No. 2017-1694

United States Court of Appeals for the Federal Circuit

MOMENTA PHARMACEUTICALS, INC.,
Appellant,

v.

BRISTOL-MYERS SQUIBB COMPANY,
Appellee.

Appeal from the Decision of the United States Patent and Trademark Office's Patent Trial and Appeal Board on Inter Partes Review, No. IPR2015-01537

BRIEF FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* SUPPORTING APPELLANT

William B. Schultz
Carlos T. Angulo
ZUCKERMAN SPAEDER LLP
1800 M Street, NW, Suite 1000
Washington, DC 20036
Tel.: 202-778-1800
Fax: 202-822-8106

Counsel for Association for Accessible Medicines

July 10, 2017

CERTIFICATE OF INTEREST

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Federal Circuit Rules 29(a) and 47.4, William B. Schultz, counsel for *amicus curiae* the 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:

   Not Applicable

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 this court are:

   ZUCKERMAN SPAEDER LLP:
   William B. Schultz, Carlos T. Angulo, Jeremy Kreisberg*

*Since first appearing in this case. Mr. Kreisberg has left Zuckerman Spaeder.

Dated: July 10, 2017

/s/ William B. Schultz
William B. Schultz

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

INTEREST OF AMICUS CURIAE[1]

The Association for Accessible Medicines ("AAM"), formerly the Generic Pharmaceutical Association, is a nonprofit, voluntary association representing the leading manufacturers and distributors of generic and biosimilar medicines, manufacturers and distributors of bulk active pharmaceutical ingredients, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. The *inter partes* review ("IPR") process at issue in this case enables AAM's members developing generic and biosimilar medicines and related products to dispute the validity of brand-name drug patents in an efficient and cost-effective manner. The IPR process paves the way for increased drug price competition and patient access to affordable medicines in cases where the patents of brand name pharmaceuticals are held invalid, and a generic or biosimilar medicine may enter the market to compete. AAM's members have a strong interest in ensuring that the IPR process remains a viable option to gain patent certainty during the course of drug development.

The availability of generic and biosimilar drugs is critical to ensuring that patients have access to affordable medicine. Generic medicines saved Americans

[1] No counsel for any party authored this brief in whole or in part, and no person other than *amicus* and its members made a monetary contribution to the preparation or submission of this brief. Appellant Momenta Pharmaceuticals, Inc. ("Momenta") has consented to, and Appellee Bristol-Meyers Squibb Company ("BMS") does not oppose, the filing of this brief.

$227 billion in 2015 and $1.46 trillion over the past ten years. Generic Pharm. Ass'n, *2016 Generic Drug Savings & Access in the United States Report* 4 (2016). With biologic drugs representing some of the highest-cost treatments available and experiencing faster cost increases than any other component in healthcare, biosimilars are projected to save Americans as much as $250 billion over ten years, with prices as low as forty percent below brand price. The Biosimilars Council, *The Next Frontier for Improved Access to Medicines* 14–15 (2015).

The continuing presence of invalid patents threatens this vitally important industry, as brand-name drug companies will often go to great lengths to maintain monopolies for their high-cost products. Indeed, some high-cost brand-name drugs are protected by more than 100 patents, some adopted decades after discovery of the compound and seemingly timed to coincide with entry of generic or biosimilar competitors. *See* Drew Pollack, *Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions*, N.Y. Times (July 15, 2016), https://www.nytimes.com/2016/07/16/business/makers-of-humira-and-enbrel-using-new-drug-patents-to-delay-generic-versions.html. Indeed, brand-name drug makers frequently engage in "evergreening"—the use of weak patent claims to cover trivial changes to drug products before a patent expires. *See* Dennis Thompson, *What's Behind the Sharp Rise in Prescription Drug Prices?*, CBS News (Aug. 24, 2016, 11:17 A.M.), http://www.cbsnews.com/news/whats-behind-

the-sharp-rise-in-prescription-drug-prices/. The additional costs imposed by patents improperly granted to brand-name drug manufacturers have been estimated to reach up to nearly $220 billion over twenty years. Dean Baker, *The Impact of Exempting the Pharmaceutical Industry from Patent Reviews*, Ctr. for Econ. & Pol. Res. 10 (July 2015). The IPR process has the potential to give generic and biosimilar drug manufacturers a tool to fight invalid patents before they disrupt the development of competitive drugs. AAM's members and consumers have a strong interest in preserving the strength of that process.

AAM's *amicus* brief focuses on the issue of Appellant Momenta's standing to appeal an adverse IPR decision related to one of Appellee BMS's patents for its rheumatoid arthritis drug Orencia®. Appellee previously raised the standing issue when it filed a motion to dismiss this appeal for lack of jurisdiction. AAM filed an *amicus* brief at the motion stage in support of Appellant's standing. This Court denied Appellee's motion but invited the parties to address the standing issue in their briefing on the merits. AAM is filing this brief to again address the standing argument which the Court has invited, and to reiterate its members' and consumers' interest in preserving the strength of the IPR process—an interest that

would be fatally undermined if this Court were to adopt Appellee's incorrect view on standing.[2]

INTRODUCTION AND BACKGROUND

Bristol-Myers Squibb Co. ("BMS") holds U.S. Patent No. 8,476,239 ("the '239 patent"), which claims a stable formulation suitable for subcutaneous administration of a "protein molecule that is used to treat immune system diseases and disorders such as rheumatoid arthritis and adverse transplant reactions." *Momenta Pharm., Inc. v. Bristol-Myers Squibb Co.*, No. IPR2015-01537, 2016 WL 7987985, at *1 (P.T.A.B. Dec. 22, 2016). BMS claims that the '239 patent covers the subcutaneous formulation of Orencia®, a rheumatoid arthritis drug approved by FDA and sold by BMS at an annual per-patient wholesale acquisition cost of over $38,000. *See* Am.'s Health Ins. Plans, *High-Priced Drugs: Estimates of Annual Per-Patient Expenditures for 150 Specialty Medications* 14 (Apr. 2016). Momenta Pharmaceuticals, Inc. ("Momenta") has invested heavily in and made substantial progress toward the development of a biosimilar version of Orencia®. Non-Confidential Appellant's Opp'n to Mot. to Dismiss for Lack of Jurisdiction [hereinafter Momenta Br.] (Apr. 27, 2017), ECF No. 25 at 3-4.

As part of its development of a biosimilar competitor to BMS's drug, Momenta petitioned the U.S. Patent and Trademark Office ("PTO") for IPR of the

[2] AAM supports, but does not discuss in this brief, Momenta's position on the merits that IPR review in this case was improperly denied.

’239 patent, arguing that all claims of the patent were obvious and therefore not patentable. Finding a “reasonable likelihood” that Momenta would prevail on “at least 1 of the claims challenged,” 35 U.S.C. § 314(a), the PTO instituted IPR before the Patent Trial and Appeal Board (“PTAB” or “the Board”). *See Momenta*, 2016 WL 7987985, at *1. The Board held that Momenta had not shown the claims of the ’239 patent to be obvious. *See id.* at *7.

After Momenta appealed the decision of the PTAB to this Court, BMS moved to dismiss this appeal on the ground that Momenta lacks Article III standing to challenge its loss before the PTAB. In BMS’s view, a biosimilar drug developer will suffer a sufficient injury-in-fact from a loss in IPR only *after* it applies to the Food and Drug Administration (“FDA”) for approval of its competing drug (“the BMS Standing Rule”). Appellee BMS Co.’s Mot. to Dismiss for Lack of Jurisdiction [hereinafter BMS Br.] (Mar. 27, 2017), ECF No. 11 at 2. As noted above, this Court denied BMS’s motion but invited the parties to address the standing issue in their merits briefs, an invitation *amicus* assumes BMS will accept. Order, *Momenta Pharm., Inc. v. Bristol-Myers Squibb Co.*, Fed. Cir. No. 2017-1694 (June 19, 2017).

ARGUMENT

This Court should reject BMS's standing argument.

Congress established the IPR process to encourage early challenges to invalidate patent claims that Congress determined were stifling innovation and delaying competition. To ensure that this process would provide certainty to patent holders and patent challengers alike, and to avoid unnecessary litigation, Congress provided that an unsuccessful IPR challenger is estopped from challenging the same patent claims again on the asserted grounds in a subsequent judicial proceeding. This estoppel provision is critical to direct competitors of the patent holder because they are inherently at risk of being sued for infringement and bound by the IPR result.

Yet BMS would have this Court deny IPR appeal rights to a core category of direct competitors—those that are developing generic or biosimilar drug products that arguably infringe brand-company patents—despite the fact that the brand-company patent holder is always guaranteed the right to appeal. This one-sided rule that would deny standing to direct competitors with a clear monetary stake in the dispute is not only contrary to fundamental principles of injury-in-fact case law, as Momenta demonstrated in its response to BMS's motion to dismiss this appeal, Momenta Br. at 6-22, but would also dramatically shift the incentives for generic and biosimilar drug developers. Without the ability to appeal, the risk of

losing in IPR and being bound by the result will often be unacceptably high. Generic and biosimilar drug developers will instead be forced to expend the enormous resources needed to prepare and submit a generic or biosimilar application to FDA before they are entitled to fair patent proceedings with appeal rights for both sides. This system would leave weak patent claims in place and disrupt investments in generic and biosimilar drugs, often leaving patients, private insurers, and taxpayers without meaningful competition for high-cost drugs.

I. The BMS Standing Rule Would Thwart or Delay Generic and Biosimilar Drug Competition, Harm Consumers Who Benefit From Pricing Competition for High-Cost, Brand-Name Drugs, and Fail To Provide Patent Certainty to the Healthcare Market.

IPR is an adversarial, administrative proceeding before the PTAB through which the PTO may cancel patent claims for lack of novelty or for obviousness. *See* 35 U.S.C. § 311. Of critical importance, if the PTO institutes IPR, and the PTAB issues a final written decision, the petitioner is estopped from asserting in a civil proceeding that the challenged patent "is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review." *Id.* § 315(e)(2).

BMS's Standing Rule would have this Court add an additional rule to the game—one that will tip the scales in many drug patent disputes in favor of the brand-name drug patent holder. Although petitioners without any plan to bring an infringing product to market—e.g., hedge funds, interest groups, and other non-

practicing entities—lack Article III standing to appeal an adverse IPR ruling, *see Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168 (Fed. Cir. 2017); *Consumer Watchdog v. Wisc. Alumni Research Found.*, 753 F.3d 1258 (Fed. Cir. 2014), BMS would have this rule cover a substantially different group of petitioners—direct competitors that are investing in the development of a potentially infringing drug product.

The BMS Standing Rule would thus convert IPR from an attractive method for generic and biosimilar drug developers to challenge weak patent claims at the outset of development to a high-risk venture with the potential to stifle generic and biosimilar drug competition without any judicial review. Under the BMS Standing Rule, a drug patent holder challenged through IPR would have two opportunities to persuade a decision-maker—once before the PTAB and again on appeal before this Court—while a competitor developing a generic or biosimilar drug would have only one such opportunity—before the PTAB.

Under the IPR estoppel provision, 35 U.S.C. § 315(e)(2), the generic or biosimilar drug competitor would also be bound by the adverse IPR result, despite having no appeal rights, when it applies for approval and is sued for patent infringement. With IPR carrying such high stakes, the risk of losing before the PTAB without the ability to appeal will often be unacceptably high. This incongruous system would strongly discourage generic and biosimilar drug

developers, who are already investing heavily in a competing product, from using IPR during the course of development. To have a fair patent dispute with equal appeal rights, generic and biosimilar drug developers would be forced to expend further, substantial resources applying for FDA approval before challenging invalid patents.[3]

By discouraging generic and biosimilar competitors from using IPR during drug development, the BMS Standing Rule would harm both consumers that benefit from pricing competition in the prescription drug market and the healthcare system as a whole. If competitors file fewer early IPR challenges to weak drug patents, generic and biosimilar drugs will be delayed from entering the market, and patients will be left with only high-cost drug options for their health care. Leaving weak drug patents on the books will also lead to "a major distortion in research spending" by drug developers that "attempt[] to innovate around [a] wrongly issued patent." Baker, *supra*, at 11.

Finally, the BMS Standing Rule would have the perverse effect of denying patent certainty to the marketplace. To the extent that anyone files an early IPR challenge to a weak drug patent, it is likely to be a non-competitor that will never

[3] Investment decisions are particularly high-stakes in the biosimilar drug industry, as the development of a biosimilar is estimated to cost between $100 million and $200 million and takes nearly a decade to complete. Fed. Trade Comm'n, *Emerging Health Care Issues: Follow-On Biologic Drug Competition* iii (June 2009).

accrue appeal rights regardless of when it files, and therefore has no incentive to wait. IPR proceedings involving non-competitors would not only be inferior to those involving direct competitors with the most at stake, but they would also fail to provide patent certainty because drug patent holders can win before the PTAB but be forced to litigate the validity of the patent again against a competitor that did not participate in the IPR proceeding. The BMS Standing Rule would therefore produce precisely the sort of inefficient litigation and market uncertainty that IPR was designed to eliminate. *See* Part II, *infra*.

II. The BMS Standing Rule Is Contrary to Congressional Intent.

Congress created IPR as part of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011), "to enable early challenges to patents," H.R. Rep. 112-98, at 47–48 (2011), because it recognized that the "continued existence" of a weak patent "can disrupt product development . . . for years," Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 Fed. Cir. B. J. 539, 600 (2012). Indeed, part of the "main argument" for establishing IPR, *id.*, was that without such review "a competitor cannot challenge a patent in litigation before the competitor incurs the costs and risks of developing and marketing a product," *id.* at 601 (quoting *Patent Quality Improvement: Post-Grant Opposition: Hearing before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary*, 108th Cong. 29 (2004) (statement of

Michael Kirk, Executive Director, AIPLA)). The creation of IPR addressed this concern by allowing for "invalid patents . . . to be fixed early in their life, before they disrupt an entire industry." 157 Cong. Rec. S1326 (Mar. 7, 2011) (Sen. Sessions).

Congress also recognized that early patent challenges by competitors can provide certainty in the market for all actors. Because a loss in IPR would estop a competitor from making the same arguments in a future suit for infringement, Congress expected IPR to provide "quiet title to patent owners to ensure continued investment resources." H.R. Rep. 112-98, at 48 (2011). Encouraging early patent disputes through IPR would consequently serve the important purpose of "limit[ing] unnecessary and counterproductive litigation costs." *Id.* at 40.

The BMS Standing Rule would thwart these clearly expressed congressional objectives at every turn. Rather than encourage early challenges to weak drug patent claims that are disrupting innovation and delaying competition, the BMS Standing Rule would discourage them by denying appeal rights to the challenger until it has applied for FDA approval. Considering Congress's emphasis on ensuring that weak patent claims are eliminated before such claims improperly disrupt an industry, it would run directly contrary to congressional intent to allow only a patent holder, and not a direct competitor, to use the appeal rights that Congress explicitly included in the America Invents Act. *See* 35 U.S.C. § 141(c).

That Congress recognized the concrete injuries imposed on competitors by weak patent claims is a strong reason for this Court to do the same in its Article III analysis. *See Fed. Election Comm'n v. Akins*, 524 U.S. 11, 22 (1998). The BMS Standing Rule would also thwart Congress's intention to provide certainty in the market for competitors and investors alike, and to avoid unnecessary, costly litigation. *See* Part I, *supra*.

Unable to muster any support for its standing argument from the law that created the IPR process that it raised in support of its motion to dismiss, Appellee also attempted to invoke a different statutory scheme—the Biologics Price Competition and Innovation Act ("BPCIA")—and argued that "the policies animating the BPCIA counsel strongly against exercise of this Court's jurisdiction." BMS Br. at 19. Precisely the opposite is true. The BPCIA creates a separate process for resolving patent disputes *after* a biosimilar application is accepted for review by FDA. *See* 42 U.S.C. § 262(l); 35 U.S.C. § 271(e)(2)(C). If BMS were correct that Congress wanted drug developers to use the BPCIA procedure, the BMS Standing Rule would directly contravene that purpose by encouraging biosimilar developers to use IPR at the very same time that the separate BPCIA procedure becomes available, rather than encouraging use of the IPR process to clear out weak patent claims before the BPCIA process is triggered.

A rejection of the BMS Standing Rule is therefore most harmonious with the post-application dispute processes that Congress has created.

BMS's argument boils down to an assertion that Congress did not want drug patent disputes to be adjudicated through IPR. That argument is contrary to the plain text of the America Invents Act, which clearly applies to both drug and non-drug patent disputes.

CONCLUSION

For the foregoing reasons, this Court should reject any argument that BMS makes that Momenta lacks standing to pursue this appeal.

Respectfully submitted,

/s/ William B. Schultz

William B. Schultz
Carlos T. Angulo
ZUCKERMAN SPAEDER LLP
1800 M Street, NW, Suite 1000
Washington, DC 20036
Tel.: 202-778-1800
Fax: 202-822-8106
wschultz@zuckerman.com

Counsel for *Amicus Curiae* the
Association for Accessible Medicines

July 10, 2017

CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 2,836 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

/s/ William B. Schultz
William B. Schultz

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of July, 2017, I electronically filed the foregoing **BRIEF FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* SUPPORTING APPELLANTS** with the Court by using the CM/ECF system. All parties to the case have been served through the CM/ECF system in this case.

/s/ William B. Schultz
William B. Schultz