Nos. 08-1461 & 08-1463

IN THE

Supreme Court of the United States

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

Petitioners,

&

ALPHAPHARM PTY., LTD. & GENPHARM INC.,

Petitioners,

v.

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

Respondents.

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

BRIEF OF *AMICUS CURIAE* GENERIC PHARMACEUTICAL ASSOCIATION IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

Founded in 2001, the Generic Pharmaceutical Association (GPhA) is a trade association devoted to making lower priced, high quality generic drugs available to patients and providers, thus assisting in the battle against rapidly growing healthcare costs. Its members include manufacturers and distributors of finished generic drug products and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry.

Generic drugs play an essential role in reducing consumer drug costs, especially for older Americans, who consume more healthcare products and services than any other age group.[2] In 2008 alone, average prices for the 185 generic drugs most widely used by Medicare beneficiaries fell by 10.6 percent, contrasted with an 8.7 percent increase in average prices for the 219 most

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[1] No counsel for a party authored this brief in whole or in part, and no counsel for a party or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae* or its counsel made a monetary contribution to its preparation or submission. Counsel of record for all parties received notice at least 10 days prior to the due date of the *amicus curiae*'s intention to file this brief. All parties have consented to the filing of this brief.

[2] *See* Federal Interagency Forum on Aging-Related Statistics, *Older Americans 2008: Key Indicators of Well-Being* 50 (2008), *available at* http://www.agingstats.gov/agingstatsdotnet/Main_Site/Data/2008_Documents/Health_Care.pdf.

widely used branded prescription drugs.[3] The combination of rising costs of branded prescription drugs, unprecedented rates of unemployment, and declining values of housing and investment creates an even greater need to accelerate access to generic drugs—particularly when consumers have less discretionary income for medical care.

The GPhA has a strong interest in preserving and strengthening incentives for manufacturers to move generic drugs based on abbreviated new drug applications into the hands of the American public as quickly as possible, consistent with the legitimate patent rights of branded drug companies. Specifically, the GPhA has a critical interest in ensuring proper application of the patent laws and the system created by the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA).

SUMMARY OF ARGUMENT

The Federal Circuit's failure to address the district court's misapplication of the law and lopsided focus on the Petitioners' abbreviated new drug application (ANDA) certifications in this case is at odds with the intent of the Hatch-Waxman Act and the Federal Rules of Civil Procedure. The unique mechanism Congress created by the Hatch-Waxman Act permits an ANDA applicant to submit an ANDA to the FDA with a

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[3] AARP Public Policy Institute, *Rx Watchdog Report: Trends in Manufacturer Prices of Prescription Drugs Used by Medicare Beneficiaries 2008 Year-End Update* vi, viii (2008), *available at* http://assets.aarp.org/rgcenter/health/2009_07_rxq408.pdf.

certification that "to the best of [its] knowledge" the patents ostensibly associated with a particular drug are invalid or not infringed. That certification is based solely on publicly available information. The purpose of the ANDA approval process is to evaluate the safety and efficacy of the drug for consumers. The FDA uses the information in the ANDA to assess ingredients, labeling, packaging, and dosage requirements. The FDA does not make any determination regarding invalidity or non-infringement of any asserted patent claims.

Rather, Congress provided that all disputes regarding infringement of ANDA-related patents would be resolved in the federal courts. Congress achieved this by designating the filing of an ANDA, which occurs before any products are actually sold, a technical act of infringement under 35 U.S.C. § 271(e)(2)(A). By creating a case or controversy in the form of an infringement claim by the patentee against the ANDA applicant as a prerequisite to bringing the generic drug to market, Congress surely intended that the litigants in Hatch-Waxman cases would also receive the benefit of fact discovery, notice pleading, liberal amendment of pleadings, and all other provisions of the Federal Rules of Civil Procedure.

The Federal Circuit's ruling sends a chilling message to the generic drug industry that in order to avoid a finding of "exceptionality" and an award of fees, an ANDA applicant may only allege at trial the exact defenses as presented in its pre-litigation ANDA certification rather than pursue defenses that conform to the evidence developed through discovery and presented at trial. Because this result is contrary to the Federal Rules of Civil Procedure and the policy

objectives of the Hatch-Waxman Act, this Court should grant the petitions and reverse the Federal Circuit's decision.

ARGUMENT

A. The Hatch-Waxman Act Establishes an Administrative ANDA Approval Process and a Patent Litigation Procedure that Address Separate Policy Interests.

The animating policy underlying the Hatch-Waxman amendments to the patent and drug laws 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); H.R. Rep. No. 98-857, pt. 1, at 14 (1984). To achieve that goal, Hatch-Waxman created an administrative ANDA approval process and a means for allowing patent owners to resolve legitimate claims related to ANDA products in litigation before the products are made and marketed. Although the ANDA approval process and patent litigation components of Hatch-Waxman interrelate in important ways, they are distinct procedures deliberately established by Congress to address separate policy interests.

On one hand, the ANDA approval process is an administrative procedure in the FDA designed to speed innovations that make drugs more effective, safer, and more affordable while protecting the public health by assuring the safety, efficacy, and security of those drugs. *See* U.S. Dept. of Health and Human Services, About FDA: What We Do, http://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last visited June 29, 2009).

The principal goal of the FDA's approval process is to assess whether the ANDA drug is bioequivalent to the branded drug, whether the information provided supports the applicant's claim that the active ingredients, dosages, and labeling are identical to those in the branded drug, and whether the methods that will be used in the manufacture and packaging of the ANDA drug are adequate to ensure its quality and purity. *See* 21 C.F.R. § 314.127.

As part of this procedure, all ANDAs must include a certification made "in the opinion of the applicant and to the best of his knowledge" regarding patents listed in the Orange Book as possibly claiming the product described in the ANDA. 21 U.S.C. § 355(j)(2)(A)(vii). The certification, as part of the ANDA, is made *to the FDA*. *Id.* Where the certification states the patent is believed to be invalid or not infringed, the applicant must provide *notice* of the certification *to the patent owner*, together with a detailed statement of the basis of the applicant's opinion. *Id.* § 355(j)(2)(B). The patent owner may or may not initiate litigation based on the notice, but the ANDA approval process will begin nonetheless and the FDA will evaluate the ANDA.

On the other hand, the patent litigation component of Hatch-Waxman was designed as "a mechanism to facilitate the adjudication of claims of infringement of patents relating to the innovator's drugs" in the federal courts before the generic drug has been marketed. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003). To create this mechanism, Congress amended the patent laws to deem the filing of an ANDA a "highly artificial" act of patent infringement, giving

the federal courts subject matter jurisdiction to adjudicate claims. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990); *Warner-Lambert*, 316 F.3d at 1365 (noting that filing an ANDA is "an 'artificial' act of infringement that creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product"). Distinct from the FDA's ANDA approval process, any civil complaint filed by the patent owner activates an ordinary patent infringement case. 35 U.S.C. § 271(e)(2).

The only relationship between the FDA's administrative process and the civil litigation is the timing of the final approval of the ANDA. If the patent owner initiated litigation within forty-five days of receiving the notice letter, the FDA may not approve the ANDA for thirty months. *Id.* § 355(j)(5)(B). If the court finds the patent to be invalid or not infringed before the end of the thirty-month stay, the FDA's approval is made effective as of the date of the court's decision. *Id.* § 355(j)(5)(B)(iii)(I). If, however, the thirty-month stay expires prior to the district court's ruling, the FDA may approve the ANDA before a decision is issued. *See* Federal Trade Commission, *Generic Drug Entry: Prior to Patent Expiration: An FTC Study* 22 & n.20 (2008), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (noting in a 2002 study that the FDA approved ANDAs in eight out of twenty-two ANDA patent infringement cases after the thirty-month stay had expired and prior to a final decision in pending litigation).

Accordingly, although the FDA's administrative procedure and the patent infringement litigation both flow from the ANDA, they serve separate purposes. Approval for market entry involves a separate analysis from the questions of validity and infringement reviewed by either the Patent and Trademark Office or a district court. The patent certification included in the ANDA indicates the applicant's opinion that the generic drug is bioequivalent to the branded drug, is non-infringing, and should therefore be quickly approved and made available to consumers as a more affordable alternative. The FDA takes the certification at face value and presumes that the attendant notice to the patent owner is complete and sufficient if certain basic requirements are met, the most substantive of which is the applicant's statement regarding the basis for the certification. *See* 21 C.F.R. § 314.95(c), (f). Whether the ANDA in fact infringes the patent owner's patent is irrelevant to the FDA's evaluation of the ANDA as this has nothing to do with the safety, efficacy, or security of the ANDA product.

Congress deliberately committed to the federal courts the adjudication of infringement claims that could impede the bringing of the generic drug to market, and, in doing so, surely intended that both the ANDA applicant defendant and the patentee plaintiff would receive the full benefit of the established rules of federal civil practice, including rules pertaining to discovery and notice pleading. To be sure, an ANDA applicant owes a "duty of care" in making its certification and providing the basis of that certification to the patent owner, but that duty, by statute, requires only an "opinion" by the ANDA applicant circumscribed by "the best of his knowledge" *at the time*. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Without the benefit of full discovery, the ANDA applicant's certification and statement are necessarily provisional. This provisional statement is all that is needed for the FDA to begin its evaluation of the ANDA and to provide the patent owner with enough information on which to decide whether it wishes to pursue an infringement claim against the applicant in litigation.

Over-reliance in litigation on the ANDA applicant's administrative certification and pre-litigation statement regarding the basis for the certification, as happened here, biases the court's fact-finding mission to resolve the case on the best available information. Particularly as the litigation *defendant*, the ANDA applicant is entitled to discovery to obtain critical non-public information necessary to its defense of the patent owner's infringement claim or invalidity defense. As noted in Mylan's petition, many defenses require non-public information available only through discovery. *See* Mylan's Pet. for a Writ of Cert. at 12-13 (explaining that components of invalidity and inequitable conduct defenses require non-public information available only from the patent owner through discovery).

Moreover, the Federal Rules of Civil Procedure contemplate that claims and defenses in litigation will evolve to conform to information learned through the discovery process and accordingly provide a system of notice pleading and liberal amendment of pleadings. *See* Fed. R. Civ. P. 15 (providing that a court should "freely" permit amendment of pleadings "when justice so requires," including "to conform [pleadings] to evidence and to raise an unpleaded issue"); *Oppenheimer Fund v. Sanders*, 437 U.S. 340, 351 (1978)

("Consistently with the notice-pleading system established by the Rules, discovery is not limited to issues raised by the pleadings, for discovery itself is designed to help define and clarify the issues. Nor is discovery limited to the merits of a case, for a variety of fact-oriented issues may arise during litigation that are not related to the merits.") (citing *Hickman v. Taylor*, 329 U.S. 495, 501 (1947)).

Precluding an ANDA applicant from developing its defenses during litigation and, if necessary based upon information developed subsequently in discovery, pursuing a defense not previously asserted in the certification and notice, is not only unfair, but, as Alphapharm points out, risks a violation of procedural due process. *See* Alphapharm's Pet. for a Writ of Cert. at 7-8; *Lindsey v. Normet*, 405 U.S. 56, 66 (1972) ("Due process requires that there be an opportunity to present every available defense.").

B. The Federal Circuit's Basing an Exceptional Case Fee Award on an ANDA Applicant's Assertion of Additional Defenses in a Hatch-Waxman Patent Infringement Action Will Undercut the Societal Benefit of the Generic Drug Market, in Frustration of Congressional Intent.

The Federal Circuit's error in affirming an exceptional case fee award that conflated the administrative ANDA process and the defense of the infringement action undermines the deliberate separation in the Hatch-Waxman Act of these two procedures. Accordingly, the Petitioners' were denied the full benefit of the Federal Rules of Civil Procedure

in presenting their best available defenses based upon information obtainable in discovery that was not available at the time of the ANDA certification. The Federal Circuit's flawed ruling has far-reaching negative effects that will do systemic harm to the generic drug approval process.

"In support of the American rule, it has been argued that since litigation is at best uncertain one should not be penalized for merely defending or prosecuting a lawsuit. . . ." *Fleischmann Distilling Corp. v. Maier Brewing Co.*, 386 U.S. 714, 717 (1967). Moreover, the finding of an exceptional case does not necessitate the award of attorney's fees under Section 285 of the Patent Act. *S.C. Johnson & Son, Inc. v. Carter-Wallace, Inc.*, 781 F.2d 198, 201 (Fed. Cir. 1986). Rather, a court should use the special fee-shifting provision of Section 285 only where doing so may serve as an "instrument of justice." *Nat'l Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1197 (Fed. Cir. 1996).

For ANDA applicants, the normal expense of patent litigation is already a significant cost that restrains applicants from filing ANDAs without deliberate consideration of the merits of all potential defenses. The economics of litigation under the American rule already provide a strong incentive to ANDA applicants to have a good faith belief that they will prevail on their defenses. Based on input from the GPhA membership, a successful patent challenge in litigation is, at best, a 50/50 proposition. ANDA applicants have strong business incentives to pursue only those litigations where they are likely to prevail. It makes no sense to incur the cost of litigation if the ANDA applicant has no

chance of avoiding the patent and making and selling the drug. Nevertheless, when preparing its ANDA certification, the only information regarding the listed patents available to the applicant is that in the public domain. Without non-public information from the patent owner, the ANDA applicant can never completely confirm its theories of invalidity or non-infringement.

The Federal Circuit's ruling here will only frustrate the purpose of the Hatch-Waxman Act by increasing the costs of getting generic drugs to market. Under the reasoning of the Federal Circuit's ruling, ANDA applicants will have no choice but to continue to pursue defenses alleged in their certifications even after learning information during discovery that would otherwise serve to focus the litigation on the most meritorious defenses. Such precedent will not only increase the costs to the individual litigants, but will also waste judicial resources and may serve as a deterrent for some ANDA applicants to even challenge patents on certain products. Changing defenses during the course of discovery is ordinary and should be permitted, not condemned.

There are several legitimate reasons why litigants change defenses during litigation. For example, discovery may reveal more pertinent prior art on which to base an invalidity defense than that which was cited in the ANDA certification. Discovery may also reveal a basis for a best mode or inequitable conduct defense that was not known previously. Additionally, discovery may produce information that makes an element of a previously asserted defense more difficult to prove and,

accordingly, a litigant may withdraw that defense in litigation.

Moreover, where a litigant misuses procedural rules and commits litigation misconduct, the narrower remedy of sanctions under Federal Rule of Civil Procedure 37 is more appropriate than fee-shifting. *See* Fed. R. Civ. P. 37(b). In fact, "when there is bad-faith conduct in the course of litigation that could be adequately sanctioned under the Rules, the court ordinarily should rely on the Rules rather than [its] inherent power." *Chambers v. NASCO, Inc.*, 501 U.S. 32, 50 (1991). Even where Rule 37 sanctions are not sufficient, the court should use its inherent power conservatively. *See FDIC v. Conner*, 20 F.3d 1376, 1383 (5th Cir. 1994) (noting that sanctions should be "narrowly tailored to serve only their necessary function").

An award of nearly $17 million in attorney's and expert fees, as happened here, is excessive and not justified. Such an application of the fee-shifting exception to the American rule is not an "instrument of justice." The message sent by the Federal Circuit's ruling in this case will deter ANDA applicants from asserting the best possible legal theories in litigation and this chilling effect will deprive the courts of meritorious defenses and hamper the accessibility of affordable life-saving and life-improving drugs to the public.

CONCLUSION

The Federal Circuit wrongly concluded that the district court properly deemed this case exceptional "based on the specific circumstances involved in this case, *viz.*, baseless certification letters compounded with litigation misconduct." Pet. App. 16a. By glossing over the district court's inappropriate reliance on Petitioners' ANDA certifications, the Federal Circuit opened the doors for patent owners to use every step of the FDA's *administrative* approval process to demonstrate bad faith on the part of the ANDA applicant during civil *litigation*. Contrary to the Hatch-Waxman Act and rules of our federal judicial system, the $16.8 million fee award in this case has the effect of placing an unreasonable burden on ANDA applicants in submitting ANDAs to the FDA and putting ANDA applicants in an unfair and untenable position in litigation.

The petitions for writs of certiorari should be granted.

Respectfully submitted,

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