

POM Wonderful Returns – Lanham Act False Advertising Claim Against Home Pregnancy Tests Not Precluded by FDCA

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On September 9, 2016, the Court of Appeals for the Second Circuit issued an interesting decision in a false advertising case involving a dispute between competitors in the home pregnancy testing market.

Church & Dwight Co. v. SPD Swiss Precision Diagnostics GMBH. The

opinion addressed whether the Food, Drug and Cosmetic Act (FDCA) precluded the plaintiff's Lanham Act false advertising claims and also confirmed the standards for liability applicable to statements that are expressly false, false by necessary implication and impliedly false. This post will focus on the FDCA claim preclusion aspects of the Second Circuit's opinion.

SPD's packaging and advertising for its Clearblue Advanced Pregnancy Test with Weeks Estimator represented that the product could provide information about how many weeks a pregnancy had advanced. The product was capable of estimating the length of pregnancy since the date of last ovulation. This is not the standard metric commonly used by the medical profession to describe how long a woman has been pregnant. The standard metric relies on the weeks elapsed since the woman's last menstrual period. The crux of Church & Dwight's claims was that the packaging and advertising for SPD's Clearblue product communicated the false message that the products used the same metric and gave information about the same number of weeks of pregnancy as would be provided by a medical professional. The district court found that SPD had deliberately set out to deceive consumers into believing that the Clearblue products would provide a measure of weeks pregnant consistent with what doctors provide, and held SPD liable for false advertising under several different theories. The court issued an extremely broad injunction that included the required removal of current products from points of sale; prohibition of use of such terms as "weeks pregnant" and "Weeks Estimator"; a corrective notice delivered to retailers and distributors; and further corrective notices to

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be made available at trade shows, professional meetings, on SPD's website and YouTube channel and in internet banner advertising. The Second Circuit affirmed.

No Preclusion of Lanham Act Claims

The first issue addressed in *Church & Dwight* was whether the U.S. Supreme Court's June 2014 decision in *POM Wonderful LLC v. Coca-Cola* applied to a home pregnancy test classified as a Class II medical device by FDA. *POM Wonderful* held that Lanham Act false advertising claims asserted against juice beverage products were not precluded by the FDCA because the two federal statutes were complementary. As the Supreme Court observed, competitors will have an awareness of unfair competition practices that "may be far more immediate and accurate than that of agency rulemakers and regulators;" the Lanham Act draws upon this "market expertise." Significantly in *POM Wonderful*, the products at issue – Minute Maid Juice Blends – are not subject to an FDA pre-approval process for sales and advertising. Rather, for beverages, FDA relies on after-the-fact enforcement actions. Because FDA does not necessarily pursue all violations, the Supreme Court deemed it necessary to preserve the ability of competitors to protect their commercial interests and the public against false and misleading claims. After the *POM Wonderful* decision was rendered, commentators immediately observed that the holding was likely to be applied to other product categories regulated by FDA. And so it was in *Church & Dwight*.

The Second Circuit held that *POM Wonderful* was "controlling" on the issue of preclusion, even though there were material differences in the way in which FDA regulates beverages vs. home pregnancy tests. As a Class II medical device, SPD's home pregnancy test required the submission of a "premarket notification" to FDA under Section 510(k) of the FDCA, including proposed labeling, so that FDA could determine if the device was "substantially equivalent" to an existing authorized device. In the case of the Clearblue product, FDA issued a "hold letter," expressing concern that the "weeks" indicator feature could provide misleading information to users. After SPD made changes to its labeling in negotiation with FDA, the agency issued a "clearance letter" that specifically required SPD to use certain labeling language and a conversion chart that would clarify how a doctor would date a woman's pregnancy as compared with the product's test results. FDA also specified that SPD could only advertise its products as providing information about "weeks since ovulation" rather than weeks pregnant.

SPD argued on appeal that *POM Wonderful* was distinguishable based on the more intensive, premarket approval regulatory process applicable to home pregnancy kits and the fact that FDA had issued a clearance letter with specific instructions on how the Clearblue products should be marketed. The Second Circuit rejected these arguments, stating: "The fact that the FDA has satisfied itself that a product's labeling is sufficiently accurate to secure FDA approval gives no assurance that the intervention of a competitor would not reveal problematic misleading messaging that is harmful to the competitor's interest, which the federal agency either overlooked or failed to appreciate as important." The court further noted that *POM Wonderful* had explicitly rejected the argument that a claim would be precluded to the extent the FDCA or FDA regulations

specifically required or authorized aspects of a label later challenged under the Lanham Act because “FDA’s requirements are a floor, not a ceiling.”

Having determined that Church & Dwight’s claims against SPD were not precluded by the FDCA, the court went on to address the district court’s findings of liability for false advertising. Stay tuned for Part 2 of this post!