No. 08-1463

IN THE

Supreme Court of the United States

ALPHAPHARM PTY., LTD. and GENPHARM INC.,

Petitioners,

v.

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

Respondents.

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

REPLY BRIEF

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CORPORATE DISCLOSURE STATEMENT

Petitioners set forth its corporate disclosure statement on page *iv* of its Petition for a Writ of Certiorari. There are no amendments to that statement.

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REPLY ARGUMENT

The district court awarded millions of dollars in sanctions against Alphapharm in large measure for deviating from its presuit Notice Letter—routine in Hatch Waxman litigation, and in fact in any civil case under the liberal rules of discovery. Like any other litigant would, Alphapharm buttressed its obviousness allegations using information obtained in the litigation from Takeda. As specifically authorized by statute, Alphapharm timely added prior art to its obviousness case, as that prior art became relevant. *See* 35 U.S.C. § 282. But the district court believed that any such deviation demonstrated sanctionable "bad faith." (Pet. App. A52; Pet. App. A60–61.)[1] Simply put, Alphapharm was deprived of millions of dollars without color of law or due process.

Nothing in Takeda's opposition brief demonstrates to the contrary. Takeda admits that the Federal Circuit specifically noted that deviations in the Notice Letter affected the district court's view of Alphapharm's case. (Opp'n Br. at 17.) Takeda's suggestion that Alphapharm was somehow on notice that it would be subject to sanctions for availing itself of the discovery obtained

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[1] "Pet. App. A__" refers to the appendix accompanying Alphapharm's petition for a writ of certiorari in No. 08–1463. "Pet. App. SA__" refers to the supplemental appendix accompanying Alphapharm's petition for a writ of certiorari in No. 08–1463. "A__" and "JA __" refer to portions of the Confidential Joint Appendix in the Federal Circuit Nos. 07–1269, –1270. "RA__" refers to Petitioners' appendix accompanying this reply brief.

from Takeda lacks merit. No other district court had ever sanctioned a patent challenger for buttressing allegations in the past. The judgment against Alphapharm should be reversed.

I. Alphapharm Fully Preserved its Due Process Claim

Takeda asserts that Alphapharm did not preserve its due process argument because there was no due process issue for the district court or the Federal Circuit to decide. (Opp'n Br. at 27.) Not so. Alphapharm's assertion on the appeal to the Federal Circuit was that it was wrongfully subjected to sanctions for wholly proper litigation conduct. (RA6; RA8–11; *see also*, RA7 ("Alphapharm's obviousness challenge was not 'exceptional' . . . ."); RA7 ("the court erroneously believed that Alphapharm was not entitled to develop its case through discovery."). That sanctions under such circumstances deprive a litigant of due process is this Court's very holding in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), which Alphpharm relied on.

Alphapharm relied on *BMW* because there this Court found that a fact finder's sanction for conduct otherwise lawful deprived a litigant of due process because it "chang[ed] the rules in the middle of the game." (RA14; *see* RA17–20.) Alphapharm consistently made the assertion that sanctions were improper for wholly proper conduct at the district court level (RA3–4), before the Federal Circuit panel (RA8–11; RA13–15),[2]

[2] Alphapharm explicitly raised the issue using the words "due process" and citing to *BMW* directly—not as Takeda suggests at the rehearing stage of the appeal—but in Alphapharm's *reply brief* to the Federal Circuit. (RA13–15.)

and en banc (RA17–20). Takeda's claim that Alphapharm should have used the words "due process" before the district court strains credulity. (Opp'n Br. at 27) The award of sanctions brought about that very violation. (Pet. App. A28–80.)

This Court and the Federal Circuit have rejected nonpreservation assertions nearly identical to the one Takeda advances here. *Connor v. Finch*, 431 U.S. 407, 421 n.19 (1977) (stating that issues may "appropriately be viewed as an issue implicitly raised by the parties"); *Long Island Sav. Bank, FSB v. United States*, 503 F.3d 1234, 1244 (Fed. Cir. 2007) (although not explicit, "defense 'is inextricably linked to, and is thus 'fairly included' within, the questions presented.'") (citations omitted). To preserve an argument for appeal, "[n]o particular form of words or phrases is essential, but only that the claim of invalidity and the ground therefor be brought to the attention of the [] court with fair precision and in due time. And if the record as a whole shows either expressly or by clear intendment that this was done, the claim is to be regarded as having been adequately presented." *New York ex rel. Bryant v. Zimmerman*, 278 U.S. 63, 66 (1927). This Court should reach the due process issue.

II. Takeda Cannot Defeat Alphapharm's Due Process Claim with Hollow Distinctions Between Punitive and Compensatory Awards

Alphapharm asserted that the district court improperly deprived it of $5.4 million of its property without due process. Takeda can only respond that fee awards under 35 U.S.C. § 285 are not "punishment" but instead are merely "compensatory." (Opp'n Br. at 28-29.) The distinction is a hollow one, and has no support in the language of the Constitution. The Fifth Amendment of the Constitution provides that no person may be "***deprived*** of life, liberty, or property, ***without due process*** of law." U.S. Const. amend. V (emphasis added). The Fifth Amendment does not say that such deprivations are permissible so long as "compensatory."

Nor can Takeda cite to any precedent suggesting that a district court can ignore well-established law and shift millions of dollars in fees to the winner so long as the award is not considered "punishment."[3] With good

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[3] The district court made plain its intent to punish Alphapharm. The district court made repeated references to Alphapharm's bad faith. (Pet. App. A29, A50, A54.) Takeda relies in its papers on those very references (Opp'n Br. at 5–6, 15–18, 28.) And like all punitive awards, the district court expected that its ruling would deter wrongful conduct in the future. *See Exxon Shipping Co. v. Baker*, 128 S.Ct. 2605, 2621 (2008) (punitives are aimed "principally at retribution and deterring harmful conduct"). The court notes that its fees award was in part justified because "[t]here should be no incentive, however, for litigation that is prolonged and complicated by a serious of attacks undertaken without a good faith and without a sound basis in science." (Pet. App. A110.)

reason. The distinction between what is punishment and compensation generally only arises in connection with a defendant's claim in a tort case that the jury's award was excessive. *See Exxon Shipping*, 128 S.Ct. at 2621 (discussing evolution of distinction between punitive and compensatory damages). That was never the basis of Alphapharm's due process claim.

The *BMW* court emphasized that the jury did not have the power to sanction a private litigant for conduct that was otherwise lawful. 517 U.S. at 572–73. The district court did so by punishing Alphapharm in substantial part for deviating from its presuit Notice Letter. The district court below was the first court to do so. *See Pfizer, Inc. v. Teva Pharms. USA, Inc.*, No. 04–754, 2007 WL 4300155, at *10 (D.N.J. Dec. 5, 2007) (finding that dropping of claims and raising of new ones insufficient evidence of bad faith litigation); *Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99–8928, 2000 WL 257125, at *1 (S.D.N.Y. Mar. 6, 2000) (refusing to dismiss affirmative patent defenses not initially plead in presuit notice letter). Tellingly, in the nearly three years since the district court's award of sanctions on this basis, not one other court has chosen to rely on the district court's reasoning. Alphapharm could not have had notice that the use of the confidential documents obtained from Takeda to hone its proofs at trial would subject it to $5.4 million in sanctions.

Takeda's assertions that Alphapharm did have notice that it would be subjected to sanctions are unavailing. Takeda first claims that Alphapharm was aware that Takeda sought sanctions pursuant to § 285. (Opp'n Br. at 29 n.17.) Takeda misses the mark. In its

complaint, Takeda never suggested what specifically about Alphapharm's conduct was exceptional. Moreover, as noted, Alphapharm was quite careful in challenging the '777 patent and did so after securing an opinion of counsel and after the due consideration of three medicinal chemists and a synthetic organic chemist. (JA1650–51.) Dr. Henry Mosberg, independently ratified the scientific basis for Alphapharm's obviousness position at trial. (A1828–32, ¶¶17–23.) But the court ignored such clear evidence of Alphapharm's good faith as a result of its mistaken belief that any deviation from a presuit Notice Letter demonstrated bad faith.[4] (A81; JA30) (commenting that Alphapharm should have limited itself to the "theories presented in [its Notice Letter]".)

Takeda next tries to defend the district court's decision to sanction Alphapharm for adding prior-art references prior to trial—permissible under 35 U.S.C. § 282—by noting that district courts may time their own discovery. (*See* Opp'n Br. at 29, n.16.) But the district court never required Alphapharm to serve notice of its

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[4] Takeda makes much of the district court's belief that the deposition testimony of Alphapharm's witnesses demonstrated its bad faith. (Opp'n Br. at 13–14.) But this testimony was taken out of context. For example, the district court believed that Alphapharm's Dr. Rosenberg selected the prior-art compound b because it was "similar to pioglitazone" but ignored those portions of his deposition where he noted that the skilled artisan would select that compound because of its very high efficacy. (A2224, 169:10–16.) The court never heard from Alphapharm's witnesses at trial, and so its findings are not entitled to any special deference. *See* Fed. R. Civ. P. 52(a) (granting district court deference to credibility findings of witnesses before it).

prior-art references earlier than required under § 282. And in any event, Takeda knew months in advance of trial that Alphapharm would rely on these references. Alphapharm's 30(b)(6) witnesses, Dr. Howard Rosenberg and Barry Spencer, specifically relied on the references during their deposition testimony to demonstrate the obviousness of the '777 patent. (RA22–23; RA25.) And Alphapharm's medicinal chemistry expert Dr. Mosberg relied on these references in his expert report and trial declaration, served 6 months before trial. (RA2–3; A1828–33, ¶¶17–27.) Under § 282, a defendant need only serve notice of additional prior-art references he intends to rely on one month in advance of trial. Although Alphapharm fully complied with the statute, it was sanctioned anyway. (Pet. App. A61) ("To the extent that the '605 and '779 patent provided any support for the selection of compound (b) as a lead compound, then Alphapharm was under an obligation to identify these two references in its [Notice Letter].").

III. The District Court's Commercial Success "Analysis" Was Infected Throughout by Legal Error

As noted in the Petition, the district court also improperly sanctioned Alphapharm for failing to address ***the patentee's*** affirmative defense of "commercial success," one of the so-called "secondary indicia of nonobviousness." (Pet. for Writ of Cert. at 12–13.) Takeda responds simply by noting that the commercial success of Takeda's Actos® product motivated its filing. (Opp'n Br. at 30–31.) Its response makes little sense. A secondary consideration of

nonobviousness allows a court to use criteria other than the hypothetical person of skill in the art referenced in 35 U.S.C. § 103 to analyze the question of obviousness. *See Graham v. John Deere*, 383 U.S. 1, 17–18 (1996). The secondary indicia are an analytical rubric, not as Takeda led the district court to believe, a simple "checklist." For example, the district court apparently believed—on the basis of Alphapharm's possession of presuit sales data—that the "commercial success of Actos® was well-known to Alphapharm . . . ." (Pet. App. A50.) But sales data alone is insufficient to warrant any inference of commercial success. *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996).

The analysis of obviousness using the secondary indicia of commercial success is much more involved than the district court appeared to appreciate. The utility of commercial success as objective evidence rests on four fundamental inferences. According to Professor Edmund Kitch in his now-classic article on the subject, these inferences are as follows:

> First, that the commercial success is due to the invention. Second, that if an improvement has in fact become commercially successful, it is likely that this potential commercial success was perceived before its development. Third, the potential commercial success having been perceived, it is likely that efforts were made to develop the improvement. Fourth, the efforts having been made by men of skill in the art, they failed because the patentee was the first to reduce his development to practice.

Edmund Kitch, *Graham v. John Deere Co.: New Standards for Patents*, 1966 *Sup. Ct. Rev.* 293, 332 (1966). Appellate courts frequently rely on Kitch's analysis. *See, e.g., Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324, 1346 (7th Cir. 1983); *Rengo Co. v. Molins Mach. Co.*, 657 F.2d 535, 541 n.5 (3d Cir. 1981); *Eli Lilly & Co. v. Premo Pharms. Labs., Inc.*, 630 F.2d 120, 126 (3d Cir. 1980); *Nat'l Filters, Inc. v. Research Prods. Corp.*, 384 F.2d 516, 520 (5th Cir. 1967).

Thus, a corporation cannot simply put on evidence at trial of impressive sales figures or market share data and baldly assert that the claims of its patent are not obvious as a result. There must be some link—some nexus—demonstrating that the merits of the invention over the prior art were responsible for the later success. In *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 315 (Fed. Cir. 1985), for example, the inventor of a holding arm for automatic graphic chart pens introduced evidence of substantial commercial success. The patent challenger countered with evidence that the success was attributable to ***nonpatent*** features, specifically: (1) the patentee's established market leadership; (2) advertising and promotion; and (3) other unpatented features of the pen. *Id.* at 316. In rejecting the patentee's claim that commercial success demonstrated nonobviousness, the court noted: "[I]t cannot be said that the commercial success here may not have been due in large part to other economic and commercial factors unrelated to the technical quality of the patented subject matter." *Id.* The district court ignored Alphapharm's evidence at trial demonstrating that non-patented features, including market forces, an aggressive advertising campaign and unusual giveaways accounted for the qualified success of Actos®. (Pet. App. SA1–48.)

But more importantly, the district court believed that Alphapharm was under a duty to rebut[5] in the Notice Letter—what it could not possibly address intelligently—let alone rebut. (Pet. App. A49–50.) In order to demonstrate that Takeda's claims of huge sales had to do with factors other than its patented features, Alphapharm needed discovery of information all pharmaceutical companies maintain as confidential: Takeda's market position, its advertising and marketing budget, and per-product profit margins. None of this data became available until ***after*** Alphapharm drafted its Notice Letter. Takeda does not maintain otherwise in its opposition brief. Nor could Alphapharm have foreseen that the failure to address this defense would have resulted in sanctions. No other district court in the country had so held. Nor has any court since.

Takeda strangely asserts that secondary considerations of obviousness are not affirmative defenses on which the patentee has the burden of proof, but instead elements of a challenger's proof. (Opp'n Br. at 31.) That was not Takeda's position at the trial below.

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[5] Takeda claims as the district court that where the "marketed product embodies the claimed features," a nexus is presumed. (Opp'n Br. at 31 n.18.) But Takeda proves too much. If Takeda's claim were correct, a patent challenger such as Alphapharm could never rebut the presumption and thus could never challenge the patent on a pretrial basis. Many patents covering products that are extensively marketed and arguably "successful" would thus be rendered immune from challenge. Such a result is hardly consistent with Congress' purpose in enacting of the Hatch-Waxman Act—to "make lower cost generic drugs available more quickly." *See* H.R. Rep. No. 108–81, at 9 (2003).

Then, Takeda argued in its pretrial brief to the district court that there was no need to address the considerations if Alphapharm failed to meet its burden to show prima facie obviousness. (*See* RA27) ("Without Alphapharm having proved a *prima facie* case of obviousness, there is no need for this Court to consider objective evidence of non-obviousness.".) The district court agreed. *See* (A92) ("Given Alphapharm's failure to show prima facie obviousness, there is no need for an extended discussion of the objective factors used to evaluate obviousness.".) Takeda and the district court's earlier analysis make little sense only if secondary considerations were a means ***for the patentee*** to alternatively demonstrate the nonobviousness of a patent in the face of a prima facie case of obviousness.

And despite Takeda's weak suggestion to the contrary (Opp'n Br. at 31), the Federal Circuit has long treated secondary indicia as an affirmative defense by the patentee to an obviousness challenge.[6] As the Federal Circuit noted in *In re Huang*, 100 F.3d 135, 139 (Fed. Cir. 1996), "[o]nce a *prima facie* case of obviousness has been established, the burden shifts to the applicant to come forward with evidence of nonobviousness to overcome the *prima facie* case." *Accord In re Beattie*, 974 F.2d 1309, 1313 (Fed. Cir. 1992)

[6] This Court has not yet opined on either the evidentiary significance or who bears the burden of secondary considerations. The *Graham* Court only noted for example that such considerations "might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." 383 U.S. at 17–18. *See also KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 400 (2007) (citing the same language).

(secondary indicia "may be sufficient to overcome a prima facie case of obviousness."). *See also SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1358 (Fed. Cir. 2000) ("[T]he mere existence of . . . licenses [i.e., secondary considerations] is insufficient to overcome the conclusion of obviousness, as based on the express teachings in the prior art that would have motivated one of ordinary skill to modify . . . cells to be used with unknown compounds."). Thus, the district court's assumption that commercial success should have been addressed in Alphapharm's Notice Letter was simply mistaken. Notably, the Federal Circuit chose not to address this error. (Pet. App. A1–26.)

CONCLUSION

Alphapharm respectfully requests that this Court grant the petition for a writ of certiorari, and reverse the judgment of the Federal Circuit.

Respectfully submitted,

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