No. 15-2411

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

CHURCH & DWIGHT CO., INC., a Delaware Corporation,
Plaintiff-Appellee,
v.
SPD SWISS PRECISION DIAGNOSTICS GMBH, a Swiss Corporation,
Defendant-Appellant.

On Appeal from the United States District Court for the
Southern District of New York, No. 14-cv-585

RESPONSE TO PETITION FOR REHEARING AND REHEARING EN BANC

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1(a), Appellee Church & Dwight Co., Inc. certifies that it has no parent corporation and that no publicly held corporation owns ten percent or more of its stock.

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INTRODUCTION

The Panel's unanimous decision in this case involves a careful application of settled Lanham Act principles to the unique facts of this case. Appellant SPD does not come close to showing that the Panel's opinion conflicts with established law or otherwise warrants rehearing or rehearing en banc.

SPD's lead rehearing argument, as it was before the Panel, is that the Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011)—which SPD did not once cite before the District Court—precludes Lanham Act liability where the FDA has "prevent[ed] a company from unilaterally changing its label." Pet.1. The Panel correctly concluded that *PLIVA* is inapposite and that the controlling precedent is *POM Wonderful v. Coca-Cola*, 134 S. Ct. 2228 (2014). Whereas *PLIVA* addresses preemption of state law, *POM* "establishes that a Lanham Act claim is not precluded by FDA regulation under the FDCA because the two statutes serve distinct and complementary purposes." Op.28.

In a curious attempt to buttress its *PLIVA* argument, SPD filed a 28(j) letter on October 5, 2016, citing as supplemental authority *Apotex Inc. v. Acorda Therapeutics*, 823 F.3d 51 (2d Cir. 2016), a case this Court decided nearly *four months before* the Panel decision here. SPD never brought *Apotex* to the Panel's attention, nor did SPD cite *Apotex* in its rehearing petition. Those failures were not some grave oversight; *Apotex*—which cites neither *PLIVA* nor *POM*—is

inapposite. *Apotex* recognizes that "representations commensurate with information in an FDA label *generally* cannot form the basis for Lanham Act liability." *Id.* at 64 (emphasis added). But—in language SPD ignores—the Court further emphasized that a Lanham Act claim may still be brought if the advertisement "does not correspond substantially to the label, or *otherwise renders the advertisement literally or implicitly false*." *Id.* at 64 n.10 (emphasis added). As both the District Court and the Panel recognized, that was precisely the case here. Moreover, as *Apotex* itself makes clear, that decision was limited to the narrow context of advertising for pharmaceuticals, *id.* at 64 & n.9, and did not purport to establish a broader rule that would apply outside that context.

Equally without basis is SPD's alternative argument for rehearing, which is addressed solely to SPD's Revised Package. In maintaining that the Panel "upend[ed]" and "fundamentally transformed the law of false advertising" by requiring "defendants who make truthful statements [to] actively educate consumers to dispel potential preexisting misconceptions," Pet.1-2, SPD wildly mischaracterizes the Panel's holding, which does nothing of the sort. In reality, the Panel's fact-based analysis of the Revised Package's implied falsity is both consistent with the law and properly deferential to the District Court's broad discretion in assessing the persuasiveness of a consumer survey.

In sum, none of SPD's arguments comes close to warranting rehearing, and its petition is merely an attempt to delay the mandate and further postpone the remedy for the consumer confusion and injury caused by SPD's intentionally misleading advertising campaign. Four federal judges have now adjudicated this case, and all four have agreed that SPD's arguments are without merit. The petition should be denied expeditiously.

BACKGROUND

A. Physicians follow a universal convention of expressing pregnancy duration as time passed since a woman's last menstrual period (LMP). SPA4, SPA8. In 2013, SPD began marketing a home pregnancy test (the Product) that tests for pregnancy and estimates pregnancy duration based on a very different metric: weeks since ovulation. SPD's so-called "weeks estimator" thus provides consumers with a pregnancy duration estimate that differs by roughly two weeks from the LMP-based estimate that a doctor would have provided. JA168; SPA4.

As Class II medical devices, home pregnancy tests require FDA clearance under section 510(k) of the FDCA. SPA10. Before clearing the Product for sale, FDA sent a "Hold Letter" to SPD, expressing concern that consumers could mistakenly substitute the Product's weeks estimate for a physician's gestational age determination, thereby leading to significant health consequences, including a potentially fatal undiagnosed ectopic pregnancy. JA8036-37; JA4713.

FDA later cleared the Product with specific limitations, which required neither a particular package design nor product name. JA3368-72; SPA 11. Nor did FDA dictate the content of the Product's outside package label; instead, *SPD* proposed labeling to FDA. JA9499. And when FDA ultimately cleared the Product for sale, it stated in no uncertain terms that its clearance "does not mean that FDA has made a determination that your device complies with other requirements of the Act *or any Federal statutes and regulations administered by other Federal agencies.*" JA3370 (emphasis added).

Following the conclusion of the clearance process, SPD switched out its "final," FDA-cleared packaging for the Launch Package without notifying FDA. JA9499-504; JA8407; JA9187-97. As a result, FDA never saw, much less "approved," the Launch Package before it went on the market. *Id.*

Fully cognizant of the risk of consumer confusion, SPD launched a major advertising campaign to mislead customers into believing the Product provided the same "weeks" estimate as a physician. For example, SPD's Launch Package never used the word "ovulation" to describe what the Product was measuring. SPA 12-13. And SPD's other marketing materials, including a nationally televised commercial, emphasized the Product's purported ability to "estimate weeks" and tell pregnant women "how far along" they are even before visiting the doctor, without disclosing the discrepancy between the Product's estimate and the

universal medical convention followed by physicians. SPA14-15, 38.

FDA subsequently contacted SPD with concerns that "SPD [was] marketing the [Product] in violation of the limitations in FDA's clearance letter." JA8207; SPA16. During the ensuing "mitigation" process, SPD proposed changes to its label, and FDA accepted, rejected, or suggested modifications to that language. JA8229-33. SPD's communications were with a "low-level" FDA employee, who eventually permitted SPD's revised advertising. SPD PFOF (Dkt. 370) ¶16.

SPD subsequently began using the Revised Package. SPA16-17. Like the Launch Package, the Revised Package does not disclose on either the front or back panel that its "weeks" estimate differs from a doctor's estimate. JA3374-83; JA9332-33. Indeed, the front and back panels of both packages include a caduceus, a "conventionalized symbol of the medical profession." SPA30 n.17.

B. Appellee C&D, SPD's main competitor in the home pregnancy test market, subsequently brought this suit, alleging that SPD's false and misleading advertising of the Product was deceiving consumers and injuring C&D's business, in violation of the Lanham Act. Before trial, the District Court rejected SPD's argument that C&D's Lanham Act claims were precluded by the FDCA. The court relied heavily on the Supreme Court's recent decision in *POM*, 134 S. Ct. 2228, which held that the FDCA does not preclude Lanham Act claims because the two statutes "serve different, but complementary purposes." SPA101-09.

The District Court subsequently held a two-week bench trial involving hundreds of exhibits and live testimony from 15 witnesses. The court issued a 54-page opinion finding that SPD engaged in an "egregious" false advertising campaign that was "intentionally designed to mislead consumers about the difference between the product's estimate of weeks since ovulation and a doctor's estimate of weeks pregnant." SPA1-54. The court held that SPD's Launch Package messaging was "unambiguous and literally false." SPA29. The court also applied a presumption—unrebutted by SPD—of consumer deception based on clear evidence that SPD "intentionally set out to deceive consumers and that this conduct was of an egregious nature." SPA33; *see* SPA19-27. And the court found the Revised Package impliedly false because "a substantial number of [survey] participants understood the Revised Package to communicate the message that the Weeks Estimator provides an estimate of weeks pregnant that is consistent with a doctor's estimate." SPA36-37. The court credited the testimony of C&D's expert and rejected SPD's "scattershot" technical challenges to the survey. SPA34-35.

Finding the other elements of a Lanham Act claim satisfied, SPA40-45, the District Court entered an injunction ordering SPD to cease communicating the false and misleading messages and to provide corrective disclosures, SPA49-50.

C. This Court unanimously affirmed. The Panel agreed with the District Court that *POM* controlled, finding "no reason why the subjugation of Defendant's

Product labeling to FDA regulation through the §510(k) process should categorically immunize it from Lanham Act claims by competitors regarding the regulated labeling." Op.24. The Court found SPD's belated reliance on *PLIVA*, 564 U.S. 604, to be "misplaced," as *POM* was the key precedent and *PLIVA* addressed distinct issues involving preemption of state law. Op.26.

Applying clear error review, the Panel also affirmed the District Court's extensive factual findings that the Launch Package and associated advertising falsely communicated that the Product measured "weeks" pregnant the same way a doctor would. Op.28-36. And the Panel further upheld the District Court's finding that the Revised Package was impliedly false. Op.36-40. Finally, the Panel affirmed the permanent injunction, which was well within the District Court's discretion to "cur[e] the effects of the harm caused by [SPD's] falsity." Op.45-46.

REASONS FOR DENYNG REHEARING

SPD bears the heavy burden of establishing that this case warrants rehearing by the Panel or the full Court. Its submission comes nowhere close. The tradition of deferring to panel decisions, rather than reconsidering cases en banc, "goes back a long way in the Second Circuit." Wilfred Feinberg, *Unique Customs and Practices of the Second Circuit*, 14 Hofstra L. Rev. 297, 311 (1986); *see also Landell v. Sorrell*, 406 F.3d 159, 165-67 (2d Cir. 2005) (Sack and Katzmann, J.J., concurring in denial of rehearing en banc). This is manifestly not the rare case that

presents a question of such exceptional importance that it warrants the full Court's attention, as the relevant legal principles are well-established and the facts giving rise to this dispute are unlikely to recur. Nor is there any basis for Panel rehearing, as the Panel's unanimous opinion faithfully applied settled Supreme Court and Second Circuit precedent to the unique facts of this case.

I. The Panel's Decision Faithfully Applies Supreme Court And Second Circuit Precedent Regarding Federal Preclusion.

SPD begins (at 6-11) by rehashing the same "preclusion" arguments that have been rejected by all four federal judges to consider these questions. Those arguments fare no better this time around.

A. The Supreme Court has held in no uncertain terms that the Lanham Act and FDCA "serve different, but complementary, purposes," and that nothing in the FDCA purports to foreclose Lanham Act claims. *POM*, 134 S. Ct. at 2234. The Lanham Act "protects commercial interests against unfair competition, while the FDCA protects public health and safety." *Id.* at 2238. The Panel correctly recognized that *POM* is the "controlling" precedent in this area, and is fatal to SPD's argument that C&D's Lanham Act claims are precluded. Op.24; *see also* SPA101-09.

SPD nonetheless asserts (at 8-9) that *POM* is inapposite because it involved the FDA's juice regulations, which "involved only a floor, *not a ceiling*," and that this case involves a regulatory "ceiling that prevents compliance with a Lanham

Act mandate in the absence of FDA approval." That argument is flawed on several levels. Even a cursory reading of *POM* makes clear that the Court's reasoning applies broadly and was not limited to the FDA's regulation of beverages: "neither the Lanham Act nor the FDCA, in express terms, forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA," and "the FDCA and the Lanham Act *complement each other in the federal regulation of misleading labels*." 134 S. Ct. at 2237, 2241 (emphasis added). All of that reasoning from a recent, on-point Supreme Court precedent is fully applicable here.

More fundamentally, SPD's premise that the FDA's clearance of the Product represented a regulatory "ceiling" is absurd. The FDA expressly warned SPD to the contrary in its clearance letter, which stated that FDA clearance "does not mean that FDA has made a determination that your device complies with other requirements of the [FDCA] *or any Federal statutes and regulations administered by other Federal agencies*." JA3370 (emphasis added). It thus strains credulity for SPD to suggest that FDA's clearance letter somehow constitutes a "ceiling" that immunizes it from liability under other federal statutes such as the Lanham Act.

B. SPD further contends (at 6-8) that *PLIVA v. Mensing*, 564 U.S. 604 (2011)—a preemption decision SPD did not even cite in its briefing before the District Court—forecloses C&D's Lanham Act claim. But *PLIVA* is inapposite, both factually and legally. In *PLIVA*, generic drug manufacturers bore no

responsibility for the "accuracy and adequacy of [their] label[s]." *Id.* at 613. Instead, federal law obligated the generics to use labeling *identical* to their brand-name counterparts. *Id.* Here, in contrast, it is undisputed that SPD prepared all of the labeling and advertising in question, and was perfectly free to propose labeling that complied with both the FDCA and the Lanham Act.[1] Indeed, SPD unilaterally *changed* the Launch Packaging from what the FDA had previously reviewed. *See* JA9499-504; JA8407; JA9187-97. SPD's own actions thus foreclose any suggestion that it "could not change its labeling once the FDA's painstaking Section 513 approval was completed," Pet.7, and nothing in the clearance letter prohibited changes so long as they complied with the limitations specified therein.

PLIVA is also inapposite because it addressed preemption of state law rather than preclusion of one federal statute by another. Op.27-28. The Supreme Court has emphasized that its preemption precedents "[do] not govern preclusion analysis," *POM*, 134 S.Ct. at 2236, and *PLIVA* says nothing about the circumstances in which an otherwise-permissible Lanham Act claim may be displaced by another federal statute. Contrary to SPD's contention (at 9-10), the Panel did not apply a "rigid distinction between preclusion and preemption." The Panel merely reached the unremarkable conclusion that the most pertinent

[1] For example, as the District Court found, during the clearance process SPD could have proposed labeling designed to mitigate consumer confusion about the Product's estimate of pregnancy length, but chose not to do so. SPA26.

precedent in a case about whether a Lanham Act claim is precluded by the FDCA is a recent Supreme Court case about whether a Lanham Act claim is precluded by the FDCA—namely, *POM*.

C. Finally, on October 5, 2016, SPD filed a 28(j) letter citing *Apotex* as a decision that supposedly supports its *PLIVA* argument and takes a "dramatically different" view of Lanham Act preclusion from the Panel's approach in this case. *Apotex* was decided in May 2016 while this case was *sub judice*, yet SPD did not bring that decision to the Panel's attention at that time, nor did SPD cite *Apotex* in its petition for rehearing (filed one month ago). Needless to say, a severely belated 28(j) letter in support of a rehearing petition is the wrong vehicle in which to attempt to air new legal arguments.

In all events, SPD's failure to timely cite *Apotex* was not some horrible oversight. *Apotex* does not support SPD's arguments and does not even cite *POM* or *PLIVA*. Before considering specific allegations concerning a pharmaceutical company's marketing efforts, the *Apotex* panel endorsed the view that "representations that are wholly *consistent* with an FDA label" generally cannot form the basis for Lanham Act liability. 823 F.3d at 64. As the decision makes clear, however, that observation was limited to the context of pharmaceutical marketing. *See id.* n.9 (citing district court decisions made "in the context of pharmaceutical drugs"). Here, however, SPD had much greater control over its

packaging and marketing than a pharmaceutical company has over its label. The FDA also intensified its scrutiny of the Product precisely because SPD's advertising campaign was *not* wholly consistent with the discrete limitations the FDA had requested. *See* JA3368-70. Indeed, after receiving FDA clearance for its "final" packaging, SPD brazenly marketed a different Launch Package without even notifying the FDA. JA9499-05; JA8407; JA9187-97.

Moreover, in language SPD ignores, the *Apotex* panel emphasized that "Lanham Act liability might arise if an advertisement uses information contained in an FDA-approved label that does not correspond to the label, *or otherwise renders the advertisement literally or implicitly false*." 823 F.3d at 64 n.10 (emphasis added). The District Court made exhaustive factual findings (affirmed by the Panel) that the Launch Packaging and Revised Packaging were "literally or implicitly false" because they falsely conveyed that the Product's estimate of "weeks" was the same as a doctor's estimate. In short, the "intra-circuit split" SPD imagines in its 28(j) letter simply does not exist, and nothing in *Apotex* provides a basis to upset the District Court's well-documented factual findings.

II. The Panel's Highly Fact-Specific Analysis Of The Poret Survey Does Not Warrant Rehearing.

Consumer surveys are an appropriate means of proving an advertisement's implied falsity. As this Court held in a case SPD itself cites, the "probative value of any given survey is a fact specific question that is uniquely contextual," and "it

[is] in the district court's province as trier of fact to weigh the evidence, and in particular the opinion research." *Johnson & Johnson * Merck Consumer Pharm. v. Smithkline Beecham*, 960 F.2d 294, 300-01 (2d Cir. 1992).

That is precisely what Judge Nathan did when she relied on the Poret survey as proof that a substantial percentage of survey participants understood the Revised Package to communicate the false message that the Product's estimate of "weeks" pregnant is the same estimate a doctor gives patients. SPA 36-37. At trial, SPD's survey expert criticized the Poret survey, including on the precise ground raised by SPD's petition—that allegedly it did not account for participants' pre-existing beliefs about how doctors measure pregnancy duration. After considering the dueling expert testimony, Judge Nathan concluded that "Mr. Poret's survey is reliable and [] SPD's criticisms are meritless." SPA 35. That finding was amply supported by Mr. Poret's testimony that he did account for possible pre-existing beliefs through the use of a control package, *see* JA9443; JA9451-52, which is the commonly accepted way to account for pre-existing beliefs. *See, e.g.,* S. Diamond, Reference Guide on Survey Research (3d ed. 2011) at 399; *Sanderson Farms v. Tyson Foods*, 547 F. Supp. 2d 491, 501 (D. Md. 2008) (control ad was appropriate method to adjust for all survey "noise," including "pre-existing beliefs"); *Merisant v. McNeil Nutritionals*, 242 F.R.D. 315, 324 n.7 (E.D. Pa. 2007) (same).

SPD's petition ignores both Mr. Poret's testimony and the District Court's

finding that his survey was reliable. Instead, SPD asserts (at 13-14) that the Panel's decision "sweeps … established law aside" by requiring sellers "not only to ensure that their advertising claims are truthful and not misleading but also to actively educate consumers to counteract misperceptions." But the Panel did no such thing. The Panel's holding is entirely consistent with this Court's long-established rule that a literally true advertising statement can still be actionable under the Lanham Act if, in context, it implies a false message. *See Time Warner Cable v. DIRECTV*, 497 F.3d 144, 153 (2d Cir. 2007).

The Panel correctly concluded that SPD was fully aware of—*and deliberately sought to exploit*—consumer ignorance about how the medical profession universally measures the advancement of pregnancy and how that universal convention relates to the estimates provided by the Product. Op. 34-36, 38-39. Even if there were a mistaken pre-existing belief among some consumers that doctors estimate pregnancy advancement based on ovulation, the Revised Package's labeling *perpetuated* that belief and took advantage of consumers' misunderstanding in an attempt to sell more products. *See*, *e.g.*, *JTH Tax v. H&R Block*, 128 F. Supp. 2d 926, 937 n.5 (E.D. Va. 2001) (defendants liable for implied false advertising, despite literal truth of key term in question, where "Defendants' own internal documents indicate their awareness of consumers' confusion regarding the term"), *aff'd in part and rev'd in part on other grounds*, 28 F. A'ppx

207 (4th Cir. 2002).

In each of the cases SPD cites (at 13-14), various district courts, exercising their broad discretion, found surveys flawed for reasons unique to those surveys and to the advertisements at issue. For example, in *Pharmacia v. GlaxoSmithKline Consumer Healthcare*, 292 F. Supp. 2d 594, 603 (D.N.J. 2003), the court merely addressed the validity of the control for the specific survey in that case. The *Pharmacia* court did not suggest that the survey in that case should have included questions about participants' pre-existing beliefs, much less (as SPD suggests) adopt a blanket Lanham Act rule requiring *all* surveys to include such questions.

As it did in its briefing before the Panel, SPD again relies heavily on *Mead Johnson v. Abbott Labs*, 201 F.3d 883 (7th Cir. 2000), but that decision is no more helpful to SPD this time around. All the court held there is that a Lanham Act plaintiff cannot use a survey to "determine the meaning of words, or to set the standard to which objectively verifiable claims must be held." *Id.* at 886. The court thus refused to rely on a survey that attempted to define the phrase "1st Choice of Doctors" as requiring an outright majority of doctors instead of just a plurality. *Id.* at 883-84. Nothing in that decision casts doubt on the use of a standard consumer survey to determine whether the labeling and messaging of the Revised Package here falsely conveyed that it was providing the same estimate of pregnancy duration as a doctor.

CONCLUSION

This Court should deny the petition for panel rehearing and rehearing en banc.

Respectfully submitted,

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October 28, 2016

CERTIFICATE OF COMPLIANCE
WITH TYPE-VOLUME LIMITATION

I hereby certify that:

1. This response to the petition for rehearing and rehearing en banc complies with the Court's October 5, 2016 order and the type-volume limitation of Fed. R. App. P. 40(b) because it does not exceed 15 double-spaced pages, excluding the exempted parts of the brief.

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2013 in 14-point font.

October 28, 2016

s/Paul D. Clement
Paul D. Clement

CERTIFICATE OF SERVICE

I hereby certify that, on October 28, 2016, an electronic copy of the foregoing Response to the Petition for Rehearing and Rehearing En Banc for Appellee was filed with the Clerk of Court using the ECF system and thereby served upon all counsel appearing in this case.

s/Paul D. Clement
Paul D. Clement