accessibility, Mylex Corporation*, published May 29, 1998 ("Mylex," Exs. 1006 and 1009).
[3] U.S. Patent No. 5,574,950, issued Nov. 12, 1996 ("Hathorn," Ex. 1005).
[4] One ground is omitted from the list as not including Mylex or Hathorn.
[5] *Managing MC/Serviceguard*, Hewlett-Packard Company, Jan. 1998 ("ServiceGuard," Ex. 1004).
[6] *Fibre Channel Arbitrated Loop* (FC-AL-2), American Nat. Standards Inst., 1999 ("ANSI," Ex. 1008).

*2. Legal Analysis*

*a. Claims 1–3 and 5–8*

Petitioner is estopped from requesting *inter partes* review in this case. Under 35 U.S.C. § 315(e)(1), once a Petitioner has obtained a final written decision, that Petitioner may not request or maintain subsequent proceedings on a ground that it "could have raised" during the prior proceeding. Specifically, section 315(e)(1) provides:

> (e) Estoppel. –
>
> (1) Proceedings before the office.— 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 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.*

(Emphasis added).

The first requirement for estoppel is met because the Petitioner here and in the '635 IPR are the same. The entry of the Final Written Decision in the '635 IPR satisfies the second requirement. For the reasons that follow, we determine Petitioner could have raised the ground asserted in this case in the '635 IPR.

What a Petitioner "could have raised" was described broadly in the legislative history of the America Invents Act ("AIA") to include "prior art which a skilled searcher conducting a diligent search would reasonably could have been expected to discover." 157 Cong. Rec. S1375 (daily ed. Mar. 8, 2011) (statement of Sen. Grassley). Indeed, the administrative estoppel codified in § 315(e)(1), as was pointed out, would effectively preclude petitioners from bringing subsequent

challenges to the patent in USPTO proceedings. *See id.* at S1376 (statement of Sen. Kyl) ("This [estoppel] effectively bars such a party or his real parties in interest or privies from later using inter partes review or ex parte reexamination against the same patent, since the only issues that can be raised in an inter partes review or ex parte reexamination are those that could have been raised in [an] earlier post-grant or inter partes review."). We need not investigate what any search might have uncovered, for the record before us shows that the prior art references in the instant Petition were asserted in the '635 IPR.

More specifically, the prior art Petitioner has asserted in the instant Petition, Mylex and Hathorn, was asserted in the '635 IPR against all the claims of the '346 patent. Hathorn was asserted as the basis of an anticipation ground under 35 U.S.C. §102. '635 IPR Pet. 45–60. Mylex was asserted as one of a combination of references in three other obviousness grounds. *Id.* at 23–45. Petitioner asserted Mylex as disclosing a RAID controller limitation in the '635 IPR (see, e.g., '635 Pet. 20–21), where, in the instant Petition, the reference is asserted as disclosing a RAID (Pet. 21). On this record, the differences in how the references have been asserted in these proceedings have no weight on our determination of whether the grounds raised in the instant Petition could have been raised in the '635 IPR. Both Mylex and Hathorn were known to Petitioner as prior art to the '346 patent, and Mylex has been asserted as an obviousness reference in this Petition and in the'635 IPR. It makes no difference to us that Petitioner may have believed Hathorn to be an anticipatory

reference in the ’635 IPR, and that such a belief may have changed during the trial of the ’635 IPR, where we ultimately determined in our Final Written Decision that Hathorn did not anticipate any claim of the ’346 patent.

On this record, we determine that the combination of Mylex and Hathorn to show obviousness of claims of the ’346 patent constitutes a ground that Petitioner could have raised in the ’635 IPR. Accordingly, Petitioner is estopped under 35 U.S.C. § 315(e)(1) from asserting that ground now.

*b. Claims 4 and 9*

Notwithstanding the preceding, § 315(e)(1) operates as an estoppel only as to “review of a claim in a patent under this chapter that results in a final written decision.” 35 U.S.C. § 315(e)(1). The Final Written Decision in the ’635 IPR resulted in a review of claims 1–3 and 5–8, but not of claims 4 and 9. ’635 IPR, Final Dec. 24. This Petition challenges all of claims 1–9 as obvious over Mylex and Hathorn. Pet. 4. Thus, *inter partes* review of claims 4 and 9 is not precluded by the estoppel provisions of section 315(e)(1).

35 U.S.C. § 315(b) provides:

> (b) Patent Owner’s Action. – An inter partes review may not be instituted *if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint* alleging infringement of the patent. The time limitation set forth in the preceding sentence shall not apply to a request for joinder under subsection (c).

(Emphasis added).

Absent joinder, the Petition here is barred under § 315(b) if it was filed more than a year after suit is served. The Petition shows the cases Petitioner lists as related, including those where each Petitioner has been the subject to a claim for infringement of the '346 patent. Pet. 1–2. We have taken judicial notice that each of the parties, the Petitioner here, was served with a complaint on December 3, 2012, more than one year before the January 8, 2015, filing date accorded to this case. Paper 6. As discussed below, we deny Petitioner's Motion for Joinder as to remaining claims 4 and 9. Absent joinder, claims 4 and 9 in this Petition are subject to § 315(b), and the Petition is barred.

*B. Denial of Motion for Joinder*

We exercise our discretion under 35 U.S.C. § 315(c) and decline to join claims 4 and 9 of this case to the '901 IPR. Section 315(c) provides:

> (c) JOINDER.—*If the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party* to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

(Emphasis added).

First, we note that Petitioner has the burden of showing that joinder should be granted, and nothing in the record shows us that joinder would be appropriate here for less than all the asserted claims. Further, in declining to join claims 4 and 9 to the '901 IPR we note that, were we to grant joinder, the case would proceed on different claims depending on the party. The '901 IPR has already been subject to joinder (see footnote 1) and has two

Petitioners. Adding a third Petitioner (or more), with grounds that are limited to a small subset of the ongoing trial, will unnecessarily complicate the '901 IPR. In addition, while Patent Owner does not oppose joinder (Paper 8), we cannot ignore the additional time, effort and expense that will fall to Patent Owner. We are also cognizant that Patent Owner's statement of non-opposition does not address the present circumstances of our denial of institution on claims 1–3 and 5–8. On the present record, we are not inclined to join Petitioner to assert a ground partially, i.e., for two claims, but not the others.

ORDER

Accordingly, it is

ORDERED that *inter partes* review of U.S. Patent No. 6,978,346 is *denied;* and

FURTHER ORDERED that Petitioner's motion for joinder is *denied*.

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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JOHNS MANVILLE CORPORATION and JOHNS MANVILLE, INC.,
Petitioner,

v.

KNAUF INSULATION, INC. and KNAUF INSULATION SPRL,
Patent Owner.

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Case IPR2016-00130
Patent D631,670 S

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Before SCOTT A. DANIELS, KRISTINA M. KALAN, and
JAMES A. WORTH, *Administrative Patent Judges.*

DANIELS, *Administrative Patent Judge.*

ORDER
Conduct of the Proceedings
37 C.F.R. § 42.5

Patent Owner requested, by an email dated January 26, 2017, a telephone conference with the Board seeking authorization to file a Motion to Terminate this proceeding under 35 U.S.C. § 315(e)(1). Patent Owner argued that the Board issued a Final Written Decision in IPR2015-01435 and that because this proceeding includes grounds that reasonably could have

been raised in IPR2015-01435 Petitioner is estopped from maintaining this subsequent *inter partes* review proceeding. The Board instructed the parties to address the § 315 issue at oral hearing in this proceeding on February 2, 2017.

Section 315(e)(1) states:

> 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) . . . 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 single claim of the ’670 design patent is the subject of this proceeding and was the subject of case IPR2015-01435. A Final Written Decision was entered in IPR2015-01435 on January 11, 2017.

During the oral hearing in this proceeding Patent Owner’s counsel argued that Exhibits 1004 and 1005, upon which Petitioner bases its grounds of anticipation and obviousness in the present proceeding, were in the possession of Petitioner at the time of filing IPR2015-01435 and thus under § 315(e)(1) “reasonably could have [been] raised during that inter partes review.” Petitioner’s counsel argued to the contrary that a diligent search was undertaken and the circumstances relating to the discovery of further documents and filing of the present petition were reasonable under § 315.

Because the parties dispute factually whether Petitioner reasonably could have raised Exhibits 1004 and 1005 in IPR2015-01435, we authorize Patent Owner to file a motion to terminate this proceeding no later than February 22, 2017. Petitioner is authorized to file an opposition to the motion no later than March 8, 2017. The motion and opposition are both limited to 7 pages. The parties should focus their respective briefs on facts

and evidence of record supporting, or not, the reasonableness of Petitioner's search for relevant prior art documents. No Reply is authorized at this time.

It is

ORDERED that Patent Owner is authorized to file a motion to terminate, no more than 7 pages, no later than February 22, 2017.

FURTHER ORDERED that Petitioner is authorized to file an opposition to the motion to terminate, no later than March 8, 2017.

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**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**
*In re: Verinata Health, Inc.*, 2017-109

## CERTIFICATE OF SERVICE

I, John C. Kruesi, Jr., being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

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February 9, 2017

/s/ John C. Kruesi, Jr.
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