Nos. 19-1147, 19-1148, 19-1323, 19-1324, 19-1325

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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 AA, WOCKHARDT USA LLC, WOCKHARD LTD., MYLAN PHARMACEUTICALS INC., MYLAN INC., WEST-WARD PHARMACEUTICALS LLC, TEVA PHARMACEUTICALS USA, INC.

Defendants-Appellees,

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

Defendants.

(*Caption continued on inside cover)*

BRIEF OF THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS AMICUS CURIAE IN SUPPORT OF APPELLEES

Jeffrey K. Francer
ASSOCIATION FOR ACCESSIBLE MEDICINES
610 New Jersey Ave., NW
Suite 850
Washington, DC 20001

William M. Jay
GOODWIN PROCTER LLP
901 New York Ave. NW
Washington, DC 20001
(202) 346-4000

Joshua J. Bone
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-1000

Counsel for Amicus Curiae

February 22, 2019

No. 2019-1148

BTG INTERNATIONAL LIMITED, JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., AND JANSSEN RESEARCH & DEVELOPMENT, LLC

Plaintiffs-Appellants,

v.

AMERIGEN PHARMACEUTICALS, INC., AMERIGEN PHARMACEUTICALS LIMITED,

Defendants-Appellants.

No. 2019-1323

JANSSEN ONCOLOGY, INC.,

Appellant,

v.

AMERIGEN PHARMACEUTICALS LIMITED, ARGENTUM PHARMACEUTICALS LLC,

Appellees.

No. 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.

No. 2019-1325

JANSSEN ONCOLOGY, INC.,

Appellant,

v.

WOCKHARDT BIO AG,

Appellee.

Appeals from the United States District Court for the District of New Jersey in case nos. 2:15-cv-05909-KM-JBC, 2:16-cv-02449-KM-JBC, 2:17-cv-06435-KM-JBC, Judge Kevin McNulty, and from the Patent Trial and Appeal Board in IPR2016-00286, IPR2016-01317, IPR2016-01332, and IPR2016-01582, and IPR2017-00853

CERTIFICATE OF INTEREST

Counsel for amicus curiae Association for Accessible Medicines certifies the following:

1. The full name of every party or amicus represented by me is:

The Association for Accessible Medicines

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

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 the court (and who have not or will not enter an appearance in this case) are:

None

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal is:

BTG International Limited, et al. v. MSN Pharmaceuticals Inc. & MSN Laboratories Private Ltd., Civil Action No. 18-02372-KM-JBC (D.N.J.); *Janssen Biotech, Inc. et al. v. Mylan Pharms., Inc. et al.*, Civil Action No. 1:15-cv-00130 (N.D. W.Va.); *BTG International Limited, et al. v. Qilu Pharmaceutical Co., Ltd. & Qilu Pharma, Inc.*, Civil Action No. 2:18-cv-16521 (D.N.J.).

Dated: February 22, 2019

/s/ William M. Jay
William M. Jay

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INTEREST OF AMICUS CURIAE[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing the leading manufacturers and distributors of finished generic pharmaceutical products and of bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry.

AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, affordable prescription medicines. To that end, AAM regularly files briefs as amicus curiae, including in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 139 S. Ct. 628 (2019), and *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 138 S. Ct. 1365 (2018).

AAM's members frequently file petitions for inter partes review ("IPR"), because the efficiency and speed of IPRs fit the industry's mission of delivering generic alternatives to brand-name pharmaceuticals to patients as soon and as cost-effectively as possible. AAM's members thus have a significant interest in resisting the attempt by Appellants (hereinafter "Janssen") to expand the scope of estoppel under 35 U.S.C. § 315(e)(2) (and the identically worded § 325(e)(2), applicable to post-grant review ("PGR")), which would undermine the efficient

[1] All parties have consented to the filing of this brief. No counsel for any party authored this brief in whole or in part, and no party, counsel, or person other than AAM, its members, and its counsel contributed money to fund the preparation or submission of this brief.

system created by the Leahy-Smith America Invents Act ("AIA"). AAM therefore limits this brief to addressing Janssen's estoppel argument (Appellants' Br. 45-50, 52).

SUMMARY OF ARGUMENT

A party does not *lose* in court by *winning* an IPR, and nothing in the AIA or the law of estoppel creates such a Catch-22. What the AIA *does* create is a speedy, efficient, and time-limited way to challenge the validity of a patent. Accepting Janssen's estoppel argument would make that focus on speed entirely pointless. On Janssen's view, upon winning a final written decision the successful petitioner achieves nothing but a trip to the waiting room. The patent is not actually cancelled until after the patent owner has an opportunity to appeal. 35 U.S.C. § 318(b). And while the petitioner is waiting, Janssen argues, it is worse off than before it won the IPR: it is disabled from making to the district court the very arguments that have just persuaded the Patent Trial and Appeal Board ("PTAB") that the patent is invalid.

The consequences are even more nonsensical in a Hatch-Waxman case like this one: Janssen contends that the moment the patentee loses an IPR on the same invalidity grounds being asserted in district court, the district court must immediately *enter judgment in the losing patentee's favor* and *grant injunctive*

relief blocking generic competition. As this brief explains, the statute does not require that counterintuitive and counterproductive result.

1. Allowing petitioners to challenge patent validity after issuance is a key component of the overall patent system. Examiners often lack the capacity to identify and examine all relevant prior art and all other potential grounds of invalidity during prosecution. Post-grant challenges serve to weed out patents that never should have issued. In the pharmaceutical context, this process of weeding out bad patents helps to eliminate obstacles to competition—improving access to life-saving treatments and reducing costs for consumers, health insurers, and the taxpaying public.

The interpretation of the estoppel statute Janssen urges would dramatically reduce the incentive for any patent challenger ever to file an IPR or PGR petition. In the context of patents deployed to keep generic drugs and biosimilars off the market, the result would be to frustrate pharmaceutical competition and maintain high prescription-drug prices.

Congress recognized that many or most petitioners would also be defendants in parallel civil litigation; it could not have expected those defendants to accept a tradeoff that includes being *completely disabled* from resisting a patent—even an egregiously invalid one—for a period of months or years after final written decision. Yet that is the consequence Janssen proposes: for the period between

final written decision and final cancellation of the patent, the successful IPR petitioner must essentially confess judgment on its invalidity theories in district court. Indeed, Janssen demands that result even if the district court was poised to find the patent invalid—meaning that the defendant is *worse* off for having pursued PTAB review, the complete opposite of what Congress intended and wrote. IPR and PGR would become a poisoned chalice.

2. Janssen argues that the plain text of § 315(e)(2) compels this result, but that argument ignores Congress's incorporation of ordinary estoppel principles into the statute. Congress expressly described the effect of § 315(e) as "estoppel"—not just in the subsection's heading, but also in the text of a related provision, 35 U.S.C. § 317(a). Estoppel gives effect to the first full and fair adjudication of a contested issue between the same parties; Janssen's interpretation fails to fit any definition of estoppel, because it would *reverse* the outcome of the first full and fair adjudication and make the loser the winner.

3. The harms of Janssen's estoppel interpretation would be particularly acute in the Hatch-Waxman context. The Hatch-Waxman statute provides for an automatic 30-month stay of FDA approval of the defendant's Abbreviated New Drug Application ("ANDA") upon the timely filing of an infringement suit, and a permanent block on FDA approval following a final judgment of infringement of a valid patent. These remedies presuppose that the court is able to decide the

invalidity of the patent on the merits; thus, for example, a finding of invalidity terminates the 30-month stay. These considerations are additional reasons why this Court should reject Janssen's interpretation of the estoppel statute, which would allow invalid patents to keep obstructing the approval of cost-effective generic versions of lifesaving treatments.

At the very least, the Court should reject the remedy Janssen demands here. Janssen cannot claim to have defeated Appellees' obviousness defense to infringement; the PTAB held the relevant claims-in-suit *in*valid. Therefore, even if Appellees were blocked from litigating obviousness in district court for the period between entry of the PTAB's final written decision and cancellation of the claims-in-suit pursuant to that decision, Janssen has not won a final judgment of infringement. It is not entitled to an order rescinding ANDA approval and the resulting pharmaceutical competition.

ARGUMENT

I. JANSSEN'S POSITION WOULD UNDERCUT THE PURPOSES OF INTER PARTES AND POST GRANT REVIEW.

Since enactment of the AIA, IPRs and PGRs have worked as intended, reducing the amount of time it takes to weed out invalid patents that serve no purpose other than to stifle competition and raise costs for consumers. But adopting Janssen's interpretation of 35 U.S.C. § 315(e)(2) would undercut these

advantages by greatly reducing the incentive for patent challengers to take advantage of IPR and PGR.

1. The PTO's ability to review its own prior patentability decisions after issuance is a vital component of a healthy patent system. Congress has barred the issuance of patents under a number of circumstances, including purported inventions that are not truly novel, or are just obvious variations on existing knowledge. But patent examination does not always uncover all the flaws in a patent application, especially when the examiners come under regular pressure to avoid undue delay.

The incredible volume of patent applications (more than 600,000 per fiscal year[2]) and limited staffing at the PTO leave examiners constrained in their ability to accurately and comprehensively assess patentability. And the examination process is an interaction between the patent applicant and the PTO with little (if any) opportunity for third parties to provide evidence or arguments relevant to patentability. Indeed, researchers have found that patent examiners spend an average of just nineteen hours on each patent application, which includes the time spent reading the application, searching for prior art that would render the

[2] U.S. Patent & Trademark Office, *FY 2018 Performance and Accountability Report* 32 (Nov. 9, 2018), https://www.uspto.gov/sites/default/files/documents/USPTOFY18PAR.pdf.

proposed patent invalid, interviewing the applicant's counsel, responding to the applicant's arguments, and rendering a decision.[3]

These issues are only exacerbated in the pharmaceutical context, with brand-name drug companies seeking dozens of patents and claims covering a single drug and using second-, third-, and even fourth-generation patents to extend a monopoly. *See, e.g.*, Andrew Pollack, *Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions*, N.Y. Times, July 15, 2016, https://nyti.ms/2kUxW18 (noting that the manufacturer of Humira® "amassed more than 70 newer patents, mostly in the last three years, covering formulations of the drug, manufacturing methods and use for specific diseases").

Pharmaceutical patent owners have incredibly powerful incentives to seek and obtain multiple rounds of patents, even dubious ones, to extend their ability to charge monopoly prices: even a questionably novel patent can be a powerful deterrent to competition, and the patent owner can use *any* patent listed in the Orange Book to obtain a 30-month stay on approval of a generic competitor. *See* 21 U.S.C. § 355(j)(5)(B)(iii). This case involves such a line-extension patent: a prior patent on the abiraterone compound and its use to treat prostate cancer

[3] Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data*, Nat'l Bureau of Econ. Research Working Paper 20337, at 7 (July 2014), http://www.nber.org/papers/w20337.pdf.

expired in 2016, and this case involves a second-round patent on a combination therapy of abiraterone with prednisone, a drug that has been used in cancer treatment for decades. Appellees' Br. 3-6.

The incentives to seek even weak patents, and the PTO's limited ability to weed out flawed applications during examination, are precisely why Congress adopted post-grant review and inter partes review as part of the "regulation" of patent rights. *Oil States*, 138 S. Ct. at 1375. These new procedures help "ensure that the poor-quality patents can be weeded out through administrative review rather than costly litigation," thus "improv[ing] patent quality and limit[ing] unnecessary and counterproductive litigation costs."[4] These new procedures give third parties a greater opportunity to interact with and present evidence to the PTAB (which is now a first-line adjudicator), as well as limited discovery, and simultaneously give patent owners an opportunity to amend their patents during proceedings. *Oil States*, 138 S. Ct. at 1371 (discussing IPR); *see also* 35 U.S.C. § 326(a)(11) (PGR).

To ensure efficiency, the AIA placed time limitations on Board decisions—no more one year to resolve an instituted PGR or IPR absent good cause to extend that deadline by no more than six additional months. 35 U.S.C. §§ 316(a)(11),

[4] 157 Cong. Rec. S5409 (daily ed. Sept. 8, 2011) (Sen. Schumer); 157 Cong. Rec. S1349 (daily ed. Mar. 8, 2011) (Sen. Leahy).

326(a)(11). These time limits ensure that decisions are reached quickly and relatively cheaply, at least compared with the years of effort and millions of dollars it often takes to resolve patent litigation in federal court. Because IPRs and PGRs are limited to patentability, technically proficient PTO administrative judges are able to review the record and render careful legal judgments quickly, within the statutory timeframe. The AIA also established a sufficiently high threshold for instituting a PGR or IPR to "weed out marginal challenges" and to "prevent abuse of these proceedings for purposes of harassment or delay."[5]

IPR and PGR are not simply alternative venues for patent litigation; they serve a distinct and crucial role in a healthy patent system. In addition to the efficiency and cost advantages discussed above, the availability of IPR and PGR relieves the burden on the federal courts by reducing the number of lengthy and discovery-intensive infringement cases they must resolve. Making flawed patents easier to eliminate also reduces the incentive for companies to pursue non-innovative patents as a means of improperly extending pharmaceutical monopolies.

Those who will benefit the most from IPR and PGR are patients who rely on innovation and timely competition to deliver more affordable medicines.

[5] 157 Cong. Reg. S1041 (daily ed. Mar. 1, 2011) (Sen. Kyl); 157 Cong. Rec. S1374 (daily ed. Mar. 8, 2011) (Sen. Kyl); *see also* 35 U.S.C. §§ 314(a), 324(a)-(b) (standards for instituting IPR and PGR).

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Competition brings down the cost of pharmaceuticals and biologic medicines, makes lifesaving therapies more broadly accessible to patients, and lowers the burden on health-insurance plans and federal and state taxpayers, who foot the bill for prescription drug coverage under Medicaid and Medicare Part D. In total, generic competition saved all pharmaceutical payors more than $265 billion in 2017.[6] For patients specifically, the average out-of-pocket copayment for a brand drug was more than six times the cost of a generic option in 2017.[7] As a result, patients who were prescribed brand drugs rather than generics abandoned treatment more than twice as often, leading to potentially drastic health consequences.[8] Under the AIA's regime of post-grant review, bad patents are far less likely to stand in the way of patient access to lower-cost generic medicines.

2. Janssen's broad interpretation of § 315(e)(2) threatens to undo these advantages of IPR and PGR. According to Janssen—joined in this position by the PTO Director—Congress established a rule in § 315(e)(2) that bars a *successful* IPR petitioner from defending against an infringement suit by raising the very invalidity grounds on which it *prevailed* before the PTAB and which (absent a successful appeal by the patent owner from the IPR) will eventually result in the

[6] Ass'n for Accessible Medicines, *2018 Generic Drug Access & Savings in the U.S.: Access in Jeopardy*, https://accessiblemeds.org/resources/blog/2018-generic-drug-access-and-savings-report.

[7] *Id.*

[8] *Id.*

cancellation of the patent under 35 U.S.C. § 318(b). Under this theory, district courts—unable to consider meritorious invalidity challenges—would often enter injunctions barring the continued "infringement" of patents the PTAB already held invalid. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1149 (Fed. Cir. 2011) (holding that a finding of infringement will often justify injunctive relief). This nonsensical result would decrease the incentive for patent challengers to bring IPR or PGR petitions, delaying the invalidation of bad patents and (in this context) the entry of generic competition for vital pharmaceuticals and biologic medicines.

As applied to *un*successful IPR or PGR petitioners, estoppel makes perfect sense. It is common for district court litigation to occur either in parallel with or following administrative patent review: the petitioner commonly files an IPR or PGR petition challenging patent validity while the patent owner pursues infringement litigation against the petitioner based on the same patent. If an IPR or PGR petitioner could present an invalidity challenge before the Board, lose, and then present that same invalidity challenge in district court litigation, the patent owner would have to defend against the same challenge twice, removing the efficiency advantage of IPR and PGR. *See B&B Hardware, Inc. v. Hargis Indus., Inc.*, 135 S. Ct. 1293, 1298-99 (2015) ("Allowing the same issue to be decided more than once wastes litigants' resources and adjudicators' time, and it

encourages parties who lose before one tribunal to shop around for another. The doctrine of collateral estoppel . . . is designed to prevent this from occurring.").

Under Janssen's theory of IPR and PGR estoppel, however, the patent owner or licensee gets to have its cake and eat it too. Not only does the owner or licensee get the benefit in district court of any victory before the PTAB, but it also gets the same benefit following a *defeat*, for a period of months or even years. A petitioner could, for example, convince the PTAB that certain claims are obviously invalid—imagine, for example, that the petitioner identified a printed publication that clearly anticipated the supposed "invention"—but the petitioner would then find itself unable to introduce the very same printed publication as prior art in district court infringement litigation. Even though the PTAB had already declared the patent invalid, and even though the district court would be overwhelmingly likely to reach the same result if it addressed the issue, the district court would have to jump over that invalidity defense. Indeed, if this Court were to accept Janssen's argument in full, the district court would have to enter judgment and grant relief, such as an award of damages and an injunction—even though the PTAB had already declared the applicable patent invalid and the district court, if allowed to, would reach the same decision and *deny* any relief. And then, once the PTAB's decision is affirmed on appeal and the patent is cancelled under § 318(b), the district court would have to undo everything it had done. *Cf. ePlus, Inc. v. Lawson Software*,

Inc., 789 F.3d 1349, 1354, 1358 (Fed. Cir. 2015) (injunction, contempt sanctions for violating it, and non-final damages award must all be set aside once the PTO cancels the underlying patent claim).

This result makes no sense on its face. It effectively would allow a patent owner to pursue an infringement case, *and win relief*, based on an invalid patent, even where the defendant has invalidity arguments that *have* persuaded the PTAB and *would* persuade the district court. While that relief would last only for the period between the final written decision and the cancellation of the claims, that period can last months and even years. The patent owner can stretch it out merely by seeking rehearing before the PTAB—as Janssen did here, resulting in a delay of nearly a year before rehearing was denied, *see* Appellees' Br. 59—and then by pursuing as lengthy an appeal as possible. This Court would be burdened with appeals and rehearing petitions that are unlikely to succeed, but all too effective in delaying the day of ultimate cancellation. And months or years of additional monopoly can be worth billions of dollars.

Congress would have had no reason to create IPR and PGR for all the reasons described at pp. 6-10, *supra*, and then kneecap the victors in this manner. Adopting Janssen's position would create a powerful *dis*incentive to use IPRs and PGRs: *either a loss or a victory* would hobble the petitioner in district court, for months or years, from the issuance of a final written decision until the patent is

finally cancelled pursuant to § 318(b). Rather than risk the entry of an infringement injunction while waiting out the lengthy IPR or PGR appeals process, most patent challengers would be better off holding their invalidity challenges until the patent owner or licensee sues them for infringement, and then presenting those invalidity defenses in district court litigation in the first instance. No longer would trained Board administrative judges be able to weed out bad patents efficiently and cheaply; instead, many more patent challenges would be funneled into costly and lengthy district court litigation, wherein the parties would have to engage in extensive discovery and federal judges would have to review invalidity challenges alongside fact-bound infringement questions.

Further exacerbating the disincentive for patent challengers to petition for IPRs and PGRs, Janssen's interpretation of estoppel would bar district courts from considering *any* invalidity ground a successful IPR or PGR petitioner raised or reasonably could have raised in the proceeding. Although at one time this Court held that the IPR estoppel provision did not cover noninstituted grounds raised in IPR petitions, *Shaw Industries Group, Inc. v. Automated Creel Systems, Inc.*, 817 F.3d 1293, 1300 (Fed. Cir. 2016), the Supreme Court has subsequently held that the Board must enter a final written decision addressing every patent claim raised in the petition when it institutes an IPR, *see SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1354 (2018). And the Board has since published Guidance interpreting *SAS*

as applying to "grounds" as well as "claims," meaning that the Board must enter a final written decision as to all invalidity *grounds* raised in an instituted IPR.[9] Combining *SAS* and the Board Guidance with Janssen's estoppel position would effectively bar IPR or PGR petitioners, whether successful or unsuccessful, from presenting *any* invalidity grounds in district-court litigation that could have been raised before the Board.

Janssen attempts to downplay the significance of all of this by arguing that "Defendants who choose to pursue an IPR to final written decision remain free to assert non-infringement, written description, and other non-prior-art defenses." Appellants' Br. 49. But oftentimes, the prior-art grounds available in an IPR are the grounds that establish invalidity—put another way, a patent claim is often invalid *because* it is obvious in light of patents and/or printed publications, not for some other reason. And in PGRs, parties may bring a whole host of invalidity defenses unavailable in IPRs, including written description defenses and prior art other than printed publications and patents. *See* 35 U.S.C. § 321(b). Thus, particularly with respect to PGR, Janssen's assurances ring hollow. Moreover, infringement is often undisputed in the Hatch-Waxman context, because the

[9] *See* Patent Trial & Appeal Bd., *Guidance on the impact of* SAS *on AIA trial proceedings*, (Apr. 26, 2018), https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial.

generic product must be bioequivalent to the brand product and use the same labeling.

In sum, Janssen has no answer to the fundamental practical problems its interpretation of § 315(e)(2) would create. Before filing an IPR or PGR petition, a potential patent challenger would have to accept that its best case scenario would likely still involve protracted district court litigation in which a large chunk of invalidity defenses (or nearly all, in the case of PGRs) would be off the table. Few potential challengers would likely accept that deal.

II. APPELLEES' INTERPRETATION IS FULLY CONSISTENT WITH STATUTORY TEXT AND STRUCTURE.

Rather than engage with the negative consequences of their position for the entire patent system, Janssen and the Director emphasize what they call the "plain" text of 35 U.S.C. § 315(e)(2), as well as the AIA's legislative and drafting history. Placed in its proper context, however, the statute's text is fully consistent with Appellees' position. And nothing in the AIA's legislative or drafting history suggests that Congress intended the bizarre result Janssen and the Director urge.

Janssen and the Director rely on reading the language of § 315(e)(2) in isolation, without any consideration of the provision's common-law roots or the statutory structure. *See* Appellants' Br. 46-47; PTO Br. 3-4. But the "literal text" must be read in light of its "context and with an eye towards the statutory scheme." *E.g., ClearCorrect Operating, LLC v. Int'l Trade Comm'n*, 810 F.3d 1283, 1290

(Fed. Cir. 2015) (relying on *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015)). Read in light of the statutory structure and its place in the overall statutory scheme, the text of § 315(e)(2) is fully consistent with Appellees' position.

1. Congress specified that Section 315(e) is an estoppel provision, and that provision must be interpreted consistently with the meaning of estoppel. Although Janssen (Appellants' Br. at 47 n.3) and the Director (Br. at 6) attempt to downplay the significance of the estoppel concept by suggesting that it appears only in the title of the subsection, that is simply incorrect: a neighboring provision expressly describes the effect of this subsection on the petitioner as "*estoppel* under section 315(e)." 35 U.S.C. § 317(a) (emphasis added).[10] Section 315(e) therefore cannot be read to impose consequences that are utterly divorced from any accepted concept of estoppel—yet that is exactly the reading Janssen proposes.[11]

The term "estoppel" has deep common-law roots: it captures situations in which the party estopped seeks some benefit inconsistent with its prior course of conduct. *See* "Estoppel," Black's Law Dictionary (10th ed. 2014) ("A bar that prevents one from asserting a claim or right that *contradicts* what one has said or

[10] Section 317(a) specifies that if the IPR is terminated with respect to a petitioner, "no estoppel under section 315(e) shall attach to the petitioner." *Accord* 35 U.S.C. § 327(a) (same for PGR).

[11] Even if "estoppel" did appear only in the title, it is well-settled that "the title of a statute and the heading of a section are tools available for the resolution of a doubt" about the meaning of a statute. *E.g.*, *Almendarez-Torres v. United States*, 523 U.S. 224, 234 (1998) (internal quotation marks omitted).

done before or what has been legally established as true." (emphasis added)); *Knowles Elecs. LLC v. Cirrus Logic, Inc.*, 883 F.3d 1358, 1370-71 (Fed. Cir. 2018) (documenting the common-law history of collateral estoppel). Estoppel may apply, for example, where a party seeks: to relitigate an issue on which the party already lost (collateral estoppel); to renege on a position the party already convinced the court to adopt (judicial estoppel); to backtrack on a commitment to a contractual counterparty after inducing reliance (promissory estoppel); or to argue that a certain patent is invalid or unenforceable after assigning that patent to someone else (assignor estoppel). Here, of course, the outcome Appellees seek in district court is entirely consistent with the outcome of the IPR, so it would make no sense to refer to Appellees as "estopped" from relying in district court on a ground on which they previously prevailed.[12]

The closest Janssen's brief comes to addressing this historic meaning is to observe, in a defensively worded footnote, that "estoppel" "does not apply solely to those who litigated and lost." Appellants' Br. 47 n.3. But the cited authority is telling: *New Hampshire v. Maine*, 532 U.S. 742 (2001), a *judicial*-estoppel case. The reason that New Hampshire was estopped in a later case was not that it won the first case, but that it *changed positions* in between, advancing a new argument

[12] Nor are Appellees seeking the sort of double recovery that would be barred by *res judicata*, or claim preclusion (even if that were treated as a form of estoppel). They seek no more than to have the obvious claims-in-suit invalidated *once*.

inconsistent with its old one. *See id.* at 749-51, 752, 755; *accord, e.g.*, *Data Gen. Corp. v. Johnson*, 78 F.3d 1556, 1565 (Fed. Cir. 1996) (judicial estoppel applies only "where a party successfully urges a particular position in a legal proceeding," but then "tak[es] a contrary position in a subsequent proceeding where its interests have changed"). Appellees, of course, are advancing the *same* argument on which they have already prevailed—and Janssen and the Director have *no* argument why the term "estoppel" would cover a party's consistent repetition of a legally correct argument.

2. Janssen and the Director attempt to buttress their argument by emphasizing snippets of the AIA's legislative and drafting history. The history they cite, however, does not come close to suggesting that Congress actually (and perversely) intended to bar *successful* IPR and PGR petitioners from raising invalidity defenses in district court litigation.

Janssen quotes floor statements describing the AIA as "strengthen[ing]" or "enhanc[ing]" statutory estoppel, *see* Appellants' Br. 47-48, but fails to cite any legislative history suggesting that Congress "strengthened" or "enhanced" estoppel in the way Janssen advocates—*i.e.*, by applying it to *successful* petitioners. To the contrary: the House Judiciary Committee report on the AIA clarifies that the relevant "strengthening" was the application of IPR "reasonably could have raised" estoppel to "subsequent administrative proceedings," not just district court

litigation. H.R. Rep. No. 112-98, Pt. 1, at 47 (2011).[13] In addition, as Appellees explain (at 52), earlier versions of the AIA had proposed dropping "reasonably could have raised" estoppel altogether and limiting estoppel to issues *actually litigated*. This "strengthening" has nothing to do with the issues presented in this case.

Janssen and the Director also compare the AIA's estoppel provision with the previous version, which provided, in relevant part:

> A third-party requester whose request for an inter partes reexamination results in an order under section 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) (2006). Janssen (Appellants' Br. at 47-48) and the Director (Br. at 4-5) emphasize the AIA's deletion of the "finally determined to be valid and patentable" language, but this revision simply served to harmonize the estoppel provisions with the AIA's creation of IPR.

[13] In a recent Supreme Court merits brief, the Government cited this same section of the House Judiciary Committee report for the proposition that "the addition of 'reasonably could have raised estoppel' in 'PTO proceedings' [was] an important improvement to those proceedings." Br. for Respondent, *Return Mail, Inc., v. United States Postal Serv.*, No. 17-1594, at 40 (U.S. filed Jan. 9, 2019) (brackets omitted).

Under the old statute, an "order under section 313" was equivalent to the institution of an IPR. *See* 35 U.S.C. § 313 (2006) (providing that the "Director" may enter an "order for inter partes reexamination of the patent"). And under the old statute, there was no term of art for the end of the process, equivalent to a "final written decision" under the AIA. In the estoppel provision, therefore, Congress had to use a wordier formulation to describe the final decision that triggered estoppel. The AIA, by contrast, uses the term of art "final written decision." *See* 35 U.S.C. § 318(a) (if an IPR is instituted, the Board "shall issue a final written decision"). Thus, in the new statute, Congress had no need to retain the "finally determined to be valid and patentable" language—it substituted the new term of art "final written decision."

Moreover, differences between IPR or PGR and the predecessor inter partes reexamination would have made the term "finally determined to be valid and patentable" less appropriate in any event. The AIA limits the PTAB to deciding the particular grounds timely asserted by the particular petitioners before it. *See SAS*, 138 S. Ct. at 1355 (in the AIA, "Congress chose to structure a process in which it's the petitioner, not the Director, who gets to define the contours of the proceeding"); *see also id.* at 1353, 1355 (explaining that unlike the "party-directed" IPR process, inter partes reexamination and ex parte reexamination both "followed a more or less inquisitorial course led by the [PTO]"). The PTAB

therefore carefully restricts itself to deciding whether the *petitioner* has shown each claim to be unpatentable on particular grounds. *E.g.*, Appx220. If it has not, other petitioners or other grounds may succeed. *Cf.* 35 U.S.C. §§ 315(e)(1), 325(d) (addressing different challenges by the same petitioner, and identical challenges by a different petitioner). But the PTAB may not take up additional grounds on its own initiative. The differences between IPR and PGR and the inter partes reexamination process makes it less appropriate to characterize what the Board is doing in a final written decision as "finally determin[ing]" a claim "to be valid and patentable."

Thus, substituting the new statutory term "final written decision" in no way suggests that Congress intended to preclude victorious petitioners from raising the same invalidity grounds as infringement defenses. Under the new statute as under the old one, only an *unsuccessful* petitioner is estopped from advancing the same arguments in district court. Janssen's contrary reading would upset the careful system of patent review developed by Congress, without any legal basis or even any coherent rationale. This Court should reject the notion that winning an IPR means losing a court case.

III. AT THE LEAST, THE COURT SHOULD HARMONIZE § 315(e)(2) WITH HATCH-WAXMAN TO AVOID ABSURD RESULTS IN ANDA LITIGATION.

As explained above, adopting Janssen's position would destabilize the system of post-grant review Congress designed in the AIA. But the harms would be particularly acute in context of Hatch-Waxman litigation, where the inability to litigate invalidity following an IPR decision could easily result in many more invalid patents blocking approval of generic drug competition—to the detriment of patients and taxpayers nationally. To avoid allowing invalid patents to prevent patients from accessing generic medicines, the Court should reject Janssen's interpretation of the estoppel statute. At the least, the Court should interpret the statutes governing relief in Hatch-Waxman cases not to require injunctive relief where, as here, a brand drug company seeks to maintain its monopoly despite a final written decision from the Board finding the relevant patents invalid.

1. Three aspects of the Hatch-Waxman framework are incompatible with Janssen's position on estoppel. For Hatch-Waxman to work as intended, district courts must be able to declare invalid patents invalid.

First, if a brand-name drug company files suit within 45 days after receiving notice of submission of an Abbreviated New Drug Application ("ANDA") with a Paragraph IV certification, FDA approval of the ANDA is automatically stayed for

30 months, *unless* the district court enters a judgment of invalidity or noninfringement before then. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I).

Second, and relatedly, the pressure to complete the litigation within the 30-month timeframe often discourages district courts from putting the litigation on hold pending other proceedings, such as an IPR. The Director suggests that the consequences of adopting his overbroad estoppel position would not be so bad, because a successful IPR petitioner "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." PTO Br. at 9. But this clearly is not a practicable option in Hatch-Waxman litigation: stays are uncommon because the framework is set up to allow the entire case to be litigated before the automatic stay expires after 30 months. Nor is it a practicable option in other contexts, such as in proceedings before the International Trade Commission, which generally will not stay an investigation pending parallel IPR or PGR proceedings, or time-sensitive district-court litigation.

Third, if the patent owner prevails in the infringement litigation, the district court *must* enter an order blocking approval of the ANDA "involved in the infringement" until the patent has expired. *See* 35 U.S.C. § 271(e)(4)(A). Thus, unlike infringement litigation in other contexts, *see* p. 11, *supra*, ANDA litigation typically results in the equivalent of preliminary injunctive relief (an automatic 30-

month stay of ANDA approval) *before* the court has even determined that the infringement plaintiff has any likelihood of success, and *always* results in the entry of injunctive relief *following* a finding of infringement.

The interaction of these Hatch-Waxman provisions with Janssen's interpretation of the estoppel statute would lead to absurd results. If a defendant in Hatch-Waxman litigation were estopped from presenting a previously successful invalidity challenge, the court would have no opportunity to enter a finding of invalidity that would terminate the automatic 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa). And if the defendant's victory removed those same arguments, and the district court—again, unable to consider invalidity challenges on which the infringement defendant prevailed—ultimately enters a judgment of infringement, the court would also have to enter an order barring generic entry at least until the IPR or PGR decision results in cancellation of the claims-in-suit. The result of all of this would be the delayed entry of more affordable FDA-approved generic alternatives to brand pharmaceuticals and biologic medicines—even where the patents barring generic entry are obviously invalid—indefensibly prolonging the patent holder's monopoly and harming consumers. And that is true regardless of whether ANDA applicants choose to preserve their invalidity challenges for district-court litigation rather than filing IPR and PGR petitions at

all, or instead choose to file IPR and PGR petitions despite the negative implications of victory. *See* pp. 10-16, *supra*.

To avoid these consequences, the Court should adopt Appellees' interpretation, which harmonizes 35 U.S.C. § 315(e)(2) with § 271(e)(4)(A) by allowing district courts in Hatch-Waxman litigation to continue considering invalidity challenges without halting their progress if the defendants prevail before the PTAB on the same argument. Courts frequently harmonize statutes in this manner, where a possible interpretation of one statutory provision would lead to absurd results under another. As the Supreme Court has explained, "[a] word in a statute may or may not extend to the outer limits of its definitional possibilities," *Dolan v. U.S. Postal Serv.*, 546 U.S. 481, 486 (2006), and a court's "task in interpreting separate provisions of a single Act is to give the Act 'the most harmonious, comprehensive meaning possible' in light of the legislative policy and purpose," *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 631–32 (1973). It would make no sense for Congress in the AIA to have created IPRs and PGRs to facilitate efficient invalidation of bad patents, while in the same statute effectively precluding one of the most important groups of patent challengers—generic drug manufacturers—from receiving the substantial benefits of efficient administrative relief.

2. At the very least, if the Court adopts Janssen's interpretation of § 315(e)(2), it should interpret § 271(e)(4)(A) not to require the entry of automatic, inequitable injunctions like the one Janssen seeks here when the defendant has previously prevailed on an invalidity challenge as to the same patents in an IPR or PGR. A Hatch-Waxman injunction can enter only when there has been a *final* decision that the ANDA product would infringe a valid patent. Such a decision cannot rest on estoppel arising from a PTAB decision holding the patent *in*valid.

"Where there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment." *Morton v. Mancari*, 417 U.S. 535, 550-51 (1974). Fidelity to the text requires that the courts give effect to *both* enactments: "To eliminate the contradiction, the specific provision is construed as an exception to the general one." *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) (Scalia, J.). Relief that Hatch-Waxman awards after the patent's *validity* is upheld cannot be awarded based on estoppel arising from the PTAB's *invalidity* decision.

First, plainly no injunction can issue. An "injunction is a matter of equitable discretion." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 32 (2008). In addition to "success on the merits[,] . . . the balance of equities and consideration of the public interest [] are pertinent in assessing the propriety of any injunctive relief, preliminary or permanent." *Id.* It certainly would not be equitable to grant a

permanent injunction restraining the infringement of a patent that (a) the PTAB has found invalid and (b) the defendant is bizarrely restrained from attacking in district court.

Second, the order to the FDA that Janssen wants—an order barring approval of Appellees' ANDAs until after the '438 patent expires—is not available either. Such an order is limited to implementing the effective-date provisions in the Federal Food, Drug, and Cosmetics Act. And under those provisions, an order like the one Janssen seeks (under 35 U.S.C. § 271(e)(4)(A)) is available *only* after "the district court decides that the patent has been infringed." 21 U.S.C. § 355(j)(5)(B)(iii)(II); *see also* 35 U.S.C. § 271(e)(4)(A) (order applies to an ANDA product "involved in … infringement"). A decision "that the patent has been infringed" necessarily must include a decision that the patent is not invalid; that is why the companion provision specifies what to do when "the district court decides that the patent is invalid *or* not infringed." 21 U.S.C. § 355(j)(5)(B)(iii)(I) (emphasis added). That accords perfectly with the general rule that a court must resolve invalidity defenses before holding a defendant liable for infringing a patent and awarding relief.[14] Janssen wants an order under § 271(e)(4)(A) even though

[14] *See, e.g.*, *TypeRight Keyboard Corp. v. Microsoft Corp.*, 374 F.3d 1151, 1157 (Fed. Cir. 2004) ("[I]nvalidity operates as a complete defense to infringement for any product, forever.").

the district court has *not* decided that the patent is valid—nor would Janssen's estoppel argument be a basis for making such a decision.

Rather than interpreting Hatch-Waxman to require the entry of inequitable relief like the order Janssen seeks, the Court should hold that the district court in a Hatch-Waxman case may not enter a permanent injunction, or make a final determination of infringement as required for relief under § 271(e)(4)(A), based on a refusal to decide invalidity under an estoppel theory like Janssen's. Even if a final written decision in the *petitioner's* favor did create some kind of estoppel in the *patent owner's* favor, the Hatch-Waxman lawsuit would at most be halted until that estoppel is lifted.[15] If the final written decision were affirmed, the patent would be cancelled and no longer the basis for an injunction; if not, further proceedings would be governed by this Court's decision reviewing the PTAB.

Again, to be clear, the consequences for Hatch-Waxman litigation, and patients who seek timely access to generic medicines, are reasons not to adopt Janssen's interpretation of § 315(e) *at all*. But even if the Court were to adopt it, it still should not award Janssen its desired windfall relief. Rather, it should read the Hatch-Waxman statute as discussed above and reject the notion that a patent owner

[15] Courts would of course retain discretion to enter *temporary* injunctions and stays as appropriate to protect the parties' rights during the pendency of litigation. But those would be based on the likelihood of success on the merits—exactly what Janssen seeks to avoid litigating by demanding an automatic entitlement to relief.

can use a decision finding its patent *invalid* as the basis for demanding an injunction barring ANDA approval and generic access.

CONCLUSION

For the foregoing reasons, the Court should reject Janssen's expansive interpretation of the estoppel statute and affirm the District Court's decision to decide obviousness on the merits, rather than award Janssen judgment *and* injunctive relief on a patent that both the PTAB *and* the District Court held invalid.

Respectfully submitted,

/s/ William M. Jay

William M. Jay
GOODWIN PROCTER LLP
901 New York Avenue, N.W.
Washington, D.C. 20001
(202) 346-4000
wjay@goodwinlaw.com

Joshua J. Bone
GOODWIN PROCTER LLP
100 Northern Ave.
Boston, MA 02210
(617) 570-1000

Counsel for Amicus Curiae

Jeffrey K. Francer
ASSOCIATION FOR ACCESSIBLE MEDICINES
601 New Jersey Ave., N.W.,
Suite 850
Washington, D.C. 20001

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the length limitation set forth in Fed. R. App. P. 29(a)(5) because this brief contains 6,900 words, excluding those parts of the brief exempted by Fed. R. App. P. 32(a)(7)(f) and Fed. Cir. R. 32(b). I further certify that the brief complies with the typeface requirements of Fed. R. App. 32(a)(5) and the style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface, 14-point Times New Roman, using Microsoft Word.

Dated: February 22, 2019

/s/ William M. Jay
William M. Jay

CERTIFICATE OF SERVICE

I hereby certify that on February 22, 2019, I electronically filed the foregoing document with the Clerk of Court of the United States Court of Appeals for the Federal Circuit through the appellate CM/ECF filing system, which will send notice of such filing to counsel for all parties.

February 22, 2019 /s/ William M. Jay
William M. Jay