No. 15-446

In The Supreme Court of the United States

CUOZZO SPEED TECHNOLOGIES, LLC,

Petitioner,

v.

MICHELLE K. LEE, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR, PATENT AND TRADEMARK OFFICE,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF GENERIC PHARMACEUTICAL ASSOCIATION AND AMERICA'S HEALTH INSURANCE PLANS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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INTEREST OF THE AMICI CURIAE[1]

The **Generic Pharmaceutical Association (GPhA)** is a nonprofit, voluntary association representing nearly 100 manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Generic pharmaceutical products are just as safe and effective as their brand-name counterparts, but substantially less expensive. Such products account for roughly 80% of all prescriptions dispensed in the United States but only 27% of the money spent on prescriptions. In this way, generic products save consumers nearly $200 billion each year. GPhA's core mission is to improve the lives of consumers by providing timely access to affordable pharmaceuticals.

To obtain FDA approval to market a generic version of a brand-name drug product, an entity must file an Abbreviated New Drug Application (ANDA). In response to an ANDA filing, brand-name drug makers often bring patent suits against the ANDA applicant under the Hatch-Waxman Act. 21 U.S.C. § 355. When such suits are brought, the FDA is statutorily prohibited from approving the applicant's ANDA for thirty (30) months unless the district court decides the patent is

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[1] The parties have consented to the filing of this amicus brief. Petitioner has filed a blanket consent with the Court, and written consent from Respondent is submitted herewith. No counsel for a party authored this brief in whole or in part; and no such counsel or any party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than amici and their counsel, made a monetary contribution intended to fund its preparation or submission.

invalid or not infringed before the expiration of this 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I); *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013). Brand-name drug makers have a strong interest in delaying resolution of such cases to maximize the benefits of the 30-month stay, and thus often sue in slower jurisdictions. ANDA applicants have a correspondingly strong interest in trying to resolve patent issues as quickly as possible.

Brand-name drug makers also frequently engage in a practice known as "ever-greening," which involves (1) making minor changes to existing drug products shortly before the original patents on those products are about to expire, (2) encouraging doctors and patients to switch to these "improved" products before generic versions of the existing products are approved, (3) obtaining patents on these minor changes, and (4) asserting these weak patents against ANDA applicants seeking approval for generic versions of the "improved" products. *See generally New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015). Because of the 30-month stay, this can significantly delay the launch of generic versions even if the patents are ultimately found invalid.

The new *inter partes* review (IPR) proceedings for challenging patents created by the America Invents Act (AIA), which are statutorily required to be completed within one year of institution, are a valuable tool for ANDA applicants to resolve certain issues involving brand-name drug patents more quickly than possible through district court litigation. This furthers the Congressionally-mandated goal of the Hatch-Waxman Act, which is to "get generic drugs into the hands of patients at reasonable prices – fast." *In re Barr Labs.,*

Inc., 930 F.2d 72, 76 (D.C. Cir. 1991). Accordingly, GPhA has a strong interest in opposing any efforts to undermine Congress's purpose in creating IPRs in the first place, which is to provide a speedy and effective procedure for eliminating weak patents. Importantly, in a case such as this one, GPhA has member interests that align with each side; GPhA, however, takes positions based on its analysis of the underlying issue at hand with a goal to promoting a fair and efficient patent system.

America's Health Insurance Plans ("AHIP") is a national trade association representing the health insurance industry. AHIP's members provide health insurance benefits, including health, pharmaceutical, long-term care, disability, dental and supplemental coverage to more than 200 million Americans. AHIP advocates for public policies that expand access to affordable healthcare coverage for all Americans through a competitive marketplace that fosters choice, quality and innovation.

AHIP's members, who include primary payers for prescription drugs in the United States, have a strong interest in a competitive market for those drugs. As our members are uniquely aware, increases in prescription drug costs are a leading driver of rising healthcare costs. Moreover, those increases have been accelerating at an alarming rate. In 2014, year-over-year national health spending grew by 5 percent compared to 2013, while prescription drug spending grew by 13 percent, to $319 billion—by far, the fastest growth rate of all major

categories of health spending.[2] Prescription drug prices increased by 6.4 percent, the highest growth rate since 1992 and, by far, the most rapid growth rate of all major categories of price growth in the health sector.[3] Faster price growth in 2014 resulted from price increases for brand-name drugs, the unit cost of which grew by 15.4 percent compared to 0.2 percent for generic unit cost.[4]

Faced with such trends, AHIP believes it is critically important to support policies that will bring more affordable options to consumers, taxpayers, and government programs. This includes policies that encourage the availability of generic drugs and through the use of the IPR process to challenge weak patents and expedite generic drug entry to the benefit of the U.S. healthcare system.

When it comes to price, there is a significant difference between generic and brand name drugs. On

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[2] *See* Altarum Institute, Initial estimates suggest health spending grew by 5.0% in 2014 (Feb. 12, 2015), http://altarum.org/sites/default/files/uploaded-related-files/CSHS-Spending-Brief_February_2015.pdf.

[3] *See* Altarum Institute, Health care price growth ticks up despite 16-year hospital growth low (Feb. 12, 2015), http://altarum.org/sites/default/files/uploaded-related-files/CSHS-Price-Brief_February_2015.pdf.

[4] *See* S&P Dow Jones Indices, Healthcare Expenditures for Commercial Plans up 3.2% in the Year to February 2014: S&P Healthcare Claims Indices (June 30, 2014), http://us.spindices.com/index-family/healthcare-claims/healthcare-national.

average, generic drug prices are 80 to 85 percent lower than comparable branded drug prices.[5] The Congressional Budget Office ("CBO") has calculated that the IPR process will save U.S. taxpayers $1.3 billion on federal healthcare costs, such as Medicare and Medicaid, over the next ten years.[6] Other studies have valued the healthcare savings of the IPR process much higher, especially when factoring in the expected costs borne by private insurers. The Center for Economic and Policy Research ("CEPR") has calculated that, without the IPR process, healthcare costs would increase by at least $73 billion in the 20-year period from 2018-2037.

We believe that the IPR process is largely working as intended by providing a more cost-effective avenue to challenge weak patents. Further, we believe that the IPR process is a critical consumer protection against abusive patent extensions that limit patient access to more affordable treatment options, delay market entry of less expensive generic therapies, and drive up drug costs.

SUMMARY OF THE ARGUMENT

As to the first question presented, Congress was not legislating on a blank slate when it passed the AIA and created IPRs. For decades, the U.S. Patent and Trademark Office (PTO) had been using the broadest reasonable interpretation (BRI) standard when

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[5] *See* U.S. Food and Drug Administration, Facts about Generic Drugs, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm.

[6] *See* Drug-Industry Rule Would Raise Medicare Costs, Wall Street Journal (Aug. 31, 2015), http://www.wsj.com/articles/drug-industry-bill-would-raise-medicare-costs-1441063248.

determining the patentability of unexpired patents. Cuozzo argues this history is irrelevant because none of the prior proceedings were (1) adjudicatory, and (2) limited the ability to amend claims. But as explained below, PTO interference proceedings – where the BRI standard is used when determining the patentability of claims in issued patents – have both of these features. Indeed, many of the procedures that the PTO adopted for IPRs were based on the PTO's interference procedures. This shows that Congress intended for the BRI standard to be used in IPRs.

Contrary to Cuozzo's argument that the PTO lacks the rule-making authority to adopt the BRI standard in IPRs, the PTO issued a rule in 2004 explicitly adopting the BRI standard in interferences based on rule-making authority that was very similar to the authority that Congress gave it for IPRs. This shows that Congress intended to give the PTO the authority to issue a rule requiring the BRI standard for IPRs.

The PTO's use of the BRI standard in IPRs comports with the purposes behind the standard. Specifically, the use of BRI in IPRs reduces the likelihood that a patent claim will be given a broader interpretation in infringement litigation than under PTO evaluation, and also encourages the elimination of ambiguous claim language. Accordingly, the PTO's use of the BRI standard deserves considerable deference.

As to the second question presented, the language of Section 314(d) providing that the PTO's decision regarding "whether to institute" an IPR is "final and nonappealable" plainly insulates that decision from judicial review. This is consistent with Congressional intent, which was for IPRs to be a speedy procedure for

eliminating weak patents. Indeed, when discussing the same "final and nonappealable" language in a predecessor statute, Congress explicitly stated in a Conference Report that that language precluded "judicial review."

ARGUMENT

I. The PTAB Should Use the BRI Standard in IPRs

A. Congress Intended for BRI to Be Used in IPRs

1. When Congress Passed the AIA, The PTO Had for Decades Been Using BRI in Interferences, Proceedings Very Similar to IPRs in All Material Respects

For decades, the PTO has conducted adjudicatory proceedings known as interferences. In interferences, the patentability of claims in issued patents is decided, and the ability to amend claims is limited. Importantly, the PTO uses the BRI standard in interferences, including when deciding the patentability of a claim in an issued patent. *See Bamberger v. Cheruvu*, 55 U.S.P.Q.2d 1523, 1527 (B.P.A.I. 1998). This severely undercuts Cuozzo's argument that the PTO's previous use of BRI in all proceedings involving unexpired patents is essentially irrelevant because those proceedings were not adjudicatory and did not limit the patent owner's ability to amend its claims.

a. Overview of Interference Proceedings

Some background on interference proceedings may prove helpful in understanding the palette Congress had before it when adopting the AIA. An interference is a proceeding in which the PTO determines which of two

entities that independently filed patent applications on the same subject matter was the first to invent the disputed subject matter. *See* 35 U.S.C. § 135 (pre-AIA). This is known as the "priority" issue. Before the AIA, this issue was important because the first entity to invent particular subject matter was generally entitled to the patent on that subject matter, even if it was not the first to file a patent application. The AIA moved the United States closer to the rest of the world by adopting a "first-inventor-to-file" system, meaning that the first inventor to file a patent application on an invention is generally entitled to the patent, even if he or she was not the first to invent that subject matter. Because of this change in the law, interferences are being phased out, although there are still interferences pending before the PTO.

Interferences can be between two pending applications, or a pending application and an issued patent. An interference between a pending application and an issued patent may arise when, for example, the owner of a pending application identifies an issued patent that appears to claim the same invention. In that situation, the owner of the pending application may ask the PTO to institute an interference with the issued patent if the owner of the pending application believes the inventor on the pending application invented the common subject matter first.

In an interference, the PTO also may decide patentability issues, including whether the claims in the pending application or issued patent are patentable over the prior art. There are no examiners in interferences. Before the AIA, interferences were decided by a three-judge panel of the PTO Board of Patent Appeals and

Interferences (BPAI or Board), a body composed of specially-trained Administrative Patent Judges. Because the AIA phased out interferences, the BPAI was renamed the Patent Trial and Appeal Board (PTAB or Board), but the PTAB is composed of the same specially-trained Administrative Patent Judges as the predecessor BPAI. The PTAB has been tasked with deciding the remaining pending interferences.

There are two possible phases in an interference – a preliminary motions phase, followed by – in some instances – a priority phase. In the preliminary motions phase, one of the issues that the parties may raise by motion is whether the claims in the opposing party's application or patent are patentable. In response, a party may move to amend its claims to address the patentability issue. The Board then decides the patentability issue, giving the claims in the application or patent their broadest reasonable interpretation. Often, interferences are resolved by a holding that a party's claims are not patentable over the prior art.[7] Thus, although interferences are proceedings for determining priority, they often result in patentability determinations.

b. Interferences Are Adjudicatory

Cuozzo lists certain features of IPR proceedings that it contends make those proceedings "adjudicatory": (1) the PTAB adjudicates the arguments of the parties rather than conducting an examination of the patent; (2) the parties have the opportunity to obtain document discovery, take depositions, present fact witness

[7] *See*, *e.g.*, *Pivonka v. Axelrod*, No. 2008-1413, 2009 WL 405816, at **2-4 (Fed. Cir. Feb. 19, 2009) (non-precedential); *Thompson v. Thompson*, 13 Fed. App'x. 925, 928 (Fed. Cir. 2001).

declarations and expert reports, submit briefs, and participate in oral argument before a three-judge panel of the PTAB; (3) the party seeking to have claims held unpatentable has the burden of doing so; (4) the three-judge panel issues a written decision; and (5) declaring claims unpatentable has the same effect as claims being declared invalid by a district court. Cuozzo Br. at 27. As set forth below, all of these features indisputably are present in interferences.

As for (1), there are no examiners or independent examination of the patent in interferences. Rather, the Board decides the issues raised by the parties. As for (2), the procedures for discovery, depositions, declarations, expert reports, briefs and oral argument in interferences are very similar to those in IPRs. Indeed, looking at these criteria, IPRs are more similar to interferences than they are to district court litigation. For example, discovery is much more limited in IPRs and interferences than in district court litigation. Similarly, direct witness testimony in IPRs and interferences is almost always presented by declaration, while cross-examination is almost always conducted at depositions, with the transcripts later being provided to the Board. In contrast, in district court litigation, direct and cross-examination of witnesses typically occurs through questioning of a witness in the courtroom. As for (3), the party seeking to have claims declared unpatentable in an interference has the burden of doing so, just as the petitioner in an IPR does. As for (4) and (5), in an interference, the Board issues a written decision deciding the issues raised by the parties, and any rulings that claims are unpatentable have the same effect as district court rulings that claims

are invalid. In short, interferences are "adjudicatory" in the same sense IPRs are adjudicatory.

Indeed, as one commentator noted, the PTO's IPR procedures were drawn directly from its procedures in interferences:

> While some may be inclined to cast the new proceedings as the evolutionary successors of the PTO's existing patent-reexamination procedures, in reality their lineage is the PTO's patent-interference practice. Only the latter system uses the same model found in the new post-grant and *inter partes* review procedures—namely, pleadings filed by opposing parties before a PTO panel acting as the adjudicator, limited discovery and use of oral hearings. Further, as the recently published draft rules on the new proceedings show, the PTO is drawing extensively from its interference "contested proceedings" model to define the way in which it will conduct the new post-grant and *inter partes* review proceedings.

See Jeffrey P. Kushan, *The Fruits of the Convoluted Road to Patent Reform: The New Invalidity Proceedings of the Patent and Trademark Office*, 30 Yale L. & Pol'y Rev. 385, 390-91 (2012).[8]

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[8] The similarity of the procedures adopted by the PTO for IPRs to those it had been using in interferences can also be seen by comparing the PTO's 2012 Trial Practice Guide setting forth procedures for IPRs and other AIA post-grant proceedings with the 2011 Standing Order for contested cases setting forth procedures to be used in interferences. *See* 77 Fed. Reg. 48756 (Aug. 14, 2012) (PTAB Trial Practice Guide); BPAI Standing Order (Mar. 8, 2011),

c. The Ability to Amend Claims Is Limited in Interferences

A party's ability to amend claims in an interference in response to a patentability challenge is limited. Indeed, the limitations on the ability to amend one's claims in an interference are remarkably similar to the limitations on the ability to amend one's claims in IPRs that Cuozzo contends makes the use of the BRI standard inappropriate in IPRs.

Cuozzo argues BRI is inappropriate in IPRs because of the following limitations on amending: (1) the patent owner may file only one motion to amend after conferring with the Board, (2) the motion is presumptively limited to substituting one amended claim for each challenged claim, (3) the amendment may be denied if it does not respond to an alleged ground of unpatentability, (4) claims cannot be broadened via amendment, (5) the motion must be filed before the Board has ruled on patentability, and (6) the patent owner must show that the amended claim is patentable over the prior art. Cuozzo Br. at 29-30. As set forth below, all of these limitations on amending are also present in interferences.

As to (1), in an interference, one may only move to add a claim to an application or patent via a preliminary motion. BPAI, Standing Order (Mar. 8, 2011) (setting forth the Board's procedures for contested cases, including

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http://www.uspto.gov/sites/default/files/ip/boards/bpai/interf/forms/standingordermar2011.pdf.

interferences) ¶ 208.5.[9] And in interferences, one may not even move to add a claim without first conferring with the Board and obtaining authorization to file the motion. *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1126-27 (Fed. Cir. 2004).

As to (2), a party is presumptively limited to adding a total of one claim in an interference in response to a preliminary motion by the opposing party that the claims in the party's application or patent are unpatentable, regardless of how many claims the opposing party is alleging are unpatentable. *See Wnek v. Dobbs*, 85 U.S.P.Q.2d 1159, 1160 (B.P.A.I. 2006) ("[g]enerally, as stated above, the default number of claims to be added in a responsive motion is one (1)."); Charles L. Gholz, *A Critique of Recent Opinions in Patent Interferences*, 91 J. Pat. & Trademark Off. Soc'y 1, 4 (2009) ("There is a Severe Limitation on the Number of Claims that One Can Ask to Add in a Responsive Motion").

As to (3), a party seeking to add a claim must explain how it overcomes any patentability problem raised by the other party. Standing Order ¶ 208.5.1.

As to (4), one can only add a claim to an issued patent in an interference by filing a reissue application,

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[9] In an interference, one technically is not permitted to amend the claims at all. Rather, one must seek cancel an existing claim and add a new claim including the proposed amended language. Standing Order ¶ 208.5.2. Moreover, the ability to amend one's claims in an interference is on a weaker statutory footing than in IPRs because the statutory provision regarding interferences (35 U.S.C. § 135 (pre-AIA)) says nothing about amending claims, while the relevant statutory provision regarding IPRs (35 U.S.C. § 316(d)) explicitly provides that a patent owner is entitled to move to amend its claims.

and then moving to add the reissue application to the interference. Standing Order, ¶¶ 208.5.1, 208.5.4; *Bamberger*, 55 U.S.P.Q.2d at 1526. And one cannot seek broader claims in an issued patent via a reissue application unless the reissue application is filed within two years of the issuance of the original patent. 35 U.S.C. § 251(d).

As for (5), in an interference, one must seek to amend a claim – by filing a responsive motion after the opposing party has moved to have one or more of the amending party's claims declared unpatentable – before the Board has indicated how it is likely to rule on the patentability challenge. Parties seeking to amend claims in an IPR are arguably better off with respect to this criterion because they do not have to move to amend until after the PTAB has issued its institution decision (37 C.F.R. §§ 42.120(b), 42.121(a)(1)), which gives the patent owner some sense of the PTAB's views on patentability.

And as for (6), in an interference, a patent owner must show that its amended claim is patentable. 37 C.F.R. § 41.208(c); *see also* Standing Order, ¶ 208.5.1.

Amici are not aware of statistics regarding the frequency with which motions to add claims in an interference are granted. But one thing is certain: such motions are often denied, and for a variety of reasons. *See, e.g.*, *Bamberg v. Dalvey*, No. 15-1548, 2016 WL 890682, at **4-5 (Fed. Cir. Mar. 9, 2016) (motion to amend claims properly denied where claim chart showing support was not provided); *Bilstad*, 386 F.3d at 1126-27 (motion to add claims properly denied where movant did not have conference call with Administrative Patent

Judge before filing motion); *303©*, 85 U.S.P.2d at 1160 (request to add 12 claims properly denied because party had not shown why it needed to add that number of claims instead of the 3 authorized); *Lanuza v. Fan*, 76 U.S.P.Q.2d 1559, 1576-78 (B.P.A.I. 2005) (motion to add broader claims denied because movant had only been authorized to add narrower claims, and motion to add 7th claim denied because movant had only been authorized to add 6 claims); *Davis v. Saito*, 75 U.S.P.Q.2d 1448 (B.P.A.I. 2004) (motion to add claims by adding reissue application denied because claims in reissue application had been rejected over the prior art); *Tseng v. Doroodian-Shoja*, 2002 WL 390537, at **23-24 (B.P.A.I. 2002) (motion to add new claims denied because they would not cure the deficiencies of the pending claims).

d. Congress Is Presumed to Have Been Aware of the Use of BRI in Interferences

As explained above, the PTO has for decades been using the BRI standard in interferences,[10] adjudicatory proceedings where the patentability of claims in issued patents is determined, and where the ability to amend claims is limited. Thus, before the AIA was enacted, there was long-standing precedent for the PTO using the BRI standard in proceedings having all of the

[10] It is not clear what the Federal Circuit meant when it stated that interferences use "a variant" of the BRI standard. Pet. App. 18a. Interferences use the same BRI standard used in all PTO proceedings involving applications or unexpired patents. The Court may have been referring to interferences using the BRI standard both in interpreting claims and in interpreting the "count," which is a construct used in interferences to define the disputed subject matter..

characteristics that Cuozzo contends make IPRs distinctive.

Congress is presumed to have been aware of this backdrop when it passed the AIA. Pet. App. 15a. Congress gave no explicit indication that the BRI standard should not be used in IPRs. Accordingly, it is reasonable to infer that Congress intended for the PTO to use BRI in IPRs. And indeed, the only statement in the legislative history that explicitly discusses the claim construction standard to be used in IPRs assumes that the BRI standard will be utilized. *See* 157 Cong. Rec. S1375 (Mar. 8, 2011) (Kyl).

2. Congress Gave the PTO the Authority to Issue a Rule Requiring That the BRI Standard Be Used in IPRs

Cuozzo argues that the PTO was not authorized to issue the rule requiring the use of the BRI standard in IPRs (37 C.F.R. § 42.100(b)) because the rule-making authority given to the PTO by the AIA (in 35 U.S.C. § 316) is not broad enough to authorize the PTO to issue such a rule. This is belied by the fact that the PTO had previously issued a rule mandating that BRI be used in interferences (37 C.F.R. § 41.200(b) (2004)) based on Congressional authority that was very similar to the rule-making authority that Congress gave to the PTO regarding IPRs.

The interference BRI rule provided that "[a] claim shall be given the broadest reasonable construction in light of the specification of the application or patent in

which it appears." 37 C.F.R. § 41.200(b) (2004).[11] When the PTO issued this rule, it did so pursuant to its rule-making authority set forth in 35 U.S.C. § 2(b)(2). 69 Fed. Reg. 49960, 49996 (Aug. 12, 2004). Section 2(b)(2)(A) gives the PTO the authority to issue rules that "shall govern the conduct of proceedings in the Office."

The AIA gives the PTO very similar authority to issue rules relating to IPRs. Specifically, 35 U.S.C. § 316(a)(4), entitled "Conduct of inter partes review," gives the PTO the authority to issue rules "establishing and governing inter partes review under this chapter. . .". Cuozzo itself argues that Section 316(a)(4) gives the PTO the same authority to issue rules for IPRs that Section 2(b)(2) gives it to issue rules for other types of proceedings. Cuozzo Br. at 36-38.

Accordingly, when Congress gave the PTO the rule-making authority in Section 316, there was precedent for the PTO using that same authority to issue a rule requiring the use of the BRI standard in interferences – adjudicative proceedings where the patentability of claims in issued patents is determined, and the ability to amend is limited. Congress is presumed to have been aware of the PTO's previous use of this rule-making authority to issue a rule requiring the use of BRI in interferences. *Lorillard v. Pons*, 434 U.S. 575, 580-81 (1978). The fact that it gave the PTO similar authority for IPRs

[11] In 1992, the PTO also issued rules (which are still in effect) requiring the use of the BRI standard in determining when prior art is sufficient to establish a *prima facie* case of unpatentability (and thus must be disclosed to the PTO). *See* 37 C.F.R. §§ 1.56(b) and 1.555(b); 57 Fed. Reg. 2012, 2022-23, 2034, 2036 (Jan. 17, 1992).

necessarily leads to the conclusion that Congress intended to give the PTO the authority to issue a rule requiring BRI in IPRs as well.[12]

3. In Creating IPRs, Congress Intended to Facilitate the Elimination of Weak Patents By Improving the *Inter Partes* Reexamination Process, Not to Duplicate District Court Procedures

Cuozzo makes much out of the statement in the AIA's legislative history that IPRs were intended to take the existing *inter partes* reexamination procedure and convert it from an "examinational" format to an "adjudicatory" format. Cuozzo relies on this statement to argue that Congress's over-riding purpose in creating IPRs was to create a PTO procedure for challenging patents that was very similar to – or a "surrogate" for – district court litigation, and that Congress thus must have intended that the PTO use the district court's claim construction standard in IPRs. Cuozzo Br. at 17-18. This is wrong for several reasons.

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[12] In 2010, the PTO cancelled the portion of 37 C.F.R. § 41.200 requiring the use of the BRI standard in interferences. *See* 75 Fed. Reg. 19558 (Apr. 15, 2010). However, this had nothing to do with the fact that the BRI standard was included in the rule. Rather, the rule was cancelled because it required that a claim in an interference be interpreted "in light of the specification or application in which it appears," and then-recent cases had held that there were situations in interferences (where one party had copied claims from the other party's application or patent) where the specification to be consulted in claim interpretation was actually the specification of the other party's application or patent. *Id.*

First, Congress's over-riding purpose in creating IPRs and the other new post-grant proceedings – just as its purpose had been in creating *ex parte* and *inter partes* reexamination – was to provide a relatively quick and inexpensive PTO procedure to eliminate improperly granted patents. The legislative history is replete with comments about the problems caused by the assertion of weak patents. For example, in discussions regarding the bill that became the AIA, Senator Leahy observed that the PTO "too often issues low-quality patents," and commented that:

> The legislation also provides a modernized, streamlined mechanism for third parties who want to challenge recently issued, low-quality patents that should never have issued in the first place. Eliminating these potentially trivial patents will help the entire patent system by improving certainty for both users and inventors.

157 Cong. Rec. S1036-37 (Mar. 1, 2011) (Leahy); *see also* 157 Cong. Rec. S1325 (Mar. 7, 2011) (Sessions) ("This will allow invalid patents that were mistakenly issued by the PTO to be fixed early in their life, before they disrupt an entire industry or result in expensive litigation."); 157 Cong. Rec. S5374 (Sep. 7, 2011) (Whitehouse) ("Unfortunately, numerous poor quality patents have issued in recent years, resulting in seemingly endless litigation that casts a cloud over patent ownership.")

Second, the AIA itself shows that Congress clearly did not intend for IPRs to duplicate district court litigation. For example, the AIA provides that the petitioner in an IPR has the burden of proving

unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e). This is in sharp contrast to district courts, where invalidity must be proven by clear and convincing evidence. In addition, patent owners in IPRs are explicitly permitted to amend their claims (35 U.S.C. § 316(a)(9) and (d)), which is not possible in district court. Moreover, discovery in IPRs is limited to depositions of individuals submitting declarations and what is otherwise needed "in the interest of justice." 35 U.S.C. § 316(a)(5). Again, this is very different from district court litigation, which permits broad document and deposition discovery.

Third, Congress's more specific intent in creating IPRs was to try to solve the primary problem with *inter partes* reexamination – namely, that it was too slow.[13] As of the time the AIA was passed, such proceedings took approximately three years.[14] Congress recognized this was a problem because, *inter alia*, when *inter partes* reexamination was ordered, district courts often stayed any parallel infringement litigation until the reexamination was concluded. 154 Cong. Rec. S9989 (Sep. 27, 2008) (Kyl). This had the effect of delaying infringement litigation for many years, to the detriment of the patent owner.

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[13] Despite being too slow, the use of *inter partes* reexamination "grew sharply over the course of the 2000s," likely due to the success rate, with about half of *inter partes* reexaminations resulting in all claims of the subject patent being cancelled as of September 30, 2010. *See* Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 Fed. Cir. B.J. 539, 603 (2012); U.S. Patent and Trademark Office, *Inter Partes* Reexamination Filing Data, http://www.uspto.gov/sites/default/files/documents/inter_parte_historical_stats_roll_up_EOY2014.pdf (PTO *Inter Partes R*eexam Statistics).

[14] *See* PTO's *Inter Partes* Reexamination Statistics.

Congress sought to solve this problem by making *inter partes* reexamination proceedings "adjudicatory" instead of "examinational." 157 Cong. Rec. S1376 (Mar. 8, 2011) (Kyl). Contrary to Cuozzo's arguments, however, this did not mean that *inter partes* reexaminations would borrow district court procedures. Indeed, this would not have made sense, as district court patent litigations were on average not resolved much more quickly than *inter partes* reexamination proceedings.[15] Rather, the key feature of the "adjudicatory" model was that – just like in interferences – the parties would present their arguments regarding patentability to the Board, with the challenger having the burden of proving unpatentability, and the Board then issuing a final written decision.

In discussing the Patent Reform Act of 2008, an earlier version of the bill that became the AIA, Senator Kyl explained how this "adjudicative" model would enable the PTO to resolve IPRs more quickly than it had been able to resolve *inter partes* reexaminations, and explained that the PTO had indicated it believed that it could comply with the statutory deadlines for IPRs with this model:

> The bill uses an oppositional model, which is favored by PTO as allowing speedier adjudication of claims. Under a reexam system, the burden is always on PTO to show that a claim is not patentable. Every time that new information is presented, PTO must reassess whether its burden has been met. This model

[15] *See* PricewaterhouseCoopers LLP, 2011 Patent Litigation Study, at 27 (2011), http://www.pwc.com/us/en/forensic-services/publications/assets/2011-patent-litigation-study.pdf.

> has proven unworkable in inter partes reexam, in which multiple parties can present information to PTO at various stages of the proceeding, and which system has experienced interminable delays. Under an oppositional system, by contrast, the burden is always on the petitioner to show that a claim is not patentable. Both parties present their evidence to the PTO, which then simply decides whether the petitioner has met his burden.
>
> If we expect post grant review proceedings to be completed within particular deadlines, I think that it is obligatory that we consult with the agency that is expected to administer the proceedings. In this case, PTO has expressed a strong preference for an oppositional model, and it believes that it can comply with reasonable deadlines if that model is adopted.

154 Cong. Rec. S9987 (Sep. 27, 2008) (Kyl).

The reason the PTO believed that it would be able to complete IPRs within the statutory deadlines was its previous experience with interferences, another adjudicatory proceeding. By adopting procedures very similar to the ones it later adopted for IPRs, the PTO had been able to reduce the average pendency of interferences to 12 months by 2010, with 88% of such proceedings terminated in less than 2 years.[16] Thus, when the PTO

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[16] U.S. Patent and Trademark Office, BPAI Statistics – FY 2010 Performance Measures, http://www.uspto.gov/patents-application-process/appealing-patent-decisions/statistics/performance-measures/fy-2010. When the PTO proposed procedures for IPRs, it explicitly noted that it was borrowing certain procedures – such as page limits – from interferences that had enabled the PTO to decide

told Congress that it wanted an "oppositional model" for *inter partes* reexaminations (as noted in Senator Kyl's comments), it was telling Congress that it wanted to use the procedures that it had successfully used in interferences to reduce pendency. And one of the procedures that the PTO had been using in interferences was the BRI standard. Therefore, there is every reason to conclude that Congress intended the PTO to use that same BRI standard in IPRs and other AIA post-grant proceedings.

The House Judiciary Report on the AIA contains another strong indication that eliminating the BRI standard was ***not*** one of the changes that Congress intended to make to *inter partes* reexamination. The Report identifies nine specific "improvements" that the AIA was making to *inter partes* reexamination in creating IPRs, but does not identify eliminating BRI as one of these changes. H.R. Rep. No. 112-98 at 46-47 (2011).

B. The PTO's Use of the BRI Standard in IPRs Deserves Deference Because, *Inter Alia*, the Purposes of the BRI Standard Support Using It in IPRs

There are two purposes behind the BRI standard, both of which warrant its use in IPRs.

First, the BRI standard is intended to serve the public interest by reducing the likelihood that claims will be interpreted more broadly in district court infringement litigation than they were interpreted by the PTO when

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interferences more quickly. *See* 77 Fed. Reg. 7041, 7051-52 (Feb. 10, 2012).

the claims were found patentable. *See In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984). Claims in infringement litigation are presumed valid and must be proven invalid by clear and convincing evidence precisely because they have previously been evaluated by the PTO and found patentable. *See Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238 (2011). But if patent claims found patentable by the PTO based on a narrower construction are then given a broader construction in infringement litigation, the whole premise behind this arrangement would disappear. Claims would be given a "benefit of the doubt" that they had not earned. The BRI standard reduces the likelihood of this unfairness.

This justification for the BRI standard is particularly strong in the IPR context because there is a very real danger that the owner of a patent that has survived an IPR will try to have it interpreted as broadly as possible in subsequent infringement litigation. At that point, the accused infringer may be estopped from raising any invalidity arguments that it raised or could have raised in the IPR (35 U.S.C. § 315(e)(2)), and thus the patent owner may believe there is no downside to seeking a broader interpretation than was used in the IPR.[17]

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[17] Indeed, even with the BRI standard, owners of patents that have survived an IPR petition have often sought – and obtained – a broader construction in subsequent district court litigation. *See*, *e.g.*, *Depuy Orthopaedics, Inc. v. Orthopaedic Hospital*, No. 3:12-CV-299-CAN, 2016 WL 96164, at **4, 15-16 (N.D. Ind. Jan. 8, 2016); *Not Dead Yet Mfg. Inc. v. Pride Solutions, LLC*, No. 13-C-3418, 2015 WL 5829761, at *10 (N.D. Ill. Oct. 5, 2015); *Kroy IP Holdings, LLC v. Autozone, Inc.*, No. 2:13-cv-888-WCB, 2015 WL 557123, at *4 (E.D. Tex. Feb. 10, 2015). This belies Cuozzo's contention that the BRI standard systematically leads to broader claim construction.

The other purpose of the BRI standard is to encourage patent owners and applicants to use clear language in claims. *See In re Zletz*, 893 F.2d 319, 321-22 (Fed. Cir. 1989). As this Court recently explained, claims should provide clear notice of what is covered and thereby apprise the public of what is still open to them. *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). Ambiguous claim language harms the public by creating a "zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims." *Id.*

When the BRI standard is used, claims that include ambiguous language and thus could be interpreted in multiple ways are interpreted in the broadest reasonable manner. If this leads to the claims being interpreted more broadly than the patent owner or applicant intended and thereby being found unpatentable, the patent owner or applicant can solve the problem by amending its claims to make them clearer.[18] *See Zletz*, 893 F.2d at 321. Patent owners in IPRs have no right to complain about having to amend their claims to make them clearer. By definition, a patent owner in an IPR with ambiguous claims has already been through *ex parte* examination, where it had an unfettered opportunity to present clear language. Such patent owners have nobody but themselves to blame for having squandered that opportunity.

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[18] A patent owner that encounters difficulties in amending its claims in an IPR can always file a reissue application and amend its claims in that application. Indeed, as noted above, this is the procedure that patent owners in interferences have been required to use for many years when they want to amend their claims.

C. Cuozzo Greatly Exaggerates the Impact of the BRI Standard on the IPR Cancellation Rate

Although not directly relevant to the merits, amici feel compelled to point out that Cuozzo greatly exaggerates the impact of the BRI standard. Cuozzo notes that in the completed IPRs to date, some or all claims have been cancelled 87% of the time[19], and asserts without support that "[a] primary reason for the high cancellation rate" is the PTAB's use of the BRI claim construction standard. Contrary to Cuozzo's assertion, the primary reason for the cancellation rate in IPRs is that there are a lot of weak patents. Indeed, this is the very problem that led Congress to create IPRs and other post-grant proceedings in the AIA.

As for why IPRs have been more successful in eliminating weak patents than district court litigation, there are reasons unrelated to the BRI standard.

First, the fact-finder in district court litigation is often a jury, which may understandably be more deferential to a PTO Examiner who allowed a patent in the first place and therefore more reluctant to find a patent invalid than would a specially-trained PTAB judge. Notably, in each of the four cases cited by Cuozzo where the PTAB held a claim invalid after a district court had previously held the same claim not invalid, the prior

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[19] IPRs in the pharmaceutical and biotech sector have been slightly less successful than IPRs in other sectors. *See* IPR and Biopharma patents: what the statistics show, Life Sciences Intellectual Property Review, *http://www.lifesciencesipreview.com/article/ipr-and-biopharma-patents-what-the-statistics-show* (Nov. 26, 2015).

district court decision had been made by a jury. Cuozzo Br. at 33-34.

Second, the pools of patents being considered in IPRs and district court litigation are not the same. The patents asserted in district court are those that a plaintiff believes will withstand invalidity challenges, while the patents challenged in IPRs by definition are ones a party believes are vulnerable enough to warrant an IPR petition. Moreover, the patents challenged in early IPRs – like the Cuozzo patent here – were likely ones that were singled out because they were particularly weak. Once this "low-hanging fruit" is eliminated, the cancellation rate in IPRs may drop. A similar phenomenon happened with *inter partes* reexamination, where the early cancellation rates were high, but then gradually decreased.[20]

That the BRI standard is not the cause of the higher cancellation rate in IPRs is supported by the amicus brief of former Federal Circuit Chief Judge Michel. Judge Michel provides a detailed comparison of the BRI and district court claim construction standards, pointing out that – at least in theory – they are the same in almost all respects, and concludes that "the putative claim construction standard between courts and the Patent Office is the same," with "the one minor difference" being that the courts sometimes hold that subject matter has been disclaimed during prosecution even if the claim language does not provide a "textual hook" for such

[20] The PTO's statistics shows that the percentage of *inter partes* reexaminations in which all claims were cancelled steadily decreased from 67% in 2008 to 44% in 2011 to 31% in 2014. *See* PTO's *Inter Partes* Reexamination Statistics.

disclaimer.[21] Michel Amicus Br. at 6. Given these similarities, the higher cancellation rate in IPRs should not be attributed to the BRI standard.[22]

II. The PTAB's Decision to Institute an IPR is Not Reviewable

A. The Language of Section 314(d) Precludes Review of IPR Institution Decisions

Section 314(d) provides that the PTO's determination on "whether to institute" an IPR is "final and nonappealable." This provision unambiguously precludes review of institution decisions.

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[21] Judge Michel goes on to assert that, in practice, the PTAB applies the BRI standard more broadly than it should. Michel Amicus Br. at 8-10. However, amici submit that this is not reflected by the numbers, which show a high Federal Circuit affirmance rate for PTAB decisions. *See* Fed. Circ.'s Embrace of PTAB to Fuel More AIA Reviews, Law360 (Mar. 8, 2016), http://www.law360.com/articles/767549/fed-circ-s-embrace-of-ptab-to-fuel-more-aia-reviews (reporting an 88% affirmance rate). If the PTAB was applying BRI more broadly than it should, one would expect a lower affirmance rate.

[22] Ironically, although Cuozzo depicts the BRI standard as one that systematically interprets claims too broadly, ***Cuozzo's complaint with the PTAB's construction here is not that it is too broad but that it is too narrow***. Pet. App. 21a. Cuozzo argues that if the PTAB had interpreted the claims currently in Cuozzo's patent more broadly, the PTAB would then not have rejected Cuozzo's motion to submit amended claims on the grounds that the amended claims were broader than the claims currently in the issued patent. Pet. App. 29a. Cuozzo's complaint with the PTO's claim construction has nothing to do with the patentability issue. Pet. App. 23a.

Cuozzo's contentions about the provision do not withstand scrutiny. Cuozzo first contends that the provision does not preclude all judicial review of decisions to institute, and that it instead provides that such decisions are not ***immediately*** appealable, but can be reviewed after the PTAB issues its final written decision. Cuozzo Br. at 46. However, this cannot be correct because even without Section 314(d), a decision to institute would not be immediately appealable due to the general principle that only "final agency action" can be appealed. 5 U.S.C. § 704. Cuozzo also contends that the provision precludes all judicial review of decisions ***not*** to institute. Cuozzo Br. at 49. However, this cannot be correct either because there is no logical basis for construing the statute to preclude all judicial review of decisions ***not*** to institute, but as only delaying judicial review of decisions to institute. The text of the statute provides no such basis, and Cuozzo does not offer one.

The legislative history of very similar language in the portion of the patent statute regarding *inter partes* reexamination – on which the language in Section 314(d) was apparently based – demonstrates that Congress intended the "final and nonappealable" language to preclude all judicial review. Specifically, 35 U.S.C. § 312(a), regarding requests for *inter partes* reexamination, provided that "the Director shall determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request." Section 312(c) then provided that "[a] determination by the Director under subsection (a) shall be final and non-appealable." Thus, Section 312(c) had the same "final and nonappealable" language as Section 314(d), although Section 312(c) had a narrower definition of ***what*** was

"final and nonappealable." While Section 314(d) makes the decision regarding "whether to institute" an IPR "final and nonappealable," Section 312(c) only made the PTO's decision on the "substantial new question of patentability" issue "final and non-appealable."

The legislative history of Section 312(c) shows that Congress intended the "final and nonappealable" language to preclude all judicial review of the "substantial new question of patentability" determination. Specifically, the Conference Report (reflecting input from both the Senate and House) on the legislation that added *inter partes* reexamination to the patent statute states as follows about Section 312:

> Similar to section 303 of existing law [regarding *ex parte* reexamination], new section 312 of the Patent Act confers upon the Director the authority and responsibility to determine within three months after the filing of a request for inter partes reexamination, whether a substantial new question affecting patentability of any claim of the patent is raised by the request. ***Also, the decision in this regard is not subject to judicial review.***

145 Cong. Rec. H11769, H11764, H11805 (Nov. 9, 1999) (Conference Report on H.R. 1554, Intellectual Property and Communications Omnibus Reform Act of 1999) (emphasis added); *see also* 145 Cong. Rec. S14720 (Nov. 17, 1999) (same).

Consistent with Congressional intent, at least one court has held that the "final and non-appealable" language in Section 312(c) bars all judicial review of the

"substantial new question of patentability" decision in *inter partes* reexaminations, but does not bar review of other issues relating to the decision to initiate such reexamination. *See*, *e.g.*, *Callaway Golf Co. v. Kappos*, 802 F. Supp. 2d 678, 685 (E.D. Va. 2011) (permitting review of PTO's decision to not vacate an *inter partes* reexamination based on the argument that the requester was barred from making the request by a previous settlement agreement, while stating "Section 312(c) only ***exempts from judicial review*** the PTO's substantive determination that a reexamination application raises a 'substantial new question of patentability.'") (emphasis added).

Cuozzo suggests that the Federal Circuit's treatment of similar "final and non-appealable" language in the portion of the patent statute regarding *ex parte* reexamination shows that the "final and nonappealable" language permits some review. Cuozzo Br. at 50-51. But a closer inspection of the language relied on by Cuozzo – and what that language makes "final and non-appealable" – shows that Cuozzo is wrong.

Section 303(a) provides that after a request for *ex parte* reexamination is filed, "the Director shall determine whether a substantial new question of patentability affecting any claim of the patent is concerned is raised by the request." Section 303(c) then provides that "[a] determination by the Director pursuant to subsection (a) of this section that ***no*** substantial question of patentability has been raised will be final and nonappealable." 35 U.S.C. § 303(c) (emphasis added). Section 303(c) is thus very clear that only a decision that there is "no" substantial new question of patentability is

"final and nonappealable." A decision that such a question exists – and the ordering of reexamination – is not "final and nonappealable."

Accordingly, to the extent that the Federal Circuit has previously reviewed PTO decisions that there ***is*** a substantial new question of patentability in an *ex parte* reexamination, that is irrelevant because such review is not precluded by the statute.[23] Cuozzo has not pointed to any decisions where courts reviewed the PTO's decision that there was no substantial new question of patentability.

Section 314(d) retains the "final and nonappealable" language of its predecessors, Sections 303(c) and 312(c), but goes further in delineating what is exempted from judicial review. Rather than making the Director's determination regarding whether a "substantial new question of patentability" exists "final and nonappealable," Section 314(d) provides that "[t]he determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable." Thus, it is the determination on "whether to institute an inter partes review" that is "final and nonappealable," meaning that the entire determination – regardless of what it is based on – is not reviewable.

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[23] Notably, however, at least one court has held that the "final and non-appealable" language in Section 303(c) does preclude any "judicial review" of a decision that an *ex parte* reexamination request does ***not*** raise a substantial new question of patentability. *See Heinl v. Godici*, 143 F. Supp. 2d 592, 597 (E.D. Va. 2001) (Section 303(c) "bars judicial review of PTO decisions to *deny* reexamination") (emphasis in original).

B. Precluding Review of Institution Decisions Comports With Congressional Intent

Making the decision on whether to institute an IPR unreviewable comports with the objectives of the AIA. Congress repeatedly indicated that it wanted to create a speedy procedure for challenging patents. Indeed, lack of speed was the very problem with *inter partes* reexaminations that Congress was attempting to solve when it created IPRs. If the Federal Circuit could review the threshold decision on whether to institute an IPR on review of the final written decision and dismiss the IPR based on technical defects in the petition having no bearing on whether the holding of unpatentability is correct, this objective would be thwarted.

Consider what this would mean in the present case. Years after the original IPR petition was filed, the IPR proceeding would be dismissed, and Cuozzo's patent would be left in place regardless of whether the PTAB's holding that the claims are unpatentable was correct. A party then seeking to challenge that patent through the IPR process would have to begin the process anew, and thus more years would pass before these unpatentable claims were actually cancelled. In the instant case, the original petitioner (Garmin) settled, and thus it presumably would not try to file a new petition if this IPR was dismissed. If the original petitioner had not settled, however, and this IPR was dismissed as Cuozzo requests, Cuozzo would surely argue that the petitioner was barred from filing a new IPR petition correcting the technical defects in the original petition because more than a year had passed since it was first sued for infringement of the

patent at issue in the IPR. *See* 35 U.S.C. § 315(b). This cannot be what Congress intended.

Delays of this sort are particularly troubling to amici. ANDA applicants are often reluctant to launch their products until they have "patent certainty" – *i.e.*, until after there has been a final decision that the brand-name drug maker's relevant patents are not infringed or invalid. This is because the damages that will be sought for "at risk" product launches (before such a decision) are potentially quite significant, and often greater than the profits that the ANDA applicant could hope to make.

If patent owners could have the courts revisit the original decision to institute and have IPRs dismissed because of technical defects in the original petition without reaching the merits, this would prevent Hatch-Waxman defendants from quickly obtaining patent certainty. For example, if the claims in a patent were declared unpatentable by the PTAB but the Federal Circuit dismissed the IPR because of defects in the original petition, a Hatch-Waxman defendant might not be willing to launch its ANDA product until a new petition was filed, the PTAB again found the claims unpatentable, and that ruling was affirmed by the Federal Circuit. This would harm the public – and undermine the purpose of the Hatch-Waxman Act – by delaying the launch of more affordable generic drugs.

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

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