UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 5th day of December, two thousand sixteen.

PRESENT: PIERRE N. LEVAL,
RICHARD C. WESLEY,
Circuit Judges,
BRENDA K. SANNES,
*District Judge.**

CHURCH & DWIGHT CO., INC.,
Plaintiff-Appellee,

v. No. 15-2411-cv

SPD SWISS PRECISION DIAGNOSTICS, GMBH,
Defendant-Appellant.

IT IS HEREBY ORDERED that (1) Defendant-Appellant's petition for panel rehearing is DENIED and (2) the opinion issued on September 9, 2016 is amended as follows.

Following the conclusion of the sentence (at page 41, line 4) reading "Although the essential elements of the materiality standard . . . we need not resolve the issue now," a footnote is hereby added, reading as follows:

* The Honorable Brenda K. Sannes, of the United States District Court for the Northern District of New York, sitting by designation.

> *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51 (2d Cir. 2016), recently settled the materiality standard in this Circuit, explaining that the standard is whether the deception is "likely to influence purchasing decisions." *Id*. at 63; *See also id*. at 67. Consideration of the *Apotex* decision has no effect on our determination, as our analysis above assumes that the standard is exactly as *Apotex* decided.

Following the conclusion of the sentence (at page 46, line 14) reading "We have considered Defendant's other arguments, and find them to be without merit," a footnote is hereby added, reading as follows:

> Defendant contends, in a petition for rehearing, that our decision cannot be reconciled with *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51 (2d Cir. 2016). We disagree. If there is some tension between our decision and *Apotex*, it is only a tension of emphasis, not content. There are at least three reasons why our decision is not incompatible with *Apotex*.
>
> First, *Apotex*'s holding does not purport to exclude all claims of falsity in an FDA-approved message. The decision indeed stated that "representations commensurate with information in an FDA label *generally*" will not be actionable under the Lanham Act, *id*. at 64 (emphasis added), but went on to acknowledge (in a footnote following this sentence) that "Lanham Act liability might arise if an advertisement us[ing] information contained in an FDA-approved label. . . [is] literally or implicitly false," *id*. at 64 n.10. That is the circumstance we have here.
>
> Second, this case and *Apotex* involve different questions of law. In *Apotex*, the propriety of the court's consideration of the claim was assumed. The issue was whether aspects of the defendant's advertising incorporating FDA-approved factual assertions about pharmacological effects of its product were nonetheless false. Here, in contrast, the question is whether the court may even entertain a claim of falsity relating to FDA-approved messaging, or whether such a claim is legally *precluded*, so that a court may not even consider the claim but must dismiss it without consideration of whether the advertising or labeling in fact misleads. As explained above, the question was answered by the Supreme Court in *POM Wonderful*, which clearly held that a Lanham Act claim is not precluded by FDA approval because the Lanham Act and the FDCA serve distinct purposes. The *Apotex* decision contained no suggestion that a court is precluded by law from entertaining such a claim of falsity. Indeed, it explicitly acknowledged that

"Lanham act liability might arise . . . [in cases where] the advertisement [is] literally or implicitly false." *Id*. at 64 n.10.

Finally, the Lanham Act claims in the two cases relate to significantly different aspects of the FDA's competence. The inquiry here does not relate to the truth or falsity of an FDA-approved factual assertion about the effects of a medical product, but rather to the question of whether the phrasing of advertising messages might be misunderstood by consumers. The contention in *Apotex* was that a fact about the pharmacological effects of a drug, which the FDA had determined to be true, should nonetheless be found by the court to be false. We ruled against the claim, noting that the FDA, as the agency responsible for approving the truthfulness of the content of the label, had expertise in the matter and had devoted exhaustive process to the inquiry, which justified court deference to its determination of truthfulness. *Id*. at 64. Here, in contrast, there is no claim that any fact relating to the effects of a medical product found by the FDA to be true should nonetheless be found by the court to be false. What is at issue is whether messages that the FDA has concluded are not misleading are nonetheless susceptible to being misunderstood by the consuming public. We have not second-guessed the FDA on matters as to which its competence vastly exceeds that of courts.

For these reasons, we have concluded that there is no inconsistency between our holding and *Apotex*, and have denied Defendant's petition for rehearing.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk of Court