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Second Circuit Affirms Dismissal of Sham Citizen Petition Claim, Summary Judgment on False Advertising Claims

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Addressing Sherman Act and Lanham Act claims arising out of an Abbreviated New Drug Application (ANDA), the US Court of Appeals for the Second Circuit upheld the district court's dismissal of the plaintiffs' Sherman Act claim that the defendant filed a sham citizen petition with the US Food and Drug Administration (FDA) to hinder plaintiffs' competing generic product, and also affirmed the district court's granting of the defendant's motion for summary judgment on the plaintiffs' Lanham Act false advertising claims relating to the defendant's advertisements for the same competing product. *Apotex Inc., et al. v. Acorda Therapeutics, Inc.*, Case No. 14-4353 (2d Cir., May 16, 2016) (Jacobs, J).

Apotex and Acorda Therapeutics are competing manufacturers of tizanidine, a drug used to treat spasticity but with drowsiness as a common side effect. Apotex began selling generic tizanidine tablets in 2004, around the same time that Acorda acquired the rights to sell tizanidine tablets and capsules under the trade names Zanaflex and Zanaflex Capsules, respectively.

In 2007, Apotex filed an ANDA relating to generic tizanidine capsules, which would compete with Acorda's Zanaflex Capsules. Acorda filed a citizen petition with the FDA, raising concerns about Apotex's ANDA. The FDA denied Acorda's citizen petition on February 3, 2012, and on the same day approved Apotex's ANDA. Apotex launched its generic tizanidine capsules product, and Acorda countered with its own authorized generic version of Zanaflex Capsules.

Apotex filed suit in district court, alleging that Acorda filed a sham citizen petition with the FDA to delay approval of Apotex's competing capsule formulation in violation of § 2 of the Sherman Act. Apotex also alleged that in the course of Acorda's marketing of its tizanidine capsules, Acorda violated the Lanham Act's proscription on false advertising by making misrepresentations to physicians and in promotional material regarding the effect of Zanaflex Capsules in reducing drowsiness as compared to the tablet form. The district court found that "the simultaneous approval by the FDA of Apotex's [ANDA] and its denial of Acorda's citizen petition (raising concerns about the ANDA) was by itself insufficient to support a Sherman Act claim." After discovery, the district court granted summary judgment and dismissed all of Apotex's Lanham Act false advertising claims on the grounds that none of Acorda's representations (with one exception) were literally false or likely to mislead consumers, and that Acorda failed to show that the false depiction in one graph "would meaningfully impact consumers' purchasing decisions." Apotex appealed.

On appeal, the Second Circuit affirmed, finding that Apotex failed to show that Acorda's citizen petition was objectively baseless. A prior case, *DDAVP*, established an inference that the citizen petition is a sham when the petition is denied simultaneously with the grant of an ANDA petition. However, the Second Circuit highlighted recent FDA guidance that undermines that inference. Specifically, the FDA guidance favors contemporaneous adjudications of ANDA applications and citizen petitions so as to safeguard the procedural rights of ANDA applicants such as Apotex.

The Second Circuit also upheld the district court's grant of summary judgment on Apotex's Lanham Act false

advertising claims. First, the Court held that Acorda's advertisements could not form the basis for Lanham Act claims to the extent they were in line with the FDA-approved label for Zanaflex Capsules. Although Apotex alleged that certain of Acorda's representations exceeded the boundaries imposed by the FDA label, the Court held that Apotex failed to show that those representations were inconsistent with the FDA label in a manner sufficient to support a false advertising claim, as there was no evidence that the representations were false.

Finally, although the Second Circuit agreed with the district court's conclusion that "a reasonable juror could determine" that one graph "communicates a literally false message," it found that Apotex failed to show that the misrepresentation was material such that it was likely to influence consumers' purchasing decisions.