IN THE

Supreme Court of the United States

MYLAN LABS., INC., MYLAN PHARMACEUTICALS, INC., and UDL LABS., INC.,

Petitioners,

v.

TAKEDA CHEMICAL INDUS., LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Respondents.

ALPHAPHARM PTY., LTD. and GENPHARM INC.,

Petitioners,

v.

TAKEDA CHEMICAL INDUS., LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Respondents.

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

BRIEF IN OPPOSITION

ANTHONY J. VIOLA
ANDRE K. CIZMARIK
EDWARDS ANGELL PALMER & DODGE LLP
750 Lexington Avenue
New York, NY 10022
(212) 308-4411

DAVID G. CONLIN
Counsel of Record
BARBARA L. MOORE
KATHLEEN B. CARR
ADAM P. SAMANSKY
EDWARDS ANGELL PALMER & DODGE LLP
111 Huntington Avenue
Boston, MA 02199
(617) 239-0100

Attorneys for Respondents

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, respondents state that Takeda Pharmaceuticals North America is wholly owned by Takeda Chemical Industries, Ltd. (now known as Takeda Pharmaceutical Company Limited), which, in turn, has neither a parent company nor a public-company owner of 10 percent or more of its stock.

TABLE OF CONTENTS

Contents

TABLE OF CITED AUTHORITIES

Page

Cases

Cited Authorities

Cited Authorities

Cited Authorities

Page

Statutes

Rule

Other Authorities

INTRODUCTION

The Federal Circuit affirmed a fact-specific, comprehensively explained determination by the district court that an award of compensatory attorneys' fees was warranted in this case for multiple reasons, including petitioners' bad faith filing of baseless Abbreviated New Drug Application ("ANDA") certifications which gave rise to these litigations, and petitioners' multiple acts of misconduct in the ensuing litigations. That litigation misconduct included violations of scheduling and discovery orders, the making and pressing of bad faith legal, factual and scientific contentions, and many other improper actions.

Both petitions for certiorari ignore these multiple, particularized findings which formed the basis for the fee awards. Instead, petitioners attempt to rewrite the lower court rulings to manufacture legal error that, in reality, does not exist. The core of both petitions is the assertion that fees were awarded merely because petitioners changed the theories set forth in their ANDA certifications (purportedly filed in good faith) by substituting new, supposedly well-grounded challenges advanced in good faith. The district court's detailed findings, however, show just the opposite: baselessness and bad faith, both with respect to petitioners' ANDA certifications and petitioners' actions and contentions during the course of the litigations. Those findings were upheld on appeal.

Both the district court and the court of appeals recognized that where a party has pursued litigation in good faith, a fee award is warranted only if that party has engaged in litigation misconduct. Pet. App. 16a-17a;

id. at 66a.[1] However, both courts found that good faith was lacking in this case. Thus, petitioners' assertions simply do not reflect the findings in this case.

The actual grounds of the decisions below are narrow and correct. They present no substantial legal question, much less a question warranting certiorari. For these and other reasons, including Alphapharm's failure properly to present its due process question below, review should be denied.[2]

STATEMENT OF THE CASE

I. Background

The Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman"), "incorporated an important new mechanism designed to guard against infringement of patents relating to pioneer drugs." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-77 (1990). Hatch-Waxman mandates that ANDAs:

> shall contain . . . a *certification*, in the opinion of the applicant and to the best of his

1. "Pet. App. __" refers to the appendix to the petition in No. 1461. "JA__" and "A__" refer to portions of the Confidential Joint Appendix in the Federal Circuit Nos. 07-1269, -1270.

2. The two respondents are referred to collectively as "Takeda." The petitioners in No. 08-1461 are referred to as "Mylan," and the petitioners in No. 08-1463 as "Alphapharm." This Opposition will refer to Mylan's petition as "Pet.," and Alphapharm's as "APet." "Amicus" refers to the Brief of *Amicus Curiae* Generic Pharmaceutical Association in Support of Petitioners.

> knowledge, with respect to each patent which claims the listed drug . . . (I) that such patent information has not been filed; (II) that such patent has expired; (III) of the date on which such patent will expire; or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .

21 U.S.C. § 355(j)(2)(A)(vii) (emphasis added). In addition:

> An applicant who makes the fourth certification is required to give notice to the holder of the patent alleged to be invalid or not infringed, stating that an application has been filed seeking approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent, and setting forth a detailed statement of the factual and legal basis for the applicant's opinion that the patent is not valid or will not be infringed.

Eli Lilly, 496 U.S. at 677-78 (citing 21 U.S.C. § 355(j)(2)(B)(iv)(II)). Pursuant to FDA regulations implementing this statute, the Section 355(j)(2)(B)(iv)(II) "Detailed Statement" "shall include . . . [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95.[3]

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3. Mylan's assertion that "the pre-suit Paragraph IV statement serves a limited notice function" (Pet. at 17) and that "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 (Cont'd)

Mylan and Alphapharm filed 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") certifications, certifying to FDA that, in their opinions and to the best of their knowledge, U.S. Patent No. 4,687,777 (the "'777 patent"), covering the active ingredient in Takeda's ACTOS® product (pioglitazone), was invalid. Mylan and Alphapharm sent Takeda 21 U.S.C. § 355(j)(2)(B) "Paragraph IV Notice" letters purporting to include Detailed Statements, stating the factual and legal bases supporting their invalidity allegations. Pet. App. 155a-60a; A4983-5009; A6648-62.

Takeda brought suit under 21 U.S.C. § 355(j)(5)(B)(iii) against Mylan and Alphapharm. After considering all

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(Cont'd)

civil litigation," turns the plain language of the statute on its head. Pet. at 16 (emphasis in original); *see* Pet. at 18; *see also* APet. at 2, 11. Hatch-Waxman's requirement for a "detailed statement" clearly does impose a higher threshold than the "short and plain statement of the claim" required under Fed. R. Civ. P. 8, even considering the Court's recent explanation of what is needed to survive a motion to dismiss (*Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009)). *See* 21 U.S.C. § 355(j)(2)(B)(iv)(II) (Pet. App. 250a); 21 C.F.R. § 314.95(c)(6) (Pet. App. 280a). Mylan posits that "[a]s long as an ANDA applicant has complied with the filing requirements of the statute and presented colorable arguments, it has discharged Congress's purpose." Pet. 18. Even if all Congress intended by requiring a "detailed statement of the factual and legal basis" for the applicant's opinions was that the applicant simply had to come up with "colorable arguments," Mylan did not do so here — its Statement was held to be "baseless and filed in bad faith." Pet. App. 101a; *see id.* at 15a.

the evidence at trial, the court issued a 124-page opinion rejecting petitioners' challenges to the '777 patent, holding that "both Alphapharm and Mylan have failed to make even a rudimentary showing that the invention was obvious or that Takeda engaged in inequitable conduct." Pet. App. 113a; *see generally*, *id.* at 111a-227a (reported at 417 F. Supp. 2d 341 (S.D.N.Y. 2006)). The court entered judgment for Takeda on March 13, 2006. A125-28. Mylan and Alphapharm appealed that judgment, including, inter alia, the district court's February 21, 2006 Opinion and Order on the merits (Pet. App. 111a-227a), and "all opinions, orders, and rulings subsumed therein or made prior thereto." A6286-88; JA9451-54. The court of appeals affirmed, rejecting Alphapharm's challenge in a published opinion (492 F.3d 1350 (Fed. Cir. 2007)), and Mylan's challenge by summary order (Pet. App. 26a; *see id.* at 5a). Mylan did not seek a writ of certiorari therefrom, but Alphapharm did. This Court denied Alphapharm's petition for a writ of certiorari on March 31, 2008. 128 S. Ct. 1739. Thus all parts of the judgment on the petitioners' respective merits cases are now final.

A. The District Court Decisions

Following entry of judgment on the underlying merits, Takeda requested an award of attorneys' fees under 35 U.S.C. § 285. The court granted Takeda's request, finding that Takeda had shown petitioners' respective bad faith and litigation misconduct by clear and convincing evidence, and that petitioners' "misconduct was exceptional and fully justifies the award of attorneys' fees." Pet. App. 64a; *see generally*, *id.*, 61a-110a.

The district court subsequently determined the amount of fees in a separate opinion. *Id.* at 27a-60a. The court relied on the well-accepted "lodestar" analysis, representing hours spent times a reasonable hourly fee, plus expenses. The award was made without enhancement, even though the district court noted that an enhancement would be justified by petitioners' "outrageous litigation conduct," noting that petitioners "increased the cost and burden of this litigation through their shifting theories of attack, none of which was meritorious or adopted in good faith," and none of which "reflected a careful analysis of the relevant documents and the application of sound science to that analysis." *Id.* at 52a; *see also id.* at 58a (petitioners "well understood that their attacks on the '777 Patent were groundless and would only succeed if Takeda did not expend the effort and resources necessary to shine a light on the flaws in the [petitioners'] arguments and if the Court did not spend the time necessary to learn the relevant science and understand the evidentiary record created by the trial submissions"). Thus, the district court calculated the "compensatory quantum of the award" based on the "level of exceptionality rising out of the offender's particular conduct," *id.* at 35a (quoting *Mathis v. Spears*, 857 F.2d 749, 754 (Fed. Cir. 1988)), under a careful application of this Court's precedents. *See, e.g.*, Pet. App. 31a-37a (applying *City of Burlington v. Dague*, 505 U.S. 557, 559 (1992); *Blanchard v. Bergeron*, 489 U.S. 87, 94 (1989); *Farrar v. Hobby*, 506 U.S. 103, 114 (1992); *Hensley v. Eckerhart*, 461 U.S. 424, 429-30 n.3 (1983)). The court also explained that "the litigation was equivalent to two atypical and massive patent cases." Pet. App. 41a (footnote omitted). The respective awards against Mylan and Alphapharm were well within the range of the "5 to 12 million dollars" that, according to Mylan's Rule 30(b)(6) testimony, is what generic pharmaceutical companies

anticipate spending on their own legal fees in an ANDA case. Pet. App. 41a n.13; JA3229 (126:4-13).[4] The court additionally awarded Takeda its reasonable expert fees under its inherent powers as a sanction for petitioners' bad faith conduct in the litigation. Pet. App. 56a-58a.

B. The Federal Circuit's Affirmance

Mylan and Alphapharm separately appealed that fee award to the Federal Circuit. The Federal Circuit affirmed, concluding that "the district court did not clearly err in finding that this was an exceptional case because of the misconduct by Mylan and Alphapharm and did not abuse its discretion in awarding attorney fees . . . ." *Id.* at 3a; *see generally*, *id.* at 1a-25a. The court also rejected challenges to the amount of attorneys' fees and to the award of expert fees – issues not raised in this Court. *Id.* at 17a-20a. Judge Bryson concurred, discussing only the expert-fees issue.[5] *Id.* at 21a-25a. The Federal Circuit denied petitioners' requests for rehearing en banc, without dissent. *Id.* at 245a-46a.

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4. As Mylan has previously acknowledged, a generic company challenging a patent in an ANDA litigation would ordinarily incur "far less" in attorneys' fees than the patentee. Pet. App. 45a.

5. Judge Bryson's concurring opinion did not "acknowledge[] . . . a punitive aspect" in the district court's Section 285 award, as Mylan suggests. *Cf.* Pet. at 19. Judge Bryson, after discussing the uncertain bounds of a court's inherent authority to award expert fees as a sanction, concluded that the court's award of expert fees did not result in a greater total fee award because the district court alternatively stated that it would and could have granted an enhancement of the attorneys' fee award to Takeda. Pet. App. 25a. Neither petition's question presented raises a challenge to the expert-fee award.

II. Mylan's Baseless Certification, Bad Faith, and Litigation Misconduct

Mylan filed its ANDA containing a Paragraph IV certification on the first day it could file, July 15, 2003, in order to garner first-to-file status and thus obtain 180-day exclusivity under 21 U.S.C. § 355(j)(5)(B)(iv).[6] On September 8, 2003, Mylan sent Takeda its Paragraph IV Notice letter and Detailed Statement, which asserted that pioglitazone (a 2-pyridyl thiazolidinedione) would have been obvious over so-called compound 14 (a 2-phenyl thiazolidinedione) of a Takeda publication which had been considered by the Patent Examiner who allowed the '777 patent. Mylan's theory of obviousness was based on a scientifically unsupportable contention that pyridine and benzene are supposedly "bioisosteres."[7] A4989-92; *see* Pet. App.

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6. Mylan attempted to ensure its first-to-file status by stationing a line-stander outside the FDA, 24-hours-a-day, 7-days-a-week, more than six-weeks before the first date to file an ANDA for pioglitazone. While Mylan claims to have obtained a legal opinion in support of its eventual Paragraph IV certification (no such opinion was ever produced), it admittedly did not do so until four days before it filed its ANDA. Pet. App. 95a-96a; JA233 (110:19-111:21); JA235; *see also* JA226-27 (37:19-38:3); JA228 (47:13-19); JA216 (21:4-8). Incidentally, FDA demanded that Mylan's line-stander leave the premises. Pet. App. 95a n.26.

7. The pertinent chemistry, and the law of chemical obviousness in view of this Court's decision in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007), is discussed in detail in the district court's opinion and Federal Circuit's affirmance on the underlying merits, which is now final, and will not be repeated in detail herein. *See* Pet. App. 111a-227a, *aff'd*, No. 06-1364 (*per curiam*), No. 06-1329, 492 F.3d 1350 (Fed. Cir. 2007), *reh'g and reh'g en banc denied* (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 1739 (2008).

155a-60a; A4983-5009; A6648-62. Mylan stonewalled Takeda concerning the factual basis for the position set forth in its Statement. Pet. App. 96a; *id.* at 228a-41a, 242a-44a. Only after fact discovery closed, and having been twice ordered by the court, did Mylan produce a Rule 30(b)(6) designee to testify regarding the contentions in its Statement. *Id.* at 231a-32a. At that deposition, Mylan's Rule 30(b)(6) designee admitted that no reason existed to select compound 14 as a lead compound. *Id.* at 15a, 99a; JA221 (239:19-240:16). Asserting privilege, Mylan's counsel refused to allow examination on any theory not in the Detailed Statement. Pet. App. 231a-32a. Then, three days after that deposition and a week after the close of fact discovery, Mylan untimely served "supplemental" responses to Takeda's interrogatories in which Mylan abandoned the compound 14 "bioisostere" theory of its Detailed Statement and instead asserted a brand new theory that pioglitazone would have been obvious "on the basis of compound 57," even though Mylan's 30(b)(6) witness had just days earlier testified that an analysis of the toxicity and efficacy profile of compound 57 would have "ruled it out" as a lead compound. *Id.* at 96a-97a, 232a, 228a-241a; JA218 (134:7-15) (testifying that Sohda reference "would and should cause one to rule [compound 57] out."). By changing theories after the close of discovery, and cutting off questions on any new theory, Mylan attempted to preclude Takeda from discovery regarding its entirely new theory of the case.

The district court precluded Mylan from advancing this new theory at trial because Mylan's untimely supplementation of its theory violated the court's "specific judicial directive for the timing of discovery."

Pet. App. 243-44a (quoting *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 551 (Fed. Cir. 1998)); *see generally* Pet. App. 242a-44a, 228a-41a.[8] At the same time, the district court did permit Mylan to amend its answer and counterclaims to plead a third new theory, inequitable conduct, "despite Mylan's tactical maneuvers, designed to hamstring Takeda . . . ." *Id.* at 103a.

On Takeda's motion for fees, the district court found not only that "Mylan's certification letter was filed in bad faith and with no reasonable basis to claim the '777 patent invalid" (*id.* at 95a), but that Mylan also committed "numerous" acts of "litigation misconduct" in pursuing an "always frivolous" inequitable conduct

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8. Mylan contends that the district court "forbade Mylan's use of an obviousness theory other than the one stated in its [ANDA] notice letter." Pet. 6-7 (citing Pet. App. 242a-244a, 228a-241a). To the extent Mylan suggests that the district court deemed it improper for Mylan to make any change from the notice-letter theory, that suggestion is false. The district court specifically noted:

> Although as a general matter an ANDA applicant may be able to assert theories other than those outlined in a notification letter, 'when the court has set and the parties have agreed to a discovery period, that procedure necessarily governs the trial . . . . [A] specific judicial directive for the timing of discovery establishes the procedures to which the parties are bound.'

Pet. App. 243a-44a (quoting *Lydall, Inc.*, 159 F.3d at 551); *see id.* at 228a-241a (opinion denying reconsideration, explaining why Mylan had no excuse for its late raising of new theory); *see id.* at 97a (describing rulings). That ruling, as part of the merits judgment, is now final.

claim, and that "the totality of the circumstances, including other instances of Mylan's untimely conduct, justified the award of attorney fees against Mylan . . . ." *Id.* at 6a; *id.* at 64a (noting Mylan "engaged in other litigation misconduct" that "was exceptional and fully justifies the award of attorneys' fees."); *see also id.* at 95a-107a.

The district court found that Mylan's inequitable conduct claim was advanced "without a reasonable basis and in bad faith." *Id.* at 106a. "Mylan never had any evidence of wrongful intent by Takeda, and despite promises at trial that it would produce some, utterly failed to do so." *Id.* at 102a. Noting that Mylan made factual assertions that were "absolutely false and misleading," "particularly egregious," and "inexcusable" (*id.* at 104a-06a), the court found that Mylan engaged in seven distinct categories of litigation misconduct in pursuing its inequitable conduct claim.[9] *Id.* at 101a-07a.

The court of appeals affirmed, observing that "Mylan's invalidity argument in its certification letter appears even more baseless than Alphapharm's." *Id.* at 15a. Noting "the scientific errors present in Mylan's certification letter," the court concluded that the district court "had ample reason to hold that Mylan's certification letter was filed in bad faith and with no

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9. Mylan "present[ed] no defense" to three of the seven before the district court, nor did it challenge any of those findings before the Federal Circuit. Pet. App. 101a-02a, 106a-07a. Mylan does not even address these multiple and well-supported findings of litigation misconduct in its petition.

reasonable basis to claim the '777 patent invalid." *Id.* "Similarly, the finding that Mylan engaged in litigation misconduct was well-supported and explained by the district court." *Id.*

The Federal Circuit directly rejected Mylan's characterization of the district court's ruling as having based its fee awards on "the mere fact that Mylan changed its theory of invalidity and then lost." *Id.* at 16a. The court explained:

> Rather, the court determined that Mylan's initial certification letter was completely baseless and that the claims Mylan offered as substitutes were similarly frivolous.

Id. For much the same reason, the court rejected the argument that the fee award will chill ANDA filings, recognizing that the district court's award was based on case-specific "baseless certification letters compounded with litigation misconduct." *Id.*; *see id.* at 16a-17a. The Federal Circuit did not "predicate[] 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." Pet. at 10. Rather, the court predicated its affirmance on the district court's detailed findings of Mylan's baseless, bad faith certification and litigation misconduct.

III. Alphapharm's Baseless Certification, Bad Faith, and Litigation Misconduct

Alphapharm also filed its ANDA containing a Paragraph IV Certification on July 15, 2003.[10] Alphapharm's January 29, 2004 Paragraph IV Notice letter and Detailed Statement alleged that pioglitazone would have been obvious over prior art compound (b) as described in the '777 patent itself, but failed to identify any reason that the skilled artisan would select compound (b) as a "lead" or "development" compound from the many other compounds disclosed in the prior art. Pet. App. 9a-10a; 74a-77a; *see id.* at 185a, *aff'd*, 492 F.3d 1350. In a "stunning admission" of impermissible hindsight (*id.* at 76a), Alphapharm's first Rule 30(b)(6) witness on this topic, Dr. Rosenberg, conceded that "he only chose compound (b)" as a basis for attacking the patentability of pioglitazone "because it was similar to pioglitazone." *Id.* at 179a; *see id.* at 76a; A2224 (169:17-18). *But see KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966) ("warning against a 'temptation to read into the prior art the teachings of the invention in issue' and instructing courts to 'guard against slipping into the use of hindsight'")). He further "admitted that there was 'nothing to recommend' compound (b) over any of the other compounds" in the article that had the same efficacy rating. Pet. App. 179a, *aff'd*, 492 F.3d at 1358-59; Pet. App. 76a-77a, 80a, 88a; A2225 (172:10-20). In addition, Rosenberg admitted in his deposition that

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10. Although Alphapharm's ANDA was the first-filed, FDA rejected it because Alphapharm failed to make a pharmaceutical that was bioequivalent to ACTOS® — the commercial name of Takeda's drug. Pet. App. 154a n.27.

pioglitazone is "clearly superior" to the closest prior art, and that "Table 1 of the '777 [p]atent established that clear superiority." Pet. App. 88a; *see id.* at 197a, *aff'd*, 492 F.3d at 1361-62; A2241 (235:8-236:4).

Alphapharm's next Rule 30(b)(6) designee, Barry Spencer, came up with an entirely different analysis, testifying that the person of ordinary skill would actually have chosen to investigate three different prior art compounds, including compound (b). Pet. App. 84a; A6082 (58:12-59:13). Next, Alphapharm's trial expert, Mosberg, contended in his expert report that the person skilled in the art would have chosen compound (b) as the lead compound based on prior art patents. However, at his deposition, Mosberg acknowledged that a person of ordinary skill in the art would *not* have focused particularly on compound (b), claiming instead that the person of ordinary skill in the art would have engaged in a research program designed to investigate various permutations on *all* of the prior art 2-pyridyl, 3-pyridyl, and 4-pyridyl compounds (although with a higher priority on 2-pyridyl and 3-pyridyl). Pet. App. 85a-86a; *id.* at 184-85a; A3144 (1189:4-14); A3146 (1192:10-14). At trial, Mosberg "turned the identification of a lead compound on its head." Pet. App. 86a. "[C]onfronted with the many problems associated with the identification of compound (b) as a lead compound," Mosberg nevertheless contended it would be the lead compound, not based on analytical or scientific reasoning, but "because Takeda was *not* actively pursuing it . . . ." *Id.* (emphasis in original); *see id.* at 179a-80a, 180a n.54; A3143 (1187:16)-3144 (1188:25); A3148 (1195:6)-3149 (1197:2).

On Takeda's motion for fees, the district court found that Alphapharm's ANDA certification was "so devoid of merit and so completely fails to establish a prima facie case of invalidity that it must be described as 'baseless.'" Pet. App. 73a; *see id.* at 5a. The court noted that Alphapharm's eventual obviousness contention at trial was that a skilled artisan would have started with one particular prior-art compound and then varied it in two (supposedly obvious) ways. *Id.* at 74a. Alphapharm was never able to come up with any reasonable basis for its crucial premise – that a skilled artisan would have started with that compound in the face of stark reasons (such as its toxicity) *not* to start with that compound. *Id.* at 74a-79a. Alphapharm's ANDA certification also made "baseless," "unsupportable" characterizations of the data presented in the '777 patent (*id.* at 79a-82a), and failed to address "secondary considerations" that are part of a proper obviousness analysis. *Id.* at 82a. Taken together, the court found the deficiencies in Alphapharm's certification to be "so glaring" as to disprove due care in making any case of obviousness. *Id.*

The court then recounted Alphapharm's groundless efforts to find a new obviousness theory during the litigation.[11] That misconduct included naked reliance on pure hindsight, *i.e.*, working backwards from

11. Alphapharm asserts that "[t]here was never any shift in Alphapharm's position." APet. 7-8. Even at the time of the merits determination, the district court found that "[Alphapharm] has presented a constantly shifting set of arguments, abandoning some, inventing others, and even contradicting itself as the trial progressed." Pet. App. 169a n.37; *see also id.* at 172a n.42; *id.* at 175a n.47.

pioglitazone, because *without* such hindsight, the skilled artisan had no basis either to select the specific alleged starting compound or to undertake the two specific modifications to arrive at pioglitazone, which was Takeda's discovery. *Id.* at 83a-90a, 86a ("without any analytical or scientific support"), 87a ("utterly indefensible"). The court held that Alphapharm's legal analysis was "flat wrong," and found that its response to the "damning recitation" of its "ever-shifting collage of arguments in a futile search for a coherent theory of obviousness . . . underscores its bad faith." *Id.* 83a-86a. The court also found that it was improper of Alphapharm to continue to dispute the superiority of pioglitazone to the closest prior art after Rosenberg admitted that pioglitazone was "clearly superior" to compound (b). *Id.* at 88a. Alphapharm simply did not have "a credible claim of obviousness." *Id.* at 92a. Finally, the court found that, although Alphapharm had pled only invalidity based on obviousness, it tried to insert a challenge of unenforceability based on alleged deception of the PTO (inequitable conduct), causing confusion and further waste of time. Alphapharm's arguments on this issue "were entirely frivolous." *Id.* at 90a, 91a. In sum, the court held that:

> Alphapharm's Section 355 Statement was deeply flawed, filed in bad faith, and failed to present even a prima facie case of invalidity. Alphapharm made these proceedings far more complex and expensive by constantly shifting its theory of obviousness in a futile effort to locate a coherent argument. Even in response to this motion [for attorneys' fees], it has misrepresented the record in this litigation.

> This is the exceptional case where an examination of the totality of the circumstances amply justifies, indeed compels, the award of attorneys' fees.

Id. at 94a. The district court additionally found that Alphapharm's "unilateral decision" to disregard discovery orders in connection with its untimely and improper assertion of an advice of counsel defense in response to Takeda's motion for attorney's fees was "vexatious and constitutes litigation misconduct." *Id.* at 71-73a.

The court of appeals affirmed. *Id.* at 1a-25a. The Federal Circuit recognized, like the district court, that Alphapharm's ANDA certification "failed to provide any reason" that a skilled artisan would have identified the particular alleged starting-point compound "and thus did not make a prima facie case of obviousness based on the structural similarity between compound (b) and pioglitazone." *Id.* at 10a.; *see id.* at 9a-11a.[12] The court specifically noted that the district court had not "faulted Alphapharm simply for changing its obviousness argument at trial from the theory advanced in the Paragraph IV letter. Rather, the [district] court

12. The court noted that, in the merits affirmance on non-obviousness, Judge Dyk wrote a separate concurring opinion, but only to question the possible overbreadth of two patent claims; the concurrence did not question the failure of Alphapharm's prima facie case based on compound (b), the particular alleged starting-point compound in Alphapharm's Statement, as Alphapharm contends. Pet. App. 10a. The fact of Judge Dyk's separate opinion thus does not suggest the reasonableness of Alphapharm's certification.

methodically examined a number of shortcomings in Alphapharm's Paragraph IV letter, which were made obvious by Alphapharm's 'constantly shifting set of arguments' that supported the finding that the certification was baseless." *Id.* at 10a; *see id.* at 11a. The court of appeals explained that these findings amply established the lack of basis for Alphapharm's Paragraph IV certification, which together with litigation misconduct, fully warranted the Section 285 award. *Id.* at 11a-13a.

ARGUMENT

The decision of the court of appeals is mischaracterized by petitioners. It is based on the particularized facts of these cases, and does not rest on the grounds petitioners assert. It creates no inter- or intra-circuit conflict, and threatens none of the consequences petitioners claim. Rather, in a highly fact-specific determination, it relies upon multiple and independent findings of petitioners' bad faith, baseless claims and litigation misconduct. Those findings are not challenged, are correct and well-supported in the record, and would not warrant review in any event. *See Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 336 U.S. 271, 275 (1949), *aff'd on reh'g*, 339 U.S. 605 (1950) ("A court of law, such as this Court is, rather than a court for correction of errors in fact finding, cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional showing of error."). Moreover, Alphapharm did not preserve (in either court below) its new due process question. For these and other reasons, the petitions should be denied.

I. Mylan's Petition Should Be Denied

A. The Federal Circuit Correctly Affirmed the District Court's Findings of Litigation Misconduct

In its petition, Mylan does not challenge the Federal Circuit's affirmance of the district court's findings that Mylan "decided to challenge the validity of the '777 Patent without any good faith basis to do so" (Pet. App. 95a) and "engaged in a host of bad faith litigation tactics" over the course of the litigation which ensued (*id.* at 57a). Mylan further does not challenge the Federal Circuit's conclusion that "the totality of the circumstances, including other instances of Mylan's untimely conduct, justified the award of attorney fees . . . ." Pet. App. 6a. Instead, Mylan entirely ignores its own litigation misconduct and the district court's analysis of the totality of the circumstances, and accuses the Federal Circuit of error in upholding the district court's award "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 [in its Paragraph IV Notice letter and Statement]." Pet. at 10.

The Federal Circuit did not affirm based on the "mere fact that Mylan changed its theory of invalidity." Rather, the Federal Circuit affirmed the district court's "determin[ation] that Mylan's initial certification was completely baseless and that the claims Mylan offered as substitutes were similarly frivolous." Pet. App. 16a. The Federal Circuit expressly noted:

> We do not find persuasive Mylan's argument that the district court took issue with the mere

> fact that Mylan changed its theory of invalidity and then lost. Rather, the court determined that Mylan's initial certification letter was completely baseless and that the claims Mylan offered as substitutes were similarly frivolous. In short, the district court, which was in the best position to evaluate the entire strategy pursued by Mylan, did not commit clear error in finding litigation misconduct.

Pet. App. 16a.

Thus the district court did not, as Mylan misleadingly suggests, "substantially" base its award on the mere fact that "Mylan had not pursued the case on the theory of invalidity set forth in its initial pre-suit notice letter, which the district court deemed meritless." Pet. at 3. In fact, the district court enumerated seven distinct categories of Mylan's misconduct during the litigation, misconduct which Mylan now ignores.

The Federal Circuit also did not announce a standard that would restrict ANDA filers to "only allege at trial the exact defenses as presented in its pre-litigation ANDA certification rather than pursue defenses that confirm to the evidence developed through discovery and presented at trial." Amicus at 3; *see* Pet. at 10-11. On the contrary, the district court granted Mylan leave to amend its answer and counterclaims to plead inequitable conduct, a defense wholly absent from its Detailed Statement. The court allowed Mylan's motion to add this defense after the close of fact discovery, "[d]espite Mylan's tactical maneuvers, designed to

hamstring Takeda's ability to confront this new theory . . . ." Pet. App. 103a. Moreover, in precluding Mylan from untimely asserting its "revised" obviousness theory, the district court explicitly recognized that "as a general matter an ANDA applicant may be able to assert theories other than those outlined in a notification letter." *Id.* at 243a-44a. The district court precluded Mylan from asserting a new theory of obviousness – not because that theory was absent from Mylan's Statement – but because it was untimely asserted after the close of fact discovery, and in violation of the court's discovery orders. *Id.* (quoting *Lydall, Inc.*, 159 F.3d at 551) (noting "when the court has set and the parties have agreed to a discovery period, that procedure necessarily governs the trial . . . . [A] specific judicial directive for the timing of discovery establishes the procedures to which the parties are bound."); *see* Pet. App. at 228a-241a (discussing Mylan's "specious" arguments on a motion for reconsideration). Mylan cannot seek to avail itself of the breadth of discovery permitted under the Federal Rules, while ignoring, and in many cases violating, other limitations imposed by the Rules.[13] *Cf.* Pet. at 10-11; *see* Pet. App. 243a-44a.

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13. In light of the Federal Circuit's affirmance of the district court's fact-intensive analysis of the totality of the circumstances, Mylan's reliance on *Merck & Co. v. Mylan Pharms., Inc.*, 79 F. Supp. 2d 552, 556 (E.D. Pa. 2000) is inapposite. *Cf.* Pet at 13. In *Merck*, "good faith persistence" was not a basis for sanctions. *Merck*, 79 F. Supp. 2d at 556. Here, Mylan's "particularly egregious . . . and inexcusable" conduct was a valid basis for sanctions. Pet. App. 104a.

B. The Federal Circuit Correctly Affirmed the District Court's Findings of Mylan's Bad Faith

The Federal Circuit did not adopt or apply an incorrect standard in reviewing the district court's findings that Mylan made its Paragraph IV certification — and proceeded to litigate the ensuing case — in bad faith. *Cf.* Pet. at 16-18. Although Mylan may have abandoned the theory advanced in its Statement before trial, Mylan is incorrect to state that this theory was "unlitigated," *id.* at 14, or was "largely irrelevant" once in litigation, *id.* at 17. Mylan abandoned this theory *after* the close of discovery, and *after* its 30(b)(6) designee's admission confirmed just how baseless it was. Pet. App. 95a-101a; *id.* at 159a-60a; *see id.* at 242a-44a; *id.* at 228a-41a. Takeda established Mylan's bad faith in connection with its Paragraph IV certification and Statement by clear and convincing evidence, including admissions from Mylan's witnesses, JA233 (110:19-111:21); JA226-27 (37:19-38:3); JA228 (47:13-19); JA216 (21:4-8), and testimony of Takeda's and Alphapharm's experts, JA221 (239:19-240:16); JA296-323; JA483-84 (324:8-325:9); JA8302-05; JA8332-36. *See generally*, Pet. App. 1a-110a. Mylan's arguments advanced in defense of its Paragraph IV certification were, at best, "utterly frivolous," and themselves were "further evidence that an award of attorney' fees against Mylan is appropriate." *Id.* at 99a.

Moreover, the district court found that Mylan's bad faith was pervasive throughout the litigation:

> Mylan engaged in a host of bad faith litigation tactics, which increased the burden of this

> litigation enormously. These included the presentation of factually indefensible positions from its ANDA filing straight through to its submissions in opposition to the motion for sanctions.

Pet. App. 57a; *see Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000) (concluding "misconduct in filing a wholly unjustified ANDA certification and misconduct during the litigation that followed warranted the district court's finding that this case was exceptional."); *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1349-51 (Fed. Cir. 2004).

Contrary to Mylan's suggestion, the lower courts did not "[c]onstrue Section 285 to allow an inference of bad faith because an ANDA applicant properly changed positions based on discovery . . . ."[14] Pet. at 14. The district court found, and the Federal Circuit affirmed, that Mylan's conduct was anything but "proper." The court of appeals affirmed that Mylan precipitated this litigation with a "baseless" certification (Pet. App. 101a), advanced "absolutely frivolous" (*id.* at 97a) and "extremely misleading" arguments in support of its "aborted effort to make a wholesale revision to its

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14. Mylan's generalized argument that *some* patent defenses require discovery before they can be asserted has no application to this case. *Cf.* Pet. at 12-13. The baseless obviousness argument Mylan chose to advance in its Statement relied on two publicly-available prior art references. A4983-5009. Thus, Mylan's suggestion that the possibility that discovery may shed some light on certain defenses somehow excuses a baseless Detailed Statement is a non-sequitur.

obviousness theory" (*id.* at 100a), and "propounded a frivolous claim of inequitable conduct" (*id.* at 95a). These positions did not "become untenable" in light of discovery, nor were its "new claims" "revealed" or "bolstered" through discovery. *Cf.* Pet. at 11-12. These positions were advanced without a reasonable basis and in bad faith, and no reading of the Federal Rules can condone such litigation misconduct. "The framework established by Congress for accelerating the approval process for generic versions of established drugs . . . is not an invitation to frivolous, bad faith attacks on patents." Pet. App. 64a.

C. Hatch-Waxman Cannot Be Read to Condone Mylan's Bad Faith

Mylan's argument that exposing ANDA filers to an award of attorneys' fees under Section 285 somehow "conflicts with the special litigation process" of Hatch-Waxman is contrary to the plain language of the statute. *Cf.* Pet. at 19. While proscribing money damages for *infringement*, Section 202 of Hatch-Waxman, codified at 35 U.S.C. § 271(e)(4), explicitly provides that "[f]or an act of infringement described in [35 U.S.C. § 271(e)(2)] . . . a court may award attorney fees under [35 U.S.C.] section 285." Hatch-Waxman thus expressly approves fee awards under the standards of Section 285, which are amply satisfied here.

Moreover, Mylan's argument that allowing the Federal Circuit's decision to stand will undercut the policies of Hatch-Waxman is unfounded. Mylan's generalized policy arguments ignore the totality of the circumstances in this case. The award in this case was

specifically tailored to the petitioners' misconduct in this case, and will not "chill the ANDA process." As the Federal Circuit held:

> [W]e find the "chilling" argument regarding ANDA filers advanced by Alphapharm and Mylan to be unpersuasive, despite the support provided by the amicus filing of the Generic Pharmaceutical Association. In making a Paragraph IV certification, appellants are statutorily required to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid." 21 U.S.C. § 355(j)(2)(B)(iv)(II) (2006). It is clear from the district court's opinion that it was not faulting Alphapharm or Mylan for the act of filing an ANDA that challenged the pioglitazone patent, nor did it limit the filers to the theories raised in their certification letters. Rather, the district court found the case exceptional based on the specific circumstances involved in this case, viz., baseless certification letters compounded with litigation misconduct. In fact, the district court addressed the deterrence argument directly:
>
> > There is no basis to find that this award will deter ANDA filings and litigation. This award addresses baseless ANDA filings and the pursuit of frivolous ANDA litigation in bad faith and other litigation

> misconduct. The Hatch-Waxman Act cannot be read to immunize such conduct.
>
> Given the court's specific articulation that its ruling was directed toward baseless ANDA filings and litigation in bad faith, we decline to disturb the court's finding of an exceptional case as potentially chilling non-frivolous ANDA filings under the Hatch-Waxman Act. Well-supported filings challenging the validity and infringement of patents owned by an NDA holder should not raise the specter of an unjustified holding of an exceptional case.

Pet. App. 16a-17a (quoting *id.* at 108a). To hold otherwise would disturb the balance between innovator and generic interests that Congress intended in enacting Hatch-Waxman:

> There is a strong public interest, as acknowledged by the statutory scheme, in challenging patents that keep the price of pharmaceuticals high. There should be no incentive, however, for litigation that is prolonged and complicated by a series of attacks undertaken without a good faith basis and without a sound basis in science. Science, medical research, and the court system demand better.

Pet. App. 53a; *see* H.R. Rep. No. 98-857, pt. 1 at 14-15 (1984, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48).

II. Alphapharm's Petition Should Be Denied

Alphapharm seeks certiorari on the question whether the fee award constitutes punishment in violation of its due process rights. The petition should be denied for multiple reasons.

A. Alphapharm's Current Due Process Claim Was Neither Addressed Nor Preserved Below

Neither the court of appeals nor the district court decided a due process issue. There is accordingly no due process ruling, express or implicit, for this Court to review.

The reason for the absence of a due process ruling below is apparent. Alphapharm did not adequately present or preserve any due process question, either before the district court or the court of appeals. *Bankers Life & Cas. Co. v. Crenshaw*, 486 U.S. 71, 78-79 (1988); *G.D. Searle & Co. v. Cohn*, 455 U.S. 404, 412 (1982); *see also United States v. Ortiz*, 422 U.S. 891, 898 (1975). Alphapharm's opening brief before the court of appeals, where all issues must be raised, presented no due process issue. *Pieczenik v. Dyax Corp.*, 265 F.3d 1329, 1332-33 (Fed. Cir. 2001) ("It is well settled that an appellant is not permitted to make new arguments that it did not make in its opening brief.").[15] Alphapharm has thus waived its due process claim.

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15. Alphapharm raised a due process issue in its rehearing petition, but that is too late where, as here, it is not the court of appeals' ruling, but the district court's ruling, that is asserted to be unconstitutional. *See Bankers Life & Cas. Co.*, 486 U.S. at 78-79. Alphapharm's reply brief to the panel inserted the words

(Cont'd)

B. There Has Been No Deprivation of Due Process

Even had it been properly preserved, the premise of Alphapharm's due process argument is inapplicable to this case. The fee award is not "punishment" or "punitive." As Mylan's own petition expressly recognizes (08-1461 Pet. 19), attorneys' fees under Section 285 are compensatory, not punitive. *See Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1347 (Fed. Cir. 2004) (en banc) (noting "Attorney fees are compensatory . . . ."); *see also Hensley*, 461 U.S. at 435 (noting "[w]here a plaintiff has obtained excellent results, his attorney should recover a fully compensatory fee."). That is plainly the case of the fee award in this case. The district court expressly noted that the amount awarded to Takeda was required to compensate Takeda for having to defend against petitioners' "shifting theories of attack, none of which was meritorious or adopted in good faith" or "reflected a careful analysis of the relevant documents and the application of sound science to that analysis." Pet. App. 52a; *id.* at 27a-60a. There is nothing "punitive" about making Alphapharm

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"due process" into a quote that it used to argue unfairness. That action did not raise a due process issue – which, in any event, would have been too late given the settled rule that an appellant cannot raise new legal arguments in reply. *Optivus Tech., Inc. v. Ion Beam Applications S.A.*, 469 F.3d 978, 989 (Fed. Cir. 2006); *Pieczenik*, 265 F.3d at 1333.

pay for the actual consequences of its unjustifiable litigation misconduct.[16]

Furthermore, such an award is not a due process violation – or unauthorized by Section 285.[17] Alphapharm cites only due-process decisions involving "punishment," rather than compensation. Neither the Constitution nor Section 285 bars the shifting of actual litigation expenses to a party that causes them through the actions

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16. The court also did not "penalize" Alphapharm for "following the rules applicable to all patent cases." APet. at 9. "The purpose of § 282, like that of the Federal Rules, is to prevent unfair and prejudicial surprise, not to facilitate last-minute production of evidence." *Lydall, Inc.*, 159 F.3d at 551. "Thus although § 282 sets a minimum period for the identification of prior art to be introduced . . . , a specific judicial directive for the timing of discovery establishes the procedures to which the parties are bound." *Id.; see supra* note 8.

17. From the outset of the case, Alphapharm was on notice that Takeda sought an award of attorneys' fees under Section 285. Pet. App. 69a. The "duty of care" required of an ANDA certifier was imposed by Hatch-Waxman in 1984. *See Yamanouchi*, 231 F.3d at 1346 (noting "the [Hatch-Waxman] Act unambiguously permits an award of attorneys fees to the prevailing party in exceptional cases on the basis of an ANDA filing."). The Federal Circuit clearly articulated that "[m]isconduct in filing a wholly unjustified ANDA certification and misconduct during the litigation that follow[s] warrant[s] [a] district court's finding that [a] case was exceptional." *Yamanouchi*, 231 F.3d at 1347; *Glaxo*, 376 F.3d at 1350 (noting "[s]uch unjustified litigation misconduct has always justified a finding of an exceptional case."). Even according to the Amicus, "[t]o 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 . . . ." Amicus at 7.

that the district court properly found here: initiation of the Hatch-Waxman process by filing a "baseless" notice of alleged invalidity for obviousness, in breach of an undisputed duty of care and in bad faith (Pet. App. 73a, 74a, 94a), followed by bad faith and vexatious litigation, including presentation of shifting new obviousness theories that themselves were "utterly indefensible" for lack of a responsible scientific basis (*id.* at 87a; *see id.* at 83a-90a), and presentation of "entirely frivolous" charges that Takeda deceived the PTO (*id.* at 90a-91a). *See generally*, *id.* at 67a-94a. As already explained *supra*, the courts below did not award fees for filing a good-faith ANDA certification and thereafter substituting reasonably grounded theories in good-faith litigation. *See*, *e.g.*, *id.* at 10a. (noting "we do not believe that the district court faulted Alphapharm for simply changing its obviousness argument at trial from the theory advanced in the Paragraph IV letter."). Alphapharm's attempt to portray the rulings below as so holding is as off-base as Mylan's similar attempt. *See id.* at 10a-11a

C. Alphapharm Cannot Ignore the Commercial Success that Motivated Its ANDA Filing

As one part of its due process grievance, Alphapharm argues that the district court erred in "sanction[ing] Alphapharm in part because Alphapharm's Notice Letter failed to address commercial success . . . ." APet. 12. As an initial matter, this argument is beside the point if only because the district court had multiple grounds for finding Alphapharm's certification and litigation positions baseless, wholly apart from Alphapharm's failure to address the so-called secondary considerations relevant

to an obviousness analysis. *See generally*, Pet. App. 67a-94a. Moreover, Alphapharm's assertion of error in the district court's analysis of commercial success is without basis in law, and is divorced from the record below. *Cf.* APet. 12-13. Alphapharm argued in the district court that it needed discovery to address such "secondary considerations," but the district court noted that an important secondary consideration, namely, the great commercial success of ACTOS®, was of public record and known to Alphapharm (which is why it wanted to copy the drug in the first place). Pet. App. 82a; *see, e.g.*, JA1089-92.[18] In its petition, Alphapharm argues that such considerations present an "affirmative defense" on which the patent holder has the burden of proof. APet. 12 (citing *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1380 (Fed. Cir. 2006); *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005)). Neither case cited by Alphapharm, nor this Court's decisions, so characterize the role of secondary considerations in an obviousness analysis. *See KSR*, 550 U.S. at 406. On the contrary, Alphapharm's own counsel admitted that "[s]econdary considerations of patentability such as commercial success . . . must be given due consideration . . . ," in reaching a good faith basis for a Paragraph IV certification. JA1580 (citing and relying on *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983)).

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18. Moreover, where, as here, the "marketed product embodies the claimed features, and is coextensive with them, then a nexus is presumed and the burden shifts to the party asserting obviousness to present evidence to rebut the presumed nexus." *Brown & Williamson Tobacco Corp. v. Phillip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000).

CONCLUSION

For the foregoing reasons, the petitions should be denied.

Respectfully submitted,

ANTHONY J. VIOLA
ANDRE K. CIZMARIK
EDWARDS ANGELL PALMER
& DODGE LLP
750 Lexington Avenue
New York, NY 10022
(212) 308-4411

DAVID G. CONLIN
Counsel of Record
BARBARA L. MOORE
KATHLEEN B. CARR
ADAM P. SAMANSKY
EDWARDS ANGELL PALMER
& DODGE LLP
111 Huntington Avenue
Boston, MA 02199
(617) 239-0100

Attorneys for Respondents