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Update on Second Circuit Ruling in Church & Dwight v. SPD Swiss Precision Diagnostics "Weeks Estimator" Home Pregnancy Test Litigation

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Last month we summarized the Second Circuit's important decision in a dispute between plaintiff-appellee Church & Dwight and its principal competitor, defendant-appellant SPD Swiss Precision Diagnostics, concerning SPD's false advertising of its Clearblue Weeks Estimator Home Pregnancy Test. As we reported, a Second Circuit panel in September unanimously affirmed rulings by Judge Alison Nathan of the Southern District of New York (i) that SPD was liable for "intentional" and "egregious" false advertising, and (ii) ordering permanent injunctive relief that included a nationwide recall of Weeks Estimator packaging that the district court found to be misleading. Following the panel's decision, SPD petitioned the Second Circuit for rehearing by the panel or, in the alternative, rehearing *en banc*.

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Communications, Media & Internet
Litigation / Trial Practice
2nd Circuit (incl. bankruptcy)

In its petition, SPD argued that the panel erred by declining to hold that Church & Dwight's Lanham Act claim was precluded by the FDA's regulation of the Weeks Estimator's labeling through the Food, Drug & Cosmetics Act (FDCA) § 510(k) process. SPD contended that a 2011 Supreme Court decision called *PLIVA v. Mensing* was the controlling authority on this issue, not the Supreme Court's subsequent 2014 decision in *POM Wonderful v. Coca-Cola* on which the panel relied, despite that *POM Wonderful* expressly held that Congress did not intend for the FDCA to preclude Lanham Act false advertising claims, whereas *PLIVA* concerned state tort law preemption, not federal preclusion. SPD also argued that the panel decision was inconsistent with the decision of another Second Circuit panel in *Apotex v. Acorda Therapeutics*, 823 F.3d 51 (2d Cir. 2016), decided a few months before the panel decision in the SPD case. Finally, SPD's rehearing petition also disputed the panel's agreement with the district court's reliance on a survey Church & Dwight offered concerning the messages communicated by SPD's current Weeks Estimator package.

None of SPD's rehearing arguments proved successful, as earlier this month, SPD's petitions for panel and *en banc* rehearing were denied without reported dissent.

Shortly after the rehearing petition was denied, the panel amended its earlier opinion to specifically address the *Apotex* decision, which SPD never raised while its appeal was pending before the panel. The panel first noted that *Apotex* had recently settled the Circuit's materiality standard to require a showing that deception resulting from a false advertisement is "likely to influence purchasing decisions." The panel explained that *Apotex* had "no effect on [the panel's] determination, as [the panel's] analysis [in the original appeal decision] assume[d] that the standard [was] exactly as *Apotex* decided."

The panel also added a footnote explaining why *Apotex*, which held that "representations commensurate with information in an FDA label generally cannot form the basis for Lanham Act liability," was entirely compatible with its decision that Church & Dwight's Lanham Act claim was not precluded by the FDCA. First, the panel noted that *Apotex* expressly left open that "Lanham Act liability might arise if an advertisement us[ing] information contained in an FDA-approved label . . . [is] literally or implicitly false." As the district court found and the panel affirmed, SPD's advertising was literally and/or impliedly false.

Second, the panel observed that *Apotex* assumed the ability in a Lanham Act case to determine whether certain FDA-approved factual assertions were false, whereas this case concerned Church & Dwight's right to challenge

SPD's FDA-cleared messaging in the first place, and that the Supreme Court's *POM Wonderful* decision, which *Apotex* did not cite, made clear that Church & Dwight had that right. Finally, the panel pointed out that *Apotex* implicated a different aspect of the FDA's competence than the case at hand. In *Apotex*, the Court deferred to the FDA's expertise concerning and exhaustive review of whether a drug had certain pharmacological effects. This case, on the other hand, involved "the question of whether the phrasing of advertising messages might be misunderstood by consumers," which was not an issue where the FDA's competence vastly exceeds that of courts.