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October 5, 2016

Catherine O'Hagan Wolfe
Clerk of Court
U.S. Court of Appeals for the Second Circuit
40 Foley Square
New York, NY 10007

Re: *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics*, No. 15-2411-cv (petition for panel and *en banc* rehearing filed Sept. 23, 2016)

Dear Ms. Wolfe:

I am writing on behalf of SPD to inform the panel and the *en banc* Court of a decision that recently came to my attention—*Apotex, Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51 (2nd Cir. 2016).

Apotex supports SPD's pending petition for rehearing, which argues that the Federal Food Drug and Cosmetic Act precludes Lanham Act liability for SPD's use of FDA-required packaging. Pet. 6-11. *Apotex* involved Lanham Act claims based on the advertising for a medication. Op. 4-6. Before turning to Apotex's argument that Acorda's advertising claims were inconsistent with the medication's FDA label, this Court addressed the "prior question" of "whether representations that are wholly *consistent* with an FDA label are subject to Lanham Act liability." *Id*. at 25-26. The Court held that "representations commensurate with information in an FDA label generally cannot form the basis for Lanham Act liability." *Id.* at 26. By contrast, the panel opinion here held that C&D's Lanham Act claims were not precluded by the FDCA even though such claims were premised on a *mandated* product name and labeling that could not be changed without FDA approval.

These two published decisions, issued within months of each other, take dramatically different views on the validity of Lanham Act claims that conflict with FDA requirements for highly-regulated medical products, causing considerable confusion for companies. Indeed, the uncertainty caused by this intra-circuit split was recently highlighted in an article calling the two decisions "incompatible" and noting that this Court now lacks clear rules for advertising products falling into the "'one-fifth to one-quarter of U.S. gross domestic product'" regulated by the FDA. Robert L. Rouder et al., *2nd Circ. Creates Confusion For FDA-Vetted Marketers*, Law360, Sept. 29, 2016, http://www.law360.com/lifesciences/articles/844730/2nd-circ-creates-confusion-for-fda-vetted-marketers (quoting Marc T. Law, History of Food and Drug Regulation in the United States, EH.Net Encyclopedia (Oct. 11, 2004)).

Apotex thus reinforces that, as discussed in SPD's petition, rehearing is necessary to clarify the law in this Circuit with respect to the scope of Lanham Act liability for FDA-mandated product labeling and to bring this Court's precedent into line with controlling Supreme Court authority.

Respectfully,

/s/ Seth P. Waxman
Seth P. Waxman

Counsel for Defendant-Appellant
SPD Swiss Precision Diagnostics GmbH

cc: Counsel of Record

14-4353-cv
Apotex Inc., et al., v. Acorda Therapeutics, Inc.

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

August Term, 2015

(Argued: November 12, 2015 Decided: May 16, 2016)

Docket No. 14-4353-cv

- -x

APOTEX INC., et al.,

Plaintiffs-Appellants,

- v.-

ACORDA THERAPEUTICS, INC.,

Defendant-Appellee.

- -x

Before: JACOBS, LIVINGSTON and DRONEY, Circuit Judges.

This appeal concerns two distinct questions: the circumstances under which the filing of a citizen petition with the Food and Drug Administration provides grounds for an antitrust claim, and the scope of false advertising

liability under the Lanham Act. Plaintiffs Apotex Incorporated and Apotex Corporation appeal from the judgment of the United States District Court for the Southern District of New York (Swain, J.) that granted defendant Acorda Therapeutics, Inc.'s motion to dismiss plaintiffs' Sherman Act claim and that granted summary judgment in favor of defendant on the Lanham Act claims (Torres, J.). Because each of these conclusions was sound, we affirm.

KEITH D. PARR (with Joseph N. Froehlich, Scott B. Feder, Hugh S. Balsam, James T. Peterka, and Andy J. Miller on the brief), Locke Lord LLP, Chicago, Illinois, for Appellants Apotex Incorporated & Apotex Corporation.

JOHN W. NIELDS, JR. (with Jason C. Raofield and Colin P. Watson on the brief), Covington & Burling LLP, Washington, D.C. for Appellee Acorda Therapeutics, Inc.

DENNIS JACOBS, Circuit Judge:

The parties are rival manufacturers of tizanidine, a drug for treating spasticity. Plaintiffs Apotex Incorporated and Apotex Corporation (collectively "Apotex") allege that defendant Acorda Therapeutics, Inc. ("Acorda") (i) filed a sham citizen petition with the Food and Drug Administration ("FDA") to hinder approval of Apotex's competing formulation in violation of Section Two of the

Sherman Act, and (ii) violated the Lanham Act's proscription on false advertising. As relevant here, the competition between the manufacturers focused on the relative efficacy of tablets or capsules in controlling somnolence, one of the side effects of tizanidine.

The United States District Court for the Southern District of New York (Swain, J.) ruled that the simultaneous approval by the FDA of Apotex's drug application and its denial of Acorda's citizen petition (raising concerns about the application) was by itself insufficient to support a Sherman Act claim. After discovery, the district court (Torres, J.) granted summary judgment and dismissed all of Apotex's false advertising claims on the grounds that (with the exception of one graph) no representation was literally false or likely to mislead consumers; and that, as to that one graph, Apotex failed to show that the false depiction would meaningfully impact consumers' purchasing decisions.

Apotex appeals both rulings, arguing that precedent from this Court allows its antitrust claim to survive dismissal and that material issues of fact pertinent to Acorda's representations remain for a jury to decide. We affirm these rulings.

Although precedent supports an inference that a citizen petition is an anticompetitive weapon if it attacks a rival drug application and is denied the same day that the application is approved, that inference has been undercut by recent FDA guidance. As to false advertising, we agree with the district court that no reasonable jury could have found that Acorda made literally false or misleading representations in its advertisements, with the exception of a single representation that Apotex has failed to show affected decisions to purchase.

BACKGROUND

Tizanidine tablets are used to treat spasticity, a symptom of multiple sclerosis and Parkinson's disease. One of the tablets' most common side effects is somnolence: sleepiness or drowsiness. Tizanidine tablets were first marketed in the United States by Elan Pharmaceuticals, Inc. ("Elan"), under the trade name "Zanaflex." (Elan later sold its rights to Acorda.)

Zanaflex tablets were initially approved for sale by the FDA on November 27, 1996. In October 2001, Elan submitted a New Drug Application ("NDA") to the FDA seeking approval to market tizanidine in capsule form. During its review, the FDA concluded that the absorption of the drug was delayed when

tizanidine capsules were taken with food (rather than without), and that the delay was associated with a mean 20 percent decrease in Cmax, the peak amount of the drug in a subject's bloodstream. More importantly, the FDA found that "[w]hen bioequivalence of *the capsule relative to the tablet* is examined under fed conditions [i.e., with food], there is a delay in absorption and the mean Cmax for the capsule is approximately 2/3 of the mean Cmax for the tablet (Figure 1)." Joint Appendix at 2230 (emphasis added). The FDA subsequently approved Elan's NDA on August 29, 2002.

The significance of this phenomenon, in plain terms, is that the faster the drug is absorbed, the more drowsy the patient may become, whereas the side effect may be reduced if absorption is slowed.

While the NDA was pending, Elan filed a patent application for methods of administering tizanidine capsules to reduce somnolence and Cmax. Less than a month after the FDA approved the NDA, Elan's patent issued as United States Patent No. 6,455,557 ("the '557 patent"). Elan then received permission to market its newly approved tizanidine capsules under the trade name "Zanaflex Capsules." In July 2004, Acorda acquired the rights to Zanaflex tablets and Zanaflex Capsules; in April 2005, it launched the sale of Zanaflex Capsules.

Apotex had begun selling its generic tizanidine tablet product in 2004, and was one of about ten companies to do so. At the time Acorda began selling Zanaflex Capsules, Apotex's tizanidine tablet product had a five percent market share.

Zanaflex Capsules on the open market carried an FDA label pertaining both to the Capsules and the tablets. The preamble to this label invites doctors to distinguish between tablets and Capsules, and between the drug when taken with food and without:

> PHARMACOKINETIC DIFFERENCES BETWEEN ZANAFLEX CAPSULES™ AND ZANAFLEX® TABLETS: ZANAFLEX CAPSULES™ ARE NOT BIOEQUIVALENT TO ZANAFLEX® TABLETS IN THE FED STATE. THE PRESCRIBER SHOULD BE THOROUGHLY FAMILIAR WITH THE COMPLEX EFFECTS OF FOOD ON TIZANIDINE PHARMACOKINETICS (see PHARMACOKINETICS and DOSAGE AND ADMINISTRATION).

Joint Appendix at 643. The Pharmacokinetics section of the label, under the subheading "Pharmacokinetic differences between Zanaflex Capsules™ and Zanaflex® Tablets," advises (consistent with the FDA review of the Zanaflex Capsules NDA) that there is a 30 percent increase in Cmax when the tablets are administered with food, but that when the Capsules are administered with food, Cmax decreases by 20 percent. "Consequently, the mean Cmax for the [C]apsule

when administered with food is approximately 2/3's the Cmax for the tablet when administered with food." Id.

The label contains a graph that figures in a number of the false advertising claims. Referred to as "Figure 1," the graph is titled "Mean Tizanidine Concentration vs. Time Profiles for Zanaflex Tablets and Capsules (2 × 4 mg) Under Fasted and Fed Conditions." It displays the mean plasma tizanidine concentration at various hours from dosing. The peak for the curve representing tizanidine capsules (taken with food) is lower, and occurs later than the peak for the curve charting concentration over time for tizanidine tablets (taken with food).

The label then explains, in the Dosage and Administration section, that pharmacokinetic differences between the fed and fasted state may affect the

frequency and onset of certain adverse events. (The text is in the margin.[1]) Somnolence is explicitly identified as one of these adverse events.[2]

In 2007, Apotex filed an Abbreviated New Drug Application ("ANDA")--a filing that seeks generic drug approval for an existing licensed medication or approved drug--in order to sell generic tizanidine capsules which would provide competition to Acorda's Zanaflex Capsules. In the ANDA, Apotex certified that it was not encroaching on any validly claimed intellectual property rights because the '557 patent was invalid. In predictable response, Acorda filed a patent-infringement suit in 2007. After a seven-day bench trial, the United States District Court for the District of New Jersey (Brown, J.) ruled in September 2011

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[1] "These pharmacokinetic differences may result in clinically significant differences when [1] switching administration of the tablet between the fed or fasted state, [2] switching administration of the capsule between the fed or fasted state, [and] [3] switching between the tablet and capsule in the fed state . . . . These changes may result in increased adverse events or delayed/more rapid onset of activity, depending upon the nature of the switch. For this reason, the prescriber should be thoroughly familiar with the changes in kinetics associated with these different conditions . . . ." Joint Appendix at 646.

[2] The FDA's Medical Review of the Zanaflex Capsules NDA observed: "The most problematic potential situation is that of patients switching from the capsule formulation to the tablet formulation in the fed state, where there is a risk of more severe side effects with excessive hypertension and somnolence." Id. at 2102 (emphasis omitted).

that the '557 patent was invalid. See Acorda Therapeutics Inc. v. Apotex Inc., No. 07-4937 (GEB-MCA), 2011 WL 4074116, at *27 (D.N.J. Sept. 6, 2011).

Soon after that ruling, Acorda filed a citizen petition with the FDA raising problems with Apotex's ANDA. The citizen petition is a means afforded by the FDA for raising concerns about products the FDA reviews; any individual may file such a petition concerning scientific or legal issues before or while the product is on the market. See 21 C.F.R. § 10.30. Conceptually, citizen petitions provide an avenue for public input into the drug approval process; but the process has been abused by pharmaceutical companies that file meritless petitions intended to delay approvals sought by their competitors and inhibit competition. Acorda's citizen petition objected to (1) Apotex's statement that its product was bioequivalent to Reference Listed Drugs (RLDs) in the fed state; and (2) allegedly misleading or untrue statements in the proposed label for the Apotex ANDA.

The FDA denied Acorda's citizen petition on February 3, 2012. That same day, the FDA approved Apotex's ANDA. The Sherman Act claim relies principally on the FDA's simultaneous dispositions.

With the green light from the FDA, Apotex launched its product. Acorda countered with its own authorized generic version of Zanaflex Capsules. Apotex contends that in the course of Acorda's marketing: (1) its representatives misrepresented to doctors that Zanaflex Capsules reduced Cmax--in comparison with the tablets--and then improperly used reduction in Cmax as a proxy for a corresponding decrease in somnolence; and (2) Acorda distributed written promotional materials to the same effect. In total, Acorda's advertising efforts contributed to sales of more than $240 million attributable to its version of Zanaflex Capsules.

Apotex commenced this lawsuit in December 2011, amending its complaint in February 2012 to include the FDA's denial of Acorda's citizen petition. Acorda countered with a motion to dismiss, which the district court (Swain, J.) granted with respect to the Sherman Act claim and denied with respect to the Lanham Act claims. The district court observed that Apotex's Sherman Act claim relied purely on temporal proximity--the denial of Acorda's citizen petition on the same day the Apotex ANDA was approved--and concluded that was insufficient to state a claim in view of recent legislation making the requirements for delaying an ANDA application more stringent: "Congress'[s] explicit directive that ANDA

processing should not ordinarily be delayed by a citizen petition, coupled with its narrowing for the grounds for any such delay and the statutory notice requirement, strongly undermines any inference that mere simultaneity of ANDA and citizen petition decisions is indicative of the delay of one by reason of pendency of the other." Apotex Inc. et al., v. Acorda Therapeutics, Inc., No. 1:11-cv-8803 (S.D.N.Y. Feb. 7, 2013), Doc. 45 at 7 (Swain, J.) ("Apotex I") . Apotex moved for leave to amend, but the motion was denied in the interest of judicial economy.

After the case was reassigned to Judge Torres, Acorda successfully moved for summary judgment on the Lanham Act claims. Judge Torres began the analysis with the principle that: "[i]n the context of pharmaceutical drugs, courts have generally rejected Lanham Act claims based on advertisements that merely repeat labeling information that has been approved by the FDA." Apotex Inc. v. Acorda Therapeutics, Inc., No. 11-cv-8803(AT), 2014 WL 5462547, at *3 (S.D.N.Y. Oct. 23, 2014) (Torres, J.) ("Apotex II") (quoting Mylan Pharms., Inc. v. Proctor & Gamble Co., 443 F. Supp. 2d 453, 460 (S.D.N.Y. 2006)). The court held that because many of the allegedly false representations were "consistent with the product label," Apotex failed to identify a genuine issue of material fact with

respect to falsity of any of Acorda's representations, except one. Id. at *5. The remaining representation was Acorda's placement of Cmax data on Figure 1, as to which the district court found that "a reasonable juror could determine that the juxtaposition of this text and image communicates a literally false message." Id. at *8. Nevertheless, the claim did not survive because Apotex failed to identify a material issue of fact as to the representation's bearing on decisions to purchase. See id. at *9.

Apotex appeals both decisions.

DISCUSSION

Apotex's Sherman Act claim was dispatched at the motion-to-dismiss stage, while its Lanham Act claims succumbed on summary judgment. "On a motion to dismiss, all factual allegations in the complaint are accepted as true and all inferences are drawn in the plaintiff's favor." Littlejohn v. City of N.Y., 795 F.3d 297, 306 (2d Cir. 2015). We review de novo a "district court's grant of a motion to dismiss under Rule 12(b)(6)." Id. And we "review a district court's denial of leave to amend for abuse of discretion." Presbyterian Church of Sudan

v. Talisman Energy, Inc., 582 F.3d 244, 267 (2d Cir. 2009).

Summary judgment "is appropriate when, having resolved all ambiguities and permissible factual inferences in favor of the party against whom summary judgment is sought, there are no genuine issues of material fact in dispute and the movant is entitled to judgment as a matter of law." Baez v. JetBlue Airways Corp., 793 F.3d 269, 273 (2d Cir. 2015). "A genuine issue of material fact exists 'if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.'" Savino v. City of N.Y., 331 F.3d 63, 71 (2d Cir. 2003) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)). The grant of summary judgment in favor of Acorda is likewise subject to de novo review. See Baez, 793 F.3d at 273-74.

I

The claim that Acorda's filing of a sham citizen petition constitutes illegal monopolization arises under Section Two of the Sherman Act, which imposes liability on: "[e]very person who shall monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several [s]tates . . . ." 15 U.S.C. § 2. A complaint alleging that a competitor filed a sham citizen petition with the FDA

states a claim under that section. See In re DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677, 694 (2d Cir. 2009). For these purposes, a single sham petition may be analogized to a single sham litigation. "A single lawsuit can violate antitrust law as long as it is both an objective and subjective sham." Id. at 686. "First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits . . . . [S]econd . . . , the court should focus on whether the baseless lawsuit conceals 'an attempt to interfere *directly* with the business relationships of a competitor.'" Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60 (1993) (emphasis in original) (quoting E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961)). Because we conclude that Apotex has failed to show that Acorda's citizen petition was objectively baseless, we affirm on the first ground and do not reach the second.

As relevant here, the factual basis for the claim in DDAVP was "that the sham petition caused a delay in generic competition, a possibility reinforced by the fact that the FDA approved the generic drug on the same day that it rejected the petition." 585 F.3d at 694. Given the simultaneous grant of the ANDA and denial of the citizen petition, Apotex argues that a straightforward application of

DDAVP justifies reversal: "the possibility that the petition was a sham, and that it impacted the FDA's decision, is sufficiently plausible to defeat the motion to dismiss." Id. at 695.

However, the FDA issued a new Guidance for Industry ("Guidance") explaining how the FDA determines if a petition implicates an issue of public health, and how the FDA's decision-making process is affected by the simultaneous pendency of an ANDA application and a citizen petition dealing with the same drug. Although this case partially arises on a motion to dismiss, we may properly take judicial notice of this document (without converting Acorda's motion to dismiss into a motion for summary judgment) because the Guidance is publicly available and its accuracy cannot reasonably be questioned. See FED. R. EVID. 201(b); Staehr v. Hartford Fin. Servs. Grp., Inc., 547 F.3d 406, 425 (2d Cir. 2008) ("Although the general rule is that a district court may not look outside the complaint and the documents attached thereto in ruling on a Rule 12(b) motion to dismiss, we have acknowledged that the court 'may also consider matters of which judicial notice may be taken.'" (quoting Kramer v. Time Warner

Inc., 937 F.2d 767, 773 (2d Cir. 1991))).[3]

The Guidance explains: "If a petition requests that the Agency take an action related to a specific aspect of a pending application, we *will consider the review status of the affected application(s)* in determining whether it would be appropriate for the Agency to respond to the request to take the action requested in the petition within the 180-day timeframe." Joint Appendix at 530 (emphasis added). Such consideration is necessary because of the differing procedural rights of an ANDA applicant and the writer of a citizen petition. "[T]he Agency must give the [ANDA] applicant notice of an opportunity for a hearing on whether the application is approvable, with a specific timeframe and process should the applicant request such a hearing." Id. at 531. FDA decisions adjudicating citizen petitions, on the other hand, "are subject to immediate review by the courts. They therefore carry with them none of the procedural rights for the affected applicants that attach to a decision to deny approval of an application." Id. To bring these procedural arrangements into sync, the FDA

[3] The document can be accessed at the following website: Food and Drug Administration, Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act-Guidance for Industry (June 8, 2011), http://www.regulations.gov/#!documentDetail;D=FDA-2009-D-0008-0011.

states that it is preferable not to issue a decision on a citizen petition until it issues a decision on the corresponding ANDA application. See id. ("If we were to respond substantively to a petitioner's request regarding the approvability of . . . the application as a whole, such [a] response could interfere with the statutory and regulatory scheme governing the review of applications and related procedural rights of applicants.").

Although it remains conceivable, notwithstanding the Guidance, that a citizen petition might cause anticompetitive delay, the Guidance tends to undermine the inference (drawn in DDAVP and advocated now by Apotex) that when a citizen petition is denied simultaneously with the grant of an ANDA petition, the citizen petition was a sham and an anticompetitive weapon. The Guidance favors contemporaneous adjudications to safeguard the procedural rights of ANDA applicants such as Apotex.[4]

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[4] While DDAVP was pending on appeal, Congress promulgated the Food and Drug Administration Amendments Act ("FDAAA"), which provides in part that consideration of a citizen petition shall not delay FDA approval of an ANDA unless a "delay is necessary to protect the public health." 21 U.S.C. § 355(q)(1)(A)(ii). If the FDA determines that delay is necessary, it must give notice to the applicant "not later than 30 days after making such [a] determination" along with a brief summary of the "specific substantive issues raised in the petition which form the basis of the determination." Id. § (B). However, it is not evident that the FDAAA has curbed all abuses of the citizen petition process.

Apotex has pled no other facts from which it can plausibly be inferred that Acorda's petition was a sham. Apotex alleges that, in the patent trial, Acorda falsely mischaracterized testimony and scientific evidence relating to the bioequivalence of Apotex's product. But that allegation shows that Apotex disagreed with the arguments Acorda advanced in its citizen petition (which is hardly surprising), not that the Acorda citizen petition was a sham.[5]

The FDA letter rejecting Acorda's citizen petition reinforces this conclusion.[6] Although Acorda's objections to Apotex's ANDA based on

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See Michael Carrier & Daryl Wander, Citizen Petitions: An Empirical Study, 34 CARDOZO L. REV. 249, 283 (2012) ("[W]hat is clear is that the 2007 amendment has not been successful in achieving its stated purposes . . . . [T]o date, the amendment has not reduced the number of unsuccessful (in other words, denied or essentially denied) citizen petitions that appear to be filed to delay generic competition."). We cannot foreclose the possibility that Sherman Act liability might be predicated on the time taken for the FDA to decide whether a citizen petition raises a legitimate public health concern. But, for reasons explained below, Apotex has not plausibly pled any such anticompetitive delay here.

[5] Apotex's assertions that Acorda falsely mischaracterized trial testimony and misrepresented Apotex's bioequivalence studies are legal contentions, not factual allegations, and therefore need not be credited. See Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) ("[O]n a motion to dismiss, courts 'are not bound to accept as true a legal conclusion couched as a factual allegation.'" (quoting Papasan v. Allain, 478 U.S. 265, 286 (1986))).

[6] We may consider this document because the pleading "'relies heavily upon its terms and effect,' which renders the document 'integral' to the complaint." Chambers v. Time Warner, Inc., 282 F.3d 147, 153 (2d Cir. 2002) (quoting Int'l

bioequivalence left the FDA unpersuaded, the grounds for rejection were: (1) Acorda's use of arithmetic mean values for Cmax instead of geometric mean values; and (2) Acorda's reliance on a cross-study comparison. Nowhere does the FDA find that Acorda misrepresented testimony in the Apotex-Acorda patent litigation. See Joint Appendix at 416-17 n.5 ("The Agency is not a party to that proceeding, and statements made in private litigation are not directly relevant to FDA's statutory obligation to determine the approvability of Apotex's ANDA.").

Similarly, with respect to Acorda's labeling argument, the FDA "disagree[d]" with Acorda that the Cmax of Apotex's product in the fed state was increased compared to the RLDs. Id. at 420. Apotex elides the distinction between arguments that fail to move the FDA and arguments that are false and objectively baseless. As the Supreme Court has cautioned, courts need to "'resist the understandable temptation to engage in *post hoc* reasoning by concluding' that an ultimately unsuccessful 'action must have been unreasonable or without foundation.'" Real Estate Inv'rs, 508 U.S. at 60 n.5 (quoting Christiansburg Garment Co. v. Equal Emp't Opportunity Comm'n, 434 U.S. 412, 421-22 (1978)). Accordingly, the objective component of Apotex's claim is lacking; so there is no

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Audiotext Network, Inc. v. Am. Tel. & Tel. Co., 62 F.3d 69, 72 (2d Cir. 1995)).

need to evaluate Acorda's subjective motivations in filing the petition.

Apotex relies on In re Suboxone Antitrust Litig., 64 F. Supp. 3d 665, 690-91 (E.D. Pa. 2014), which is inapposite. The district court in Suboxone held that a Section Two claim based on the filing of a sham citizen petition survived dismissal because of the many indicia that the petition was objectively baseless. Among the indicia: the "FDA acknowledged in its ruling that it had no authority to grant much of [the] requested relief," id. at 689; and the competitor that filed the citizen petition requested that "the FDA investigate why Suboxone tablets had been withdrawn from the market" even though the competitor "was continuing to sell the product at that time." Id. at 690. It was therefore plausibly pled that the petition was "objectively baseless in that no reasonable litigant could have realistically expected success on the merits." Id. Here, however, the only fact Apotex has pled other than the timing of the FDA's decision on Acorda's citizen petition is that Acorda's citizen petition was ultimately fruitless.[7]

[7] Apotex's reliance on Tyco Healthcare Grp. LP v. Mut. Pharm. Co., 762 F.3d 1338 (Fed. Cir. 2014) is misplaced. The Federal Circuit found a disputed issue of fact as to whether Tyco's citizen petition was objectively baseless because the FDA's response stated that the petition "relie[d] entirely on uncorroborated generalities and theoretical speculation" and "fail[ed] to provide any evidence at all" on a key issue. Id. at 1347. Furthermore, Mutual provided an expert who testified that the citizen petition was baseless. See id. In contrast, the FDA's

In the alternative, Apotex argues that the district court's denial of leave to amend the antitrust claim was based on a misapplication of the rules set forth in the Southern District's Pilot Project Regarding Case Management Techniques for Complex Civil Cases ("Pilot Rules"). However, the district court denied the motion to amend in the interests of judicial economy, not because of Apotex's noncompliance with the Pilot Rules. Apotex sought to amend in order to cite the FDA's fourth annual report to Congress, issued in December 2012, detailing the ineffectiveness of the FDAAA. The district court found that this report was available to Apotex before its decision issued dismissing Apotex's claims in February 2013, that Acorda expressly relied on the FDAAA in its initial motion to dismiss Apotex's Sherman Act claim, and that Apotex brought the FDA annual report to the district court's attention only after Acorda's motion to dismiss was adjudicated. Because Apotex delayed seeking leave to include the FDA's fourth annual report until March 2013, and because the general findings of the report were largely immaterial to Apotex's specific claim, the district court concluded that the interests of judicial economy warranted denial of Apotex's motion. We

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letter to Acorda provided no such language indicating the citizen petition was wholly baseless, and Apotex did not plead any other facts that would indicate baselessness.

have consistently afforded district courts latitude to deny leave to amend on this basis. See Ruffolo v. Oppenheimer & Co., 987 F.2d 129, 131 (2d Cir. 1993) ("Where it appears that granting leave to amend is unlikely to be productive, however, it is not an abuse of discretion to deny leave to amend.").

In sum, Apotex has not stated a claim under Section Two of the Sherman Act, and the district court did not abuse its discretion in denying Apotex leave to amend. The district court's decision dismissing Apotex's antitrust claim is affirmed.

II

The Lanham Act's prohibition on false advertising states:

> Any person who, on or in connection with any goods or services . . . uses in commerce . . . any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1). False advertising claims based on this proviso contain two components.

First (and obviously), a plaintiff bringing a false advertising claim must show falsity. There are two ways to do that. First, a "plaintiff can demonstrate that the challenged advertisement is literally false, *i.e.*, false on its face." Time Warner Cable, Inc. v. DIRECTV, Inc., 497 F.3d 144, 153 (2d Cir. 2007). "[C]onsumer deception is presumed, and 'the court may grant relief without reference to the advertisement's [actual] impact on the buying public.'" Id. (quoting Coca-Cola Co. v. Tropicana Prods., Inc., 690 F.2d 312, 317 (2d Cir. 1982)). This inquiry requires evaluating "the message conveyed in full context." Id. at 158 (quoting Castrol Inc. v. Pennzoil Co., 987 F.2d 939, 946 (3d Cir. 1993)). "If the words or images, considered in context, necessarily imply a false message, the advertisement is literally false and no extrinsic evidence of consumer confusion is required." Id. Importantly, however, "'only an *unambiguous* message can be literally false,'"; "if the language or graphic is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false." Id. (quoting Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Pharms. Co., 290 F.3d 578, 587 (3d Cir. 2002)). One kind of literally false claim is a claim of test-proven superiority. The premise is that the "defendant's ad[vertisement] explicitly or implicitly represents that tests or studies prove its product superior"

and "plaintiff satisfies its burden by showing that the tests did not establish the proposition for which they were cited." Castrol, Inc. v. Quaker State Corp., 977 F.2d 57, 63 (2d Cir. 1992).

"Alternatively, a plaintiff can show that the advertisement, while not literally false, is nevertheless likely to mislead or confuse consumers." Time Warner, 497 F.3d at 153. Such an implicit falsity claim requires "a comparison of the impression [left by the statement], rather than the statement [itself], with the truth." Id. (quoting Schering Corp. v. Pfizer Inc., 189 F.3d 218, 229 (2d Cir. 1999)). "[W]hereas 'plaintiffs seeking to establish a literal falsehood must generally show the substance of what is conveyed, . . . a district court *must* rely on extrinsic evidence [of consumer deception or confusion] to support a finding of an implicitly false message.'" Id. (second alteration in original) (quoting Schering Corp., 189 F.3d at 229).

Falsity alone does not make a false advertising claim viable; "[u]nder either theory, the plaintiff must also demonstrate that the false or misleading representation involved an inherent or material quality of the product." Id. n.3. Such a "requirement is essentially one of materiality, a term explicitly used in other circuits." S.C. Johnson & Son, Inc. v. Clorox Co., 241 F.3d 232, 238 (2d Cir.

2001) (quoting Nat'l Basketball Ass'n v. Motorola, Inc., 105 F.3d 841, 855 (2d Cir. 1997)). This Court has defined materiality as "likely to influence purchasing decisions," a definition in harmony with other Circuits' use of the term. Nat'l Basketball Ass'n, 105 F.3d at 855 (quoting Am. Tel. & Tel. Co. v. Winback & Conserve Program, Inc., 42 F.3d 1421, 1428 n.9 (3d Cir. 1994)).[8]

A majority of Apotex's claims attack Acorda's representations as inconsistent with the FDA-approved label for Zanaflex Capsules. A prior question is whether representations that are wholly *consistent* with an FDA label

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[8] See also Grubbs v. Sheakley Grp., Inc., 807 F.3d 785, 798 (6th Cir. 2015) (defining "material" in the false advertising context as likely to "influence the deceived consumer's purchasing decisions") (quoting Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc., 185 F.3d 606, 613 (6th Cir. 1999)); Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave., 284 F.3d 302, 311 (1st Cir. 2002) ("The materiality component of a false advertising claim requires a plaintiff to prove that the defendant's deception is 'likely to influence the purchasing decision.'") (quoting Clorox Co. P.R. v. Proctor & Gamble Commercial Co., 228 F.3d 24, 33 n.6 (1st Cir. 2000)); ALPO Petfoods, Inc. v. Ralston Purina Co., 913 F.2d 958, 964 (D.C. Cir. 1990) (noting that to succeed on a false advertising claim, a plaintiff must show that representations were "material in their effects on buying decisions"); Taquino v. Teledyne Monarch Rubber, 893 F.2d 1488, 1500 (5th Cir. 1990) ("To succeed, it must be proved that . . . the deception is material, in that it is likely to influence the purchasing decision . . . ."); 5 MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 27:35 (4th ed. 1996) ("Plaintiff must make some showing that the defendant's misrepresentation was 'material' in the sense that it would have some effect on consumers' purchasing decisions.").

are subject to Lanham Act liability. This Court has yet to so hold, although a number of district courts in this Circuit have sensibly adhered to this principle.[9] We agree with these courts and now hold that representations commensurate with information in an FDA label generally cannot form the basis for Lanham Act liability.[10]

Such a rule reflects proper "deference to the expertise" of the FDA as the regulatory agency responsible for issuing the label by respecting the exhaustive process preceding the issuance of a label. Am. Home Prods. Corp. v. Johnson & Johnson, 672 F. Supp. 135, 144 (S.D.N.Y. 1987) (Conner, J.); see also Smithkline Beecham, 1996 WL 280810, at *13. This principle rightfully insulates pharmaceutical companies from liability when they engage in First Amendment

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[9] See Mylan Pharms., 443 F. Supp. 2d at 460 (Castel, J.) ("In the context of pharmaceutical drugs, courts have generally rejected Lanham Act claims based on advertisements that merely repeat labeling information that has been approved by the FDA."); Smithkline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharms. Co., No. 95 Civ. 7011, 1996 WL 280810, at *13 (S.D.N.Y. May 24, 1996) (Baer, J.) ("[T]o enjoin SmithKline Beecham from claiming that TAGAMET HB works faster than PEPCID AC on the basis of package [labeling], would substitute this Court's discretion for that of the FDA in approving package [labeling] for over-the-counter medications.").

[10] Lanham Act liability might arise if an advertisement uses information contained in an FDA-approved label that does not correspond substantially to the label, or otherwise renders the advertisement literally or implicitly false.

speech that is consistent with the directive of the regulatory body having oversight of product labels.

We "have been careful not to permit overextension of the Lanham Act to intrude on First Amendment values." Groden v. Random House, Inc., 61 F.3d 1045, 1052 (2d Cir. 1995). Accordingly, in order to avoid chilling speech that ought to be protected, Acorda's advertisements cannot form the basis for Apotex's claims to the extent they were in line with the FDA-approved label.

Apotex, however, goes further and contends that Acorda's advertisements exceeded the boundaries imposed by the FDA label. Each of Apotex's specific Lanham Act challenges is now considered.

1. Statements by Acorda's Sales Representatives

Apotex challenges statements, attributable to Acorda sales representatives, that patients taking Zanaflex Capsules with food enjoy the benefits of reduced Cmax, including dosing flexibility and diminished somnolence. Representative samples of these sales pitches include the following:

> Upon learning of the ability to decrease somnolence . . . by using Zanaflex Capsules, the doctors agreed to give it a try.

Joint Appendix at 3072;

> I explained to [the doctor] that the [C]apsule[] [is] really unique in that it counteracts a lot of the drowsiness when you dose it with food. He said he would give that a try and see how well it works for his patients.

Joint Appendix at 3093.

When Acorda learned that its representatives may have made unauthorized promotional claims for Zanaflex Capsules, Acorda's head of sales sent a memorandum to the sales team explicitly forbidding promotions that Zanaflex Capsules had fewer side effects and less sedation than the tablets.

Apotex specifically objects to representations that Zanaflex Capsules provide more flexibility than the Capsules' counterpart--the tablets--a point on which the FDA label is silent. However, statements that Zanaflex Capsules reduce Cmax when taken with food are fully consistent with the FDA label, as the district court correctly found, and Lanham Act liability therefore cannot attach to these statements. See Apotex II, 2014 WL 5462547, at *5. To the extent Apotex challenges statements about dosing flexibility, it misconstrues its burden. It is not enough to show that Acorda made representations absent from the FDA label; instead, Apotex must show that these comments were *inconsistent* with the

FDA label in a manner sufficient to support a false advertising claim. See Procter & Gamble Co. v. Chesebrough-Pond's Inc., 747 F.2d 114, 119 (2d Cir. 1984) ("[E]ach plaintiff bears the burden of showing that the challenged advertisement is false and misleading, not merely that it is unsubstantiated by acceptable tests or other proof." (internal citations omitted)). Apotex has adduced no evidence that Acorda's promotion of dosing flexibility was either literally false or likely to cause consumer confusion.

Apotex next argues that Acorda's sales representatives used Cmax as a proxy for somnolence and improperly claimed that Zanaflex Capsules reduce it. Critically, Apotex relies on a test-proven superiority argument--that the representations relied on tests or studies allegedly proving the superiority of Zanaflex Capsules. The district court, however, properly rejected liability under the test-proven superiority theory.

The theory comes into play only when the "defendant's ad[vertisement] explicitly or implicitly represents that *tests or studies* prove its product superior . . . ." Castrol, 977 F.2d at 63 (emphasis added). Apotex proffers no evidence that sales representatives referred to tests or studies when they discussed the potential of Zanaflex Capsules to reduce somnolence. At most, Acorda's

representatives used Figure 1 (or a similar graph of pharmacokinetic results) as a tool to aid their reduced somnolence pitch. There is no record evidence that Acorda representatives used graphs of pharmacokinetic results to represent that Zanaflex Capsules reduced somnolence. Consider one of the statements at issue:

> Talked to Dr. Corondan for the first time. I asked him about the most common complaint with Zanaflex tablets and he said the drowsiness and then we went to the graph and I discussed the [C]apsules (which is how I love a call to work out).

Joint Appendix at 1520. At no point in this passage is it explicitly stated or implied that Figure 1 necessarily shows that Zanaflex Capsules reduce somnolence; instead, the graph was used as a tool for further discussion. The district court's reasoning on this issue was sound: "[a]t most, the statements suggest that, due to pharmacokinetic differences between the products, Zanaflex [C]apsules cause less somnolence than Zanaflex tablets when taken with food. The statements do not, by contrast, 'explicitly or implicitly represent[] that tests or studies prove' that there is less somnolence with Zanaflex [C]apsules." Apotex II, 2014 WL 5462547, at *7 (third alteration in original) (quoting Castrol, 977 F.2d at 63). Unable to identify a misrepresentation based on test-proven superiority, Apotex is left to find a genuine issue of material fact on falsity on

some other theory--something it has failed to do. It is immaterial that no study has shown a reduction in somnolence associated with Zanaflex Capsules; Chesebrough makes clear that Apotex must show falsity, not merely uncertainty. Moreover, Acorda's somnolence representations find a harbor in the FDA label, which states that increased adverse events, such as somnolence, may occur when switching between the tablets and Capsules in the fed state. Reinforcing this conclusion, the FDA's medical review concluded that the most problematic situation in terms of exacerbating somnolence was switching from the Capsules to the tablets in the fed state. In other words, the FDA has given some support to Acorda's representations; more importantly, however, there is no evidence that the representations are false. There is no basis to disturb the grant of summary judgment relating to Acorda's sales representatives' statements.

2. Acorda's Promotional Materials

Supplementing representations by Acorda's sales team were written promotional materials heralding the benefits of Zanaflex Capsules in a manner Apotex believes was false and misleading. Apotex specifically attacks Acorda's "gatefold brochure," a piece of advertising that Acorda disseminated in the thousands. The front cover announces: "Flexible Control in a Capsule" directly

above two images of the sun and the moon with the words "DAY" and "NIGHT" printed underneath. The bottom of the front cover urges: "For Treatment of Spasticity When Relief is Most Important." The second page contains Figure 1 juxtaposed with relevant Cmax data, along with additional text at the bottom of the graph. The text reads:

> Effects and Adverse Events are Dose Related to Plasma Levels of Tizanidine.
>
> - Significant pharmacokinetic changes including plasma level differences occur when administering Zanaflex Capsules or tablets with food.
> - These (pharmacokinetic) differences can result in clinically important differences in effectiveness and adverse events.

Joint Appendix at 3327-28. See Appendix A.

Apotex asserts that the brochure is misleading as a whole because the sun and moon imagery, with the text underneath the graph on page 2 of the brochure, delivers the message that Zanaflex Capsules undoubtedly reduce Cmax and somnolence.

Although Acorda argues that it merely reprinted the graph from the FDA label in its advertisements (including the gatefold brochure) Apotex accuses Acorda of manipulation because the following text is superimposed on the

graph: "30 % INCREASE FOR TABLETS"; "20 % DECREASE FOR CAPSULES." Joint Appendix at 3258. Apotex argues that the graphic, as a whole, conveys a false message because Figure 1 depicts mean tizanidine concentration, which is the average drug concentration at different points in time, while the text relates to Cmax data, which is the maximum drug concentration at different time points and, by definition, different from the mean drug concentration. See Appendix B.

With the exception of the version of Figure 1 with superimposed text, Apotex fails to create a triable issue of fact as to the falsity of the brochure. Literal falsity cannot be shown because no unambiguous message is conveyed by the remainder of the brochure; Apotex argues that the presence of the sun and the moon implies that the drug is equally effective during the day and at night and thereby implies efficacy in combating somnolence. This conclusion is plausible, but it is not *unambiguous*, especially because the cover never mentions somnolence. Nor has Apotex shown extrinsic evidence of consumer confusion with respect to the sun-moon imagery. Apotex relies on internal marketing statements from Acorda focusing on reduced Cmax and somnolence; but Acorda's motivations for launching the gatefold brochure do not constitute extrinsic evidence as required.

Apotex contends that the district court erred by examining the brochure in isolation while ignoring the context of Acorda's launch letters and other documents detailing Acorda's marketing efforts. True, a "district court evaluating whether an advertisement is literally false 'must analyze the message conveyed in full context.'" Time Warner, 497 F.3d at 158 (quoting Pennzoil Co., 987 F.2d at 946). But the relevant context of the advertisement is the overall message conveyed by the brochure. The district court was not required to consider external marketing documents. A review of the brochure in its entirety does not change the conclusion reached here: there is no unambiguous message that Zanaflex Capsules reduce somnolence nor has Apotex proffered evidence of consumer confusion on this point.

Acorda's use of the version of Figure 1 with superimposed text, seen on the second page of the gatefold brochure, raises a closer issue.

- Figure 1 shows the average concentration for a group of subjects over time after the drug is administered (i.e., the mean drug concentration); while
- Cmax is the maximum concentration of the drug that is reached in a subject, which varies from subject to subject and is not correlated

with the time elapsed from administration of the drug.

Since Cmax values are not time-dependent, and Figure 1 displays mean drug concentration over time, Figure 1 cannot display mean CMax values. We therefore agree with the district court that "a reasonable juror could determine that the juxtaposition of this text and image communicates a literally false message." Apotex II, 2014 WL 5462547, at *8. However, falsity is not enough; Apotex must also raise a factual issue as to materiality. "Under *either* theory, the plaintiff must also demonstrate that the false or misleading representation involved an inherent or material quality of the product." Time Warner, 497 F.3d at 153 n.3 (emphasis added). Apotex contends that it is not required to show that the relevant misrepresentation would have an effect on consumers' purchasing decisions. This argument ignores precedent from this Court which endorsed that definition of materiality--in line with the vast majority of our sister circuits. See Nat'l Basketball Ass'n, 105 F.3d at 855. Apotex counters that, when an advertisement is literally false, "consumer deception is presumed, and 'the court may grant relief without reference to the advertisement's [actual] impact on the buying public.'" Time Warner, 497 F.3d at 153 (alteration in original) (quoting Coca-Cola Co., 690 F.2d at 317). The argument conflates falsity with materiality.

Once literal falsity is proved, there is no requirement of extrinsic evidence showing consumer deception. But Apotex is not thereby relieved of the burden of showing materiality, which requires that the allegedly "false or misleading representation involved an inherent or material quality of the product," id. n.3--i.e., that the representation was "likely to influence purchasing decisions," Nat'l Basketball Ass'n, 105 F.3d at 855 (quoting Am. Tel. & Tel., 42 F.3d at 1428 n.9).

Applying the materiality standard, the district court concluded that, at most, Acorda "overstated the increase in mean tizanidine plasma concentration" but that this evidence ultimately "does not reveal anything about the impact on consumers' purchasing decisions." Apotex II, 2014 WL 5462547, at *9. This conclusion was sound; the only plausible effect attributable to the misrepresentation in the graph was an exaggeration of the scale of the mean drug concentration curves, or an improper conflation of the mean Cmax with the highest mean drug concentration for a given treatment. However, there is no record evidence that this inaccuracy would dissuade consumers from purchasing Zanaflex Capsules. Certainly, Apotex has provided none. Apotex's showing on this point consists of generalized evidence that Acorda's increased sales of Zanaflex Capsules stemmed from its advertisement efforts. Apotex fails to make

the necessary showing that the specific misrepresentation in the graphic--in any of Acorda's advertisements--was likely to influence consumers' purchasing decisions.

The remainder of Apotex's attacks on Acorda's promotional materials suffer from a common flaw: although Acorda unquestionably made statements that were not drawn from the FDA label, the thrust of Chesebrough is that this fact is insufficient to show falsity. A pharmaceutical company is entitled to make advertising statements outside the four corners of an FDA label so long as none of its representations is inconsistent with it.

In sum, the district court correctly granted summary judgment on all of Apotex's false advertising claims.

CONCLUSION

For the foregoing reasons, we AFFIRM the judgment of the district court.

2nd Circ. Creates Confusion For FDA-Vetted Marketers

Law360, New York (September 29, 2016, 11:17 AM EDT) -- While advertising off-label claims for medical devices and pharmaceuticals may be like sailing into stormy waters, companies might assume that advertising their products based on U.S. Food and Drug Administration-vetted labeling is, if not a safe harbor, at least a reasonably sheltered cove. The recent Second Circuit decision in Church & Dwight Co. Inc. v. SPD Swiss Precision Diagnostics GmbH, Dkt. No. 15-241, 12016 (2d Cir. Sept. 9, 2016), affirming a finding of Lanham Act false advertising liability based on an over-the-counter (OTC) home pregnancy test's "Weeks Estimator" advertising, challenges this seafaring assumption:


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> 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 interests...

The Second Circuit's ruling that FDA approval "gives no assurance" that advertising claims based on approved labeling are not "misleading" appears contrary to another unanimous Second Circuit decision issued less than four months earlier. Apotex Inc. v. Acorda Therapeutics Inc. Dkt. No. 14-4353, ___F.3d___, 2016 (2d Cir. May 16, 2016), held "that representations commensurate with information in an FDA label *generally cannot* form the basis for Lanham Act liability." (emphasis added).

Given these contradictory directions from the Second Circuit, advertisers of products whose promotional and labeling claims are subject to FDA vetting and

oversight — including the manufacturers and distributors of foods, medical foods, drugs, cosmetics, medical devices and biologics — must navigate cautiously even when basing their advertising on FDA approved labeling.

Church & Dwight v. SPD Swiss Precision Diagnostics

New Jersey-based Church & Dwight markets the leading OTC home pregnancy test kit, First Response. In direct competition, Swiss Precision Diagnostics (SPD) also markets home pregnancy test kits, including ClearBlue. Like most OTC home pregnancy tests, both First Response and ClearBlue detect the human chorionic gonadotropin (hCG) hormone in a woman's urine. When present hCG signals pregnancy.

While First Response offers a "yes" or "no" (two lines, or one) signal, SPD's ClearBlue goes a step further and also provides the customer with a "weeks estimator" calculation based on the amount of hCG in the sample tested. The formula SPD uses measures pregnancy duration from the time of ovulation. However, the medical profession generally calculates pregnancy duration based on the weeks since the expectant mother's last menstrual period.

While SPD's methodology is arguably a more scientifically accurate means of expressing pregnancy duration, it is not a method generally used in the field of obstetrics and gynecology, and provides a "weeks estimation" that understates pregnancy duration — as it is commonly measured — by about two weeks.

Both First Response and ClearBlue are FDA-regulated Class II medical devices, cleared by the FDA as substantially equivalent to predicate devices already recognized as safe and effective. During clearance of ClearBlue, the FDA expressed concern about SPD's pregnancy duration calculation, and imposed limitations on SPD's advertising and labeling of the product. The FDA's clearance letter required, among other things, that SPD "include a specific 'conversion chart' explaining how a doctor would date the pregnancy compared to [ClearBlue's] results," using language provided by the FDA. It also specified that the pregnancy duration results not be expressed as 'weeks pregnant,' but only as the number of weeks since ovulation." SPD also was required to include a specific "indications for use statement" provided by the FDA detailing the meaning and limited value of the weeks estimator, including the caveat: "This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy."

While SPD's "launch package" complied with the FDA's clearance letter, Church & Dwight nevertheless complained to the FDA because word size and placement on the packaging obfuscated the limitations of the product's pregnancy duration calculation ("ovulation," for example, was allegedly placed in small print and only on a side panel, while the front panel included a row of boxes with "Pregnant" above the time estimates of "1-2 weeks," "2-3 weeks," and "3+ weeks"). Similarly, while SPD's television advertising included disclaimers, they were fleeting, with "ESTIMATED WEEKS SINCE OVULATION" appearing for only two seconds.

In response to this complaint, SPD negotiated a "mitigation proposal" with the FDA, requiring SPD to replace the word "weeks" with the phrase "weeks along" in all instances. For example, when promoting its kit as "The ONLY pregnancy test that estimates weeks," SPD now was required to state: "The ONLY pregnancy test that estimates weeks along." SPD also had to clarify that the calculation involved "weeks since ovulation." After SPD's negotiations with the FDA, Church & Dwight sued for injunctive relief.

Following a bench trial, the district court held that both SPD's "launch package" and its revised advertising were misleading and false by necessary implication in violation of § 43(a) of the Lanham Act. The court found a reasonable consumer would understand the challenged advertising's "weeks estimator" to communicate the same pregnancy duration as would a doctor's advice. Along with evidence that SPD knew its advertising was likely to confuse or mislead consumers, this finding also was bolstered by a consumer survey conducted by the plaintiff, showing that almost 20 percent of consumers believed that SPD's expression of the number of weeks a woman has been pregnant is the same as a doctor's estimate of duration. The trial court issued a sweeping permanent injunction, both mandatory and prohibitory, requiring, in part, that SPD:

- Remove all current products from points of sale within 45 days;
- Refrain from communicating in any advertising that SPD's product provides an estimate of weeks pregnant that is the same as a doctor's estimate;
- Refrain from using certain phrases in its advertising, including "weeks pregnant," "weeks along" or "weeks estimator";
- Include with its products a specified statement clarifying the difference in the estimates;

- Deliver within a week to all retailers and distributors a specified written corrective notice with a copy of the injunction, and for the next year to make these materials available at all U.S. trade shows and professional meetings attended by SPD or its representatives;

- Set up and maintain for a year a stand-alone webpage with a specified message about the lawsuit and its history of providing misleading information, and to publish a similar statement in retailer circulars and in full-page ads in three parenting magazines;

- Publish an internet banner advertisement prominently displaying its logo and stating that a federal court has determined that it "engaged in false advertising";

- Produce and post on SPD's website, YouTube and Facebook a video explaining the difference between SPD's and the medical profession's pregnancy length estimates, along with a statement that a federal court found it engaged in false advertising.

Affirming the trial court's judgment and injunction, the Second Circuit rejected SPD's argument that the FDA's vetting of the ClearBlue labeling, or the fact its advertising was consistent with this labeling, precluded SPD's false advertising liability under the Lanham Act.

Relying on POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228 (2014), the court of appeals reasoned that "the subjugation of the defendant's product labeling to FDA regulation through the § 510(k) process should [not] categorically immunize it from Lanham Act claims by competitors regarding the regulated labeling." In other words, "FDA approval of the accuracy of a subject's representations does not create a ceiling that bars still better protections against the capacity of the representations to mislead."

Accordingly, irrespective of FDA consideration, "[i]f an advertising message means something different from what reasonable consumers would understand it to mean, that message can be considered false." The Second Circuit affirmed the district court's finding "that a reasonable consumer would have assumed from the text of the launch package, TV commercial and other associated advertising that the product was not giving a different number than a medical professional would give," and that SPD's advertising message therefore was false.

Apotex Inc. v. Acorda Therapeutics Inc.

The Second Circuit issued its Apotex decision on May 16, 2016, less than four months before deciding Church & Dwight. The prior decision issued after briefing closed in the subsequent case, however. No supplemental briefing filed with the Church & Dwight court, and the Apotex decision was not referenced in the Church & Dwight opinion.

Apotex concerned Acorda's marketing of the drug tizandidine, under the brand name Zanaflex, in both capsule and tablet form. Approved for spasticity in Parkinson's and MS patients, the drug has a common side effect of inducing somnolence (that is, drowsiness). As described in the FDA-approved labeling, Zanaflex tablets and capsules are not bioequivalent to each other because, when taken with food, the amount of sleepiness is different between the two. Specifically, "there is a 30 percent increase in Cmax when the tablets are administered with food, but that when the capsules are administered with food, Cmax decreases by 20 percent."

Following successful patent litigation against Acorda, competitor Apotex sought FDA approval of a generic tizandidine for both the capsule and tablet form of Zanaflex. Acorda filed a citizen petition objection with the FDA, which the FDA denied on the same day it approved Apotex's generic. Apotex then sued Acorda, claiming both antitrust violations and false advertising under § 43(a) of the Lanham Act. Following a bench trial, the district issued a defense judgment on all claims.

Among Apotex's false advertising claims was its contention that, while consistent with Zanaflex's FDA-approved labeling, Acorda's advertising of Zanaflex capsules was nonetheless misleading. The Second Circuit styled this "question" as "whether representations that are wholly consistent with an FDA label are subject to Lanham Act liability."

Citing "a number of district courts in this circuit [which] have sensibly adhered to this principle," the Apotex court agreed and held "that representations commensurate with information in an FDA label generally cannot form the basis for Lanham Act liability." As the court explained:

> Such a rule reflects proper "deference to the expertise" of the FDA as the regulatory agency responsible for issuing the label by respecting the exhaustive process preceding the

> issuance of a label. This principle rightfully insulates pharmaceutical companies from liability when they engage in First Amendment speech that is consistent with the directive of the regulatory body having oversight of product labels. (citations omitted).

Thus, "in order to avoid chilling speech that ought to be protected, Acorda's advertisements cannot form the basis for Apotex's claims to the extent they were in line with the FDA approved label."

Making Sense of Church & Dwight and Apotex

Typically, circuit courts treat prior published authority as stare decisis to which they are bound, barring some intervening U.S. Supreme Court or legislative change in the law. U.S. v. King, 276 F.3d 109, 112 (2d Cir. 2001). After the Apotex panel concluded the FDA should have the final word on the truthfulness of advertising claims based on an FDA-approved label, the Church & Dwight panel nevertheless held that the FDA's consideration carried no weight in a court's determination of whether advertising claims based on FDA-approved labeling is false or misleading.

Appellate courts faced with such an apparent intra-circuit split may refer the issue for en banc consideration, or adopt one of several competing approaches to inconsistent precedent. See Walker v. Mortham, 158 F.3d 1177, 1188 (11th Cir. 1998) (analyzing cases adopting different approaches to resolving intra-circuit split, including those applying earliest precedent, applying most recent precedent and applying precedent most consistent with Supreme Court authority and common sense). Here, it is unclear how future Second Circuit panels will reconcile these two apparently incompatible rulings.

In the meantime, these competing decisions impact companies potentially at risk of false advertising litigation in the jurisdictions comprising the Second Circuit, notably New York, and which are involved in the "one-fifth to one-quarter of U.S. gross domestic product" directly regulated by the FDA. Marc T. Law, History of Food and Drug Regulation in the United States, EH.Net Encyclopedia (Oct. 11, 2004). Until these rulings are resolved or clarified, advertisers of products regulated by the FDA may wish to err on the side of caution, and assume that even advertisements based on product labeling can be scrutinized without deference to the FDA's approval, and could subject the advertiser to liability under § 43(a) of the Lanham Act.

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