No. 08-

IN THE

Supreme Court of the United States

MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC., & UDL LABORATORIES, INC.,

Petitioners,

v.

TAKEDA CHEMICAL INDUSTRIES, LTD. & TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Does 35 U.S.C. § 285 permit the imposition of a ten-million-dollar attorney-fee award based substantially on (i) a generic drug maker's challenge to a patent's validity on different grounds than those stated in its pre-suit notice to the brand company, and (ii) the trial court's post-trial determination that the drug maker's initial (and ultimately unlitigated) theory lacked merit.

PARTIES TO THE PROCEEDINGS

Petitioners are Mylan Laboratories, Inc. (n/k/a Mylan Inc.), Mylan Pharmaceuticals, Inc., and UDL Laboratories, Inc. Respondents, Takeda Chemical Industries, Ltd. and Takeda Pharmaceuticals North America, Inc. were the plaintiffs-appellees below. Alphapharm Pty. Ltd. and Genpharm, Inc., defendants-appellants below (now owned by Mylan Inc.), are not parties to this petition.

CORPORATE DISCLOSURE STATEMENT

Petitioner Mylan Laboratories, Inc. (n/k/a Mylan Inc.) has no parent corporations, and no publicly held company owns 10% or more of Mylan Inc.'s stock. Petitioners Mylan Pharmaceuticals, Inc. and UDL Laboratories, Inc. are wholly owned subsidiaries of Mylan Inc.

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In the Supreme Court of the United States

No. 08-___

MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC., & UDL LABORATORIES, INC., PETITIONERS,

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TAKEDA CHEMICAL INDUSTRIES, LTD. & TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., RESPONDENTS

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PETITION FOR A WRIT OF CERTIORARI

Mylan Laboratories, Inc. (n/k/a Mylan Inc.), Mylan Pharmaceuticals, Inc., and UDL Laboratories, Inc. (collectively "Mylan") respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Federal Circuit (Pet. App. 1a-25a) is reported at 549 F.3d 1381. The opinion of the United States District Court for the Southern District of New York (Pet. App. 61a-110a) deeming the case exceptional is reported at 459 F. Supp. 2d 227. The district court's

decision establishing the amount of the fee award (Pet. App. 27a-60a) is unreported. The district court's decision in favor of respondents on the merits (Pet. App. 111a-227a) is reported at 417 F. Supp. 2d 341. The Federal Circuit's summary affirmance of that opinion (Pet. App. 245a-246a) is unreported. The district court's decisions denying Mylan permission to change its invalidity theory (Pet. App. 242a-244a), and denying Mylan's motion to reconsider that decision (Pet. App. 228a-241a) are unreported.

JURISDICTION

The judgment of the U.S. Court of Appeals for the Federal Circuit was entered on December 8, 2008. A petition for rehearing *en banc* was denied on January 23, 2009. The Chief Justice extended the time within which to file a petition for a writ of certiorari to and including May 25, 2009. App. No. 08A882. Because May 25, 2009 is a federal legal holiday, under this Court's Rule 30 the last day to timely file this petition is the following day, May 26, 2009. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

RELEVANT STATUTORY AND REGULATORY PROVISIONS

35 U.S.C. § 285 provides: "The court in exceptional cases may award reasonable attorney fees to the prevailing party." The appendix to this brief reproduces the relevant portions of 21 U.S.C. § 355(j), 35 U.S.C. § 271(e), and 21 C.F.R. § 314.95. Pet. App. 247a-281a.

STATEMENT

Petitioner Mylan filed an abbreviated new drug application ("ANDA") for a drug patented by respondents, maintaining in its required pre-suit notice letter that the patent was invalid as obvious. Respondents then sued Mylan for patent infringement.

Based on disclosures during discovery, Mylan identified and pursued a different theory of invalidity. At trial, respondents prevailed. Deeming the case "exceptional," the district court awarded respondents more than $10 million in attorney fees from Mylan. The district court relied substantially on the fact that Mylan had not pursued the case on the theory of invalidity set forth in the initial pre-suit notice letter, which the district court deemed meritless. The Federal Circuit affirmed.

1. The Hatch-Waxman Act, 21 U.S.C. § 355 and 35 U.S.C. § 271(e), establishes the statutory scheme by which a generic manufacturer can apply to bring a drug to market when it believes that it can make and sell a generic version of the drug at substantially lower prices to those consumers who need it. Congress's purpose in enacting the relevant provisions of the Hatch-Waxman Act was to speed the development and entry into the market of generic equivalents of brand-name drugs, with the goal of "mak[ing] available more low cost generic drugs by establishing a generic drug approval procedure." H.R. Rep. No. 98-857, pt. 1 at 14 (1984).

To accomplish that goal, Hatch-Waxman created a process through which drug manufacturers can obtain FDA approval to market a generic version of an existing drug without replicating the expensive and time-consuming tests which proved that the brand-name drug was safe in the first place. *See In re Omeprazole Patent Litig.*, 490 F. Supp. 2d 381, 395 (S.D.N.Y. 2007). An ANDA allows a generic drug manufacturer to quickly demonstrate the safety and effectiveness of its proposed generic by showing that

the generic is "bioequivalent" to an already approved drug. *See generally* 21 U.S.C. § 355(j)(2).

In addition, the statutory scheme helps resolve the infringement and validity of any existing patent on the brand-name drug by allowing generic drug manufacturers to challenge the infringement and validity of patents covering brand-name drugs without actually marketing an accused infringing product and incurring the risk of potentially catastrophic patent infringement damages. *See* 35 U.S.C. § 271(e)(2), (e)(4)(c); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-78 (1990) (describing the function of the ANDA process under the Hatch-Waxman Act). To challenge the drug patent's validity, however, the generic manufacturer must depend on publicly available information. Unless and until litigation ensues, the generic manufacturer cannot conduct discovery or obtain non-public documentation to support its pre-suit notice letter with, for example, the patent holder's internal documents and other relevant information bearing on the invalidity and enforceability of the patent.

2. Petitioner Mylan Pharmaceuticals, Inc. manufactures quality, lower-priced generic drugs. This petition arises out of Mylan's attempt to bring to market a generic version of a leading anti-diabetic drug, pioglitazone. Currently sold under the brand name Actos by Takeda Chemical Industries, Ltd., pioglitazone is one of a few drugs available in a class of diabetes treatments called thiazolidinediones ("TZDs"). *See* Pet. App. 119a-120a. Diabetics who require TZDs

to treat their disease generally pay between $164 and $241 per month for Actos.[1]

In July 2003, Mylan and three other generic drug manufacturers filed ANDAs seeking to market a generic version of pioglitazone. In its ANDA, as required by statute, Mylan stated that, in its opinion and to the best of its knowledge, Takeda's patent on pioglitazone was invalid—a so-called Paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV"). A Paragraph IV certification is a "highly artificial act of infringement" that, by conferring a right on the patent holder to bring a suit for technical infringement before the competing product is brought to market, "enable[s] the judicial adjudication" of the patent's infringement and validity. *Eli Lilly & Co.*, 496 U.S. at 678. Paragraph IV thus is designed to spare generic drug manufacturers the prospect of crippling money judgments that would arise if they entered the market before the patent's validity was resolved and that would deter the marketing of needed lower-priced generic drugs.

When a generic manufacturer's ANDA invokes Paragraph IV, the manufacturer is required by law to set forth a statement of the reasons it believes, based on the limited information available at that time, that the patent is invalid. Here, Mylan asserted that the Takeda patent was obvious. A patent is invalid due to obviousness if "the differences between the subject matter sought to be patented and the prior

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[1] Consumers Union of the U.S., *Consumer Reports Best Buy Drugs: Treating Type 2 Diabetes: The Oral Diabetes Drugs: Comparing Effectiveness, Safety, and Price* 22 (2009).

art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). Mylan's pre-suit notice letter explained that the Takeda patent was invalid because it would have been obvious to one skilled in the relevant art, who would have been motivated to begin with one highly efficacious compound identified in the prior art and merely substitute a pyridine ring for the prior art's benzene ring, producing pioglitazone—with a reasonable expectation that the compound would work.

3. As specifically contemplated by Hatch-Waxman, Takeda responded by bringing this "damage-less" patent infringement suit against Mylan and one other ANDA filer (Alphapharm Pty., Ltd.). Mylan asserted the patent's invalidity as a defense. As the case proceeded, Mylan sought to modify its invalidity defense to reflect its discovery of previously unknown facts and test data known only to respondents. In particular, based on the evidence uncovered in discovery, Mylan developed a second theory of obviousness, in which it identified a different compound (compound 3894) in the prior art as the basis from which a person skilled in the art would arrive at pioglitazone. The only difference between the prior art compound and pioglitazone is the presence of an ethyl group (C_2H_5) in a particular location on the pioglitazone molecule's pyridine ring. Mylan posited that one skilled in the art would have thought it obvious, and would have been motivated, to add an ethyl group to the pyridine ring. But Mylan never had an opportunity to develop this theory at trial, because the district court forbade Mylan's use of an ob-

viousness theory other than the one stated in its Paragraph IV notice letter. Pet. App. 242a-244a, 228a-241a. Thus, the district court never heard any testimony on this theory at trial.

After completing discovery, Mylan elected to pursue a different theory of invalidity instead of obviousness. Mylan maintained that the Takeda patent was unenforceable due to Takeda's inequitable conduct in securing the patent from the U.S. Patent and Trademark Office ("PTO"). A patent is unenforceable if the patentee affirmatively misrepresented a material fact, failed to disclose material information, or submitted false information to the PTO with an intent to deceive. *See, e.g.*, *Rentrop v. Spectranetics Corp.*, 550 F.3d 1112, 1119 (Fed. Cir. 2008). Mylan asserted that Takeda intentionally made material misrepresentations to the PTO in its comparison of six promising compounds in the patent, and that it omitted a relevant seventh compound entirely from the results. Mylan based this defense entirely on respondents' internal documents and other information obtained through discovery—information unavailable to Mylan before the suit.

Mylan advanced this unenforceability defense throughout the remainder of the proceedings in the district court, but Takeda eventually prevailed on the merits. *See* Pet. App. 227a. The court of appeals affirmed the district court's ruling without opinion. Pet. App. 26a.

After winning its infringement suit, Takeda sought attorney fees under 35 U.S.C. § 285, which allows a fee award in "exceptional" patent cases. Under settled precedent, a prevailing party must first demonstrate by clear and convincing evidence that

something exceptional about the case warrants the imposition of attorney fees. *Forest Labs., Inc. v. Abbott Labs.*, 339 F.3d 1324, 1327–28 (Fed. Cir. 2003) (internal citation omitted). The court then has discretion to determine whether, and in what amount, fees should be awarded to the prevailing party. *Id.* at 1328.

The district court deemed this case exceptional in substantial part because Mylan "attempt[ed] to substitute a new theory of obviousness following the close of fact discovery," which the court deemed "misconduct." Pet. App. 95a. The court also held that Mylan filed its ANDA in bad faith because the pre-suit notice letter that it sent to respondents after submission of the ANDA failed to state a "prima facie case of invalidity." Pet. App. 66a. The court further faulted Mylan's final inequitable conduct defense and various actions during the trial that the court also construed as misconduct. *See* Pet. App. 101a-107a.

The court awarded respondent a total of $16.8 million in attorney fees: more than $11.4 million from Mylan, with an additional $5.4 million from Mylan's co-defendants, Alphapharm and Genpharm. The award was the largest amount ever granted under Section 285 in Hatch-Waxman patent litigation.

4. The court of appeals affirmed. *See* Pet. App. 20a. The court of appeals held that the district court did not err in finding the case exceptional and upheld the large attorney-fee award. *Id.* at 14a-15a, 19a. The court viewed Mylan's Paragraph IV notice letter as baseless because discovery allegedly uncovered scientific errors in it, and adopted the district court's view that Mylan's inequitable conduct claim was "always frivolous." *Id.* at 15a-16a. Moreover, while the

panel majority found "the award of the total amount of a fee request . . . unusual," it refused to disturb the lower court's decision on attorney fees or the award of expert fees. *Id.* at 18a.

Judge Bryson concurred in the result, writing separately to question the district court's failure to observe the normally higher threshold of litigation misconduct required for an award of expert fees. *Id.* at 24a-25a.

Mylan's petition for rehearing en banc was denied. Pet. App. 245a-246a.

REASONS FOR GRANTING THE WRIT

The Federal Circuit has exclusive jurisdiction over attorney-fee awards in patent cases under 35 U.S.C. § 284. *See, e.g., Imagineering, Inc. v. Van Klassens, Inc.*, 53 F.3d 1260, 1263 (Fed. Cir. 1995). Thus, the court's decision upholding this massive fee award based on an improper legal standard for fees that confounds the purpose of the statutory regime established binding nationwide precedent that only this Court can correct.

THE FEDERAL CIRCUIT HAS ADOPTED AS BINDING NATIONAL PRECEDENT AN IMPROPER STANDARD FOR AWARDING ATTORNEY FEES UNDER THE HATCH-WAXMAN ACT

A. The Court Improperly Relied On The Modification Of Claims In Response To Discovery

1. The Federal Circuit upheld what is (to Mylan's knowledge) the largest attorney-fee award ever authorized under the Hatch-Waxman Act. This Court's

review is warranted because the Federal Circuit predicated its award on a legal standard that no other court of appeals applies to fee awards and that frustrates the very purpose of the Hatch-Waxman Act scheme.

The Federal Circuit upheld the award, which the district court assessed against Mylan on the ground that Mylan litigated a theory of patent invalidity that it had developed after discovery, rather than the pre-litigation legal theory it had advanced. Pet. App. 95a ("Mylan then engaged in further misconduct, attempting to substitute a new theory of obviousness following the close of fact discovery . . . . Mylan's misconduct was exceptional and deserves the imposition of sanctions."). That standard is legally untenable and has no counterpart in the law of other circuits administering attorney-fee statutes.

First, the federal court system's notice pleading and discovery system is specifically structured to allow and encourage parties to revisit and revise their initial claims for relief based upon discovery. Discovery under the Federal Rules is designed to help parties to "obtain the fullest possible knowledge of the issues and facts before trial." *Hickman v. Taylor*, 329 U.S. 495, 500-01 (1947). Moreover, the Federal Rules specifically contemplate a party's revision of its theory of the case in the wake of receiving discovery. *See, e.g.*, Fed. R. Civ. P. 15(a)(2) (instructing courts to "freely give leave [to amend pleadings] when justice so requires"); Fed. R. Civ. P. 15(b)(2) ("A party may move—at any time, even after judgment—to amend the pleadings to conform them to evidence and to raise an unpleaded issue."); *PAE Gov't Svcs., Inc. v. MPRI, Inc.*, 514 F.3d 856, 859 (9th Cir. 2007) ("Par-

ties usually abandon claims because . . . they have learned more about the available evidence and viable legal theories, and wish to shape their allegations to conform to these newly discovered realities. We do not call this sham pleading; we call it litigation."); *Winer Family Trust v. Queen*, 503 F.3d 319, 337 (3rd Cir. 2007) (noting that in proceedings against a corporation, the revelation of individual culpability through discovery is sufficient grounds to seek leave to amend the complaint to cover culpable individuals); *cf. Conley v. Gibson*, 355 U.S. 41, 47-48 (1957) (observing that simplified pleading is made possible by the availability of discovery to clarify issues later in the proceedings).

For that reason, courts generally encourage parties to revisit their pre-litigation positions based on information obtained through discovery and to abandon claims that have become untenable and add new claims that have surfaced or been bolstered by factual discovery. The Federal Circuit's standard, however, stands that practice on its head by holding that the decision to litigate based on a legal claim developed in light of discovery, rather than a pre-litigation position, constitutes conduct that can support an award of $10 million in attorney fees. The court did so without citing any support for that standard in the decisions of other courts of appeals administering attorney-fee statutes. Moreover, the court rested its fee determination on the conclusion that Mylan's pre-litigation position was lacking in merit and that the decision to litigate a claim that had insufficient merit to proceed to trial warranted sanction. That turns ordinary federal procedure on its head.

Second, the flaw in the Federal Circuit's approach is compounded by the fact that Mylan was *not* the plaintiff in this case; respondent was. The sanction here thus rests on Mylan's decision during litigation and post-discovery to pursue an affirmative defense that differed from a *pre-litigation* administrative position, which in turn was taken under a statutory scheme the very purpose of which is to liberalize challenges to patents by generic manufacturers. Congress understood that ANDA applicants would provide notice letters before litigation begins, without the benefit of any discovery and access to internal documents that can, and often do, lead to new defenses to an infringement claim.

Indeed, some patent defenses almost necessarily require discovery before they can be asserted. For example, inequitable conduct claims like that advanced by Mylan almost always reveal themselves after discovery because a patentee's misrepresentations or the withholding of material information are rarely matters of public record. The same can be true for on-sale bar defenses, by which an alleged infringer asserts the patent's invalidity based on the fact that the patented invention was on sale in the United States more than a year before a patent application was made. *See* 35 U.S.C. § 102(b); *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1047 (Fed. Cir. 2001). If the patentee has made secret sales, the alleged infringer will need discovery to uncover them. And, of course, internal documents also can be relevant to some prior art defenses. A brand company's internal testing, for instance, can help refute or support a claim of unexpected results in an obviousness challenge. *See, e.g., McNeil-PPC, Inc. v. L. Perrigo*

Co., 207 F. Supp. 2d 356, 365-66 (E.D. Pa. 2002), *aff'd in relevant part*, 337 F.3d 1362 (Fed. Cir. 2003).

Indeed, prior to the Federal Circuit's ruling in this case, lower courts had held that a generic manufacturer does not act in bad faith when, upon receiving discovery, it forgoes its pre-suit defenses in favor of those that emerged during discovery. In *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, No. 04-754, 2007 WL 4300155 (D.N.J. Dec. 5, 2007), the district court held that the case was not appropriate for attorney fees even though Teva ultimately dropped every reference from its pre-suit notice letter. The court reasoned that reconsidering claims does not establish, by clear and convincing evidence, that the litigated claims were made in subjective bad faith.

Likewise, in *Merck & Co. v. Mylan Pharms., Inc.*, 79 F. Supp. 2d 552 (E.D. Pa. 2000), the court held that "it is far from unreasonable that a party to such a financially significant lawsuit would want to explore multiple theories of recovery and defense and engage in the discovery necessary to support these theories." *Id.* at 556. Such "good faith persistence cannot be deemed to constitute 'exceptional' behavior." *Ibid.*

In this case, as Mylan learned more about respondent's patent and its conduct, it elected not to pursue its initial theory of obviousness in favor of the argument that respondent had engaged in inequitable conduct—a claim that was sufficiently tenable to require resolution through trial and that Mylan thought was its best defense. Mylan accordingly had no cause to build a litigation record in support of its pre-litigation administrative claim, and no reason to defend that pre-litigation administrative claim at

trial. Yet, after Mylan lost at trial, the district court used its own assessment of the merits of Mylan's *unlitigated* theory as a basis for awarding attorney fees. That decision discourages the very review and refinement of claims that the discovery process promotes and forces parties to continue litigating potentially weaker claims just to avoid having them cited as a basis for fees.

3. The decision also confounds congressional purpose. In Hatch-Waxman, Congress designed a statutory scheme that depends on ANDA applicants' willingness to make initial claims of patent invalidity before obtaining discovery. Congress counter-balanced that incentive by creating a streamlined litigation procedure for patent holders to resolve the invalidity claims. Construing Section 285 to allow an inference of bad faith because an ANDA applicant properly changed positions based on discovery and instead litigated through trial a claim rooted in discovery evidence puts the administrative scheme and attorney-fee provision at cross-purposes. The decision also skews the balance Congress legislated, by giving patent holders all the benefits of streamlined litigation to protect their claims while erecting barriers to the pre-suit administrative assertion of claims by ANDA applicants.

There are, in fact, myriad examples of ANDA filers prevailing on theories put forth for the first time in litigation and, as a result, cheaper generic drugs reached the market as Congress desired and to the great benefit of consumers. *See Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955 (Fed. Cir. 2001) (fluoxitine/Prozac) (patent was invalidated based on a theory asserted for the first time during discovery);

SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312 (Fed. Cir. 2006) (paroxetine/Paxil) (successful invalidity defense developed during discovery); *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007) (ramipril/Altace) (court of appeals held the patent invalid based on an obviousness defense developed for the first time in litigation); *Alza Corp. v. Mylan Laboratories, Inc.*, 464 F.3d 1286 (Fed. Cir. 2006) (oxybutynin/Ditropan XL) (prevailing on theory not contained in the ANDA notice); *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362 (Fed. Cir. 2003) (loperamide/Imodium Advanced) (two patents invalidated based on theory developed post-discovery).

Four other cases involved other post-discovery defenses, such as non-infringement or inequitable conduct before the PTO. *See Ferring B.V. v. Barr Laboratories, Inc.*, 437 F.3d 1181 (Fed. Cir. 2006) (desmopressin/DDAVP); *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 176 F. App'x 117 (Fed. Cir. 2006) (enoxaparin/Lovenox); *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*, 438 F.3d 1123 (Fed. Cir. 2006) (oxycodone/OxyContin); and *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003) (gabapentin/Neurontin).

Those cases suggest that using the attorney-fee provision to deter and chill ANDA claims and to sanction the development of post-discovery claims will deprive the court of winning arguments of invalidity and so deprive the public of affordable life-saving and life-improving drugs.

To be sure, the court of appeals wrapped its holding in language indicating that it considered the claims to be "baseless." Pet. App. 15a. But the prob-

lem here is that the court of appeals rested its "baseless" label in significant part on the fact that Mylan had changed its pre-litigation administrative position and had formulated a new claim based on discovery. It is that critical aspect of the court's ruling that both contravenes established law and practice favoring such review and refinement of claims and derails Congress's statutory scheme encouraging pre-suit administrative claims of patent invalidity to ensure that generic equivalents get to market as often as possible.

B. The Court Adopted An Erroneous Standard For Assessing Bad Faith

The damage wrought by the court of appeals' decision is compounded by the threshold the court adopted for determining whether a Paragraph IV claim has been filed in bad faith. The court of appeals upheld, based on prior circuit precedent, *Yamanouchi Pharm. Co., Ltd v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000), the district court's conclusion that bad faith was established because the ANDA notice failed to state a "prima facie case of invalidity." Pet. App. 66a.

That legal standard lacks any basis in law. Indeed, this Court has held that a *complaint* need not establish a prima facie case to survive a motion to dismiss. *See Swierkiewicz v. Sorema, N.A.*, 534 U.S. 506, 511 (2002); *see also Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1965-66 (2007). Absolutely nothing in Hatch-Waxman supports the court's conclusion that the pre-litigation administrative ANDA filing and notice letter must meet a *higher* threshold than a complaint in civil litigation.

Quite the opposite, the *raison d'être* of the administrative scheme is to permit filings based on a more informal showing, and in exchange, protecting patent holders with a more informal route to defend their patents. To that end, the contents of the notice are prescribed by 21 U.S.C. § 355(j)(2)(B)(iv)(I)–(II). That provision mandates that the Paragraph IV notice letter set forth "the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." *Ibid.* The statute does not require the generic drug applicant to set forth facts that would make out a prima facie case of invalidity. Rather, the applicant's notice need only be sufficient to advise the patent holder of the generic manufacturer's assertion that the patent is invalid and thus to set the stage for litigation.

Once the case enters litigation the content of the pre-suit Paragraph IV notice is largely irrelevant. Nothing in the statute binds the applicant to the theories presented in the pre-suit notice; the ordinary rules of litigation apply, so the statutory scheme and rules of pleading in the federal courts thus provide that notice of an applicant's litigation theories comes from the answer to the complaint and any subsequent court filings. In short, the pre-suit Paragraph IV statement serves a limited notice function. Its principal purpose is to trigger the litigation, which is where the theories are developed and tested in full. Indeed, years often pass between the filing of the pre-suit notice and the trial—years in which discovery often produces the bases for new infringement defenses.

Furthermore, the principal purpose for deeming the ANDA filing to be an act of infringement is to

provide a "jurisdictional basis" for the litigation. *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1349 (Fed. Cir. 2004). As long as the ANDA applicant has complied with the filing requirements of the statute and presented colorable arguments, it has discharged Congress's purpose. The Federal Circuit rule, by contrast, imposes an exceptionally high pleading standard on an informal *pre-suit* administrative process and creates a substantial risk that, as occurred here, 20/20 hindsight will be used by courts to adjudicate the merits of an administrative pre-litigation claim years later at the *end* of litigation—pre-suit claims, as in this case, that were never litigated or otherwise tested at trial. That approach cannot be reconciled with statutory text or purpose, and carves the ANDA filing out for exceptional burdens that this Court has held may not even be imposed on civil litigants (such as the plaintiff's own complaint in this case).

C. The Unprecedented Size Of The Fee Award Merits Review Because It Will Chill The ANDA Process

The lower courts granted Takeda a fee award so massive that its counsel touts it as "the largest fee award ever in the history of ANDA litigation."[2] Given the rapidly rising costs of patent litigation, *see infra* n.3, the ruling below opens ANDA filers to ever-expanding downside risks in exchange for their undertaking the socially beneficial project of marketing

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[2] Biography of Andre K. Cizmarik, http://www.eapdlaw.com/professionals/detail.aspx?attorney=205 (last visited Mar. 30, 2009).

cheaper drugs. That exposure conflicts with the special litigation process Congress designed specifically to minimize and avoid the substantial financial deterrent that patent awards otherwise erect against the vital effort to bring generic products to market.

Moreover, the size of the disparity between *this* award and others suggests that the purpose of the award was as much to punish Mylan as to compensate Takeda. But compensation, not punishment, is the purpose of Section 285. *See Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1347 (Fed. Cir. 2004) (observing that awards made pursuant to Section 285 are meant to be compensatory in nature). Indeed, Judge Bryson acknowledged in his partial concurrence that the district court's award had a punitive aspect. *See* Pet. App. 24a-25a (Bryson, J., concurring in part and concurring in the result in part). In addition to attorney fees, the district court awarded expert fees—a sanction, as Judge Bryson observed, that is both extraordinary and punitive. *Ibid.*

Congress enacted the ANDA filing process in general and the Paragraph IV certification process in particular to allow generic manufacturers to test the validity and enforceability of a patent without assuming a massive financial risk—the prospect of large money damages that attend a traditional infringement action. *See* H.R. Rep. No. 98-857, pt. 1 at 28 (opining on the value of the Hatch-Waxman created cause of action as a "remedy [that] permits the commencement of a legal action for patent infringement *before the generic drug maker has begun marketing* . . . fairly balances the rights of a patent owner . . . and the rights of third parties") (emphasis added).

The rulings below, however, open the door to punitive attorney-fee awards and thus create the very type of multi-million dollar monetary risk that Congress strove to avoid.[3] *See, e.g.*, Teva Pharm. Indus. Ltd., Annual Report (Form 20-F), at 6-7 (Feb. 27, 2009) (generic manufacturers' business is especially sensitive to litigation risks).

Congress did not intend Section 285 to be employed as a *post hoc* tool for punishing ANDA filers for invoking the informal administrative process that Congress designed specifically to encourage the testing of patents when a generic drug is available. The Federal Circuit's decision and the legal standards it adopted defy that purpose. Only this Court can put this program, which is a critically important aspect of reducing medical costs, back on track.

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[3] And the degree of risk is increasing as the costs of patent litigation increase: rapidly. *Compare* Am. Intellectual Prop. Law Ass'n, *Report of the Economic Survey* I-91 tbl.Q36f (2007) (showing an average cost of $5.499 million to litigate a patent worth over $25 million) *with* Am. Intellectual Prop. Law Ass'n, *Report of Economic Survey* 85 tbl.22 (2001) (showing an average cost of $2.992 million to litigate a patent worth over $25 million).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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