The Lanham Act: Another Vehicle to Enforce the Food, Drug, and Cosmetic Act?

by John R. Fleder

No one questions that the Federal Food, Drug, and Cosmetic Act (FDCA) is the primary statutory vehicle used to enforce the obligations imposed by that Act. Indeed, the Food and Drug Administration (FDA) has repeatedly argued, and the courts have generally agreed, that FDA, through the U.S. Department of Justice (DOJ), exclusively enforces that statute.[1]

Many businesses believe that FDA does not aggressively take enforcement action against competitors. As a result, companies wanting to stop competitors' practices often look to bring a private enforcement action. One of the primary vehicles used to sue a competitor regulated by FDA is to file an action under the Lanham Act. That statute authorizes a plaintiff to bring a case in federal court alleging that a defendant has engaged in false or deceptive advertising.[2]

Increasingly, plaintiffs have brought Lanham Act claims which arguably asserted private enforcement of the FDCA. In those cases, defendants commonly argue that a plaintiff cannot use the Lanham Act to enforce the FDCA. In the absence of any bright-line rule from the Supreme Court or statutory clarification from Congress, the issue of whether a plaintiff is privately enforcing the FDCA in a Lanham Act case is likely to be decided on a case-by-case basis.

One court recently addressed this issue and other important issues in *Schering-Plough Healthcare Products, Inc., v. Schwarz Pharma, Inc., Kremers Urban, LLC, Breckenridge Pharmaceuticals, Inc. and Paddock Laboratories, Inc.*[3] The United States Court of Appeals for the Seventh Circuit affirmed a district court decision dismissing a complaint. The Court of Appeal Opinion rendered instructive guidance on a number of issues, including FDA's "primary jurisdiction" over FDCA matters, and also what constitutes "final agency action."

The Facts of the Case

The underlying facts were fairly straightforward. Schering-Plough Healthcare Products, Inc. (Schering) developed and marketed (after approval by FDA) polyethylene glycol 3350 as a prescription oral laxative under the trade name MiraLAX. After the exclusivity period on the drug ended, FDA approved the defendants' Abbreviated New Drug Applications (ANDAs), and the defendants brought generic versions of the prescription drugs to market. FDA's approval of the generics required the companies to place the words "Rx only" on products labels. Subsequently, Schering sought and obtained FDA approval to market MiraLAX for over-the-counter-only (OTC) use. However, the defendants continued to market their drugs as prescription drugs, employing the "Rx only" statement on product labels.

Schering asserted in a suit filed in the United States District Court for the Eastern District of Wisconsin that the label "Rx only" statement on defendants' products was false because Schering's MiraLAX was then only sold OTC. Schering claimed that the defendants had engaged in false and misleading advertising by labeling their products in a way that allegedly implied that all polyethylene glycol (including Schering's product) was available by prescription only. On this basis, it argued that the alleged falsity of defendants' labels harmed consumers (and Schering) by obscuring the existence and availability of an OTC version of the drug. Schering also argued that the court

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need not wait for a definitive FDA interpretation of this issue because the "Rx only" statement on the generics' products was literally false.

Separately, the Director of FDA's Office of Generic Drugs, Center for Drug Evaluation and Research (CDER) wrote to Defendants stating that their products were misbranded—despite their valid ANDAs—because the labels on their products read "Rx only" when there existed an OTC polyethylene glycol formulation, namely Schering's MiraLAX. FDA also subsequently initiated a proceeding to determine whether to withdraw the defendants' ANDAs if FDA determines that there is a "meaningful difference" between the OTC MiraLAX and the Rx-only generic drugs.[4] FDA has not conducted a hearing in that proceeding or reached any decision as to whether the ANDAs should be withdrawn.[5]

The Court of Appeals' Decision

The Circuit Court's decision is nicely summed up by a statement that it need not get into the weeds of consumer expectations regarding the labeling on the various products because "we do not know, and see no need to guess while the misbranding proceeding is wending its way through the FDA."[6] Essentially, the Court upheld the district court's ruling that the controversy over the generic products' labels was unripe for decision because FDA has primary jurisdiction over the issues raised, and has not taken final action.

FDA's "Primary Jurisdiction"

The Court of Appeals noted that the district court had not stayed the suit pending a final ruling by FDA "as he might have done." Under the primary jurisdiction doctrine, courts sometimes refer issues to administrative agencies that have exclusive jurisdiction to resolve an issue. The *Schering* Court concluded that it was unclear what the result of the agency's own proceeding mentioned above would be. Instead, the Court cited prior case law for the proposition that FDA, not a Lanham Act court, should be permitted to opine on the question of what is the proper labeling for the generics' products because FDA "has more experience with consumers' understanding of drug labels than judges do."[7]

What Is "Final Agency Action"

The Court of Appeals agreed with the district court that plaintiff had "jumped the gun" by filing its court action prior to FDA completing its review of the issues raised in the case.[8]

The Court dismissed out of hand Schering's argument that the courts could deem an agency official's letters, which had

stated that the defendants' products were misbranded, to constitute final agency action that would be judicially reviewable, or binding upon the district court. The Court observed that the defendants had approved ANDAs for their prescription versions of polyethylene glycol, and noted FDA must provide the manufacturers "with due notice and opportunity for hearing" in order to rescind those approvals.[9] Letters by an Office Director at CDER could not suffice.

This part of the Court's ruling is quite significant. How often do we hear that "the FDA has required" or that "the FDA has stated," referring to Warning Letters and other communications from FDA officials other than the Commissioner? If the Court's Opinion is followed to its logical extreme, plaintiffs in product liability lawsuits and other cases may find it difficult to argue to juries that companies failed to comply with a "demand" or FDA interpretation of the FDCA, when it is issued by an FDA official to whom final FDA decision-making authority has not been given.

The FDCA's Relationship to the Lanham Act

Schering argued that it was not privately enforcing the FDCA. It claimed that the Lanham Act is designed to protect competitors from the effects of false advertising, whereas the misbranding provisions of the FDCA are intended to protect consumers. As a result, Schering claimed, there could be no conflict between the two statutes and hence there was no reason to await an FDA ruling before the case could proceed.

The Court squarely rejected these claims, finding that a judicially-imposed mandate to the defendants to alter their labels in the name of protecting a competing seller (Schering) might lead to consumers being misled, which could render a drug misbranded.[10] Instead, the Court doubted that the matter "can be resolved intelligently without a decision by the FDA."[11] The Court discussed what many lawyers believe are conflicting rulings by the federal courts[12] as to whether a Lanham Act claim is really a thinly-disguised FDCA enforcement action.

What is a "Literally False" Drug Claim?

The Court gave a robust rejection to Plaintiff's assertion that the Lanham Act false advertising claim could proceed because the purportedly false statement, "Rx only," was "literally false." The literal falsity doctrine allows a plaintiff to bring a Lanham Act claim without the need to show proof of people actually being misled or likely to be misled.

The Seventh Circuit dismissed the argument that the defendants' drugs were misbranded because they were labeled as prescription drugs. In fact, the drugs *were* "prescription drugs so their labels *have* to say that, even if a close substitute (OTC MiraLAX) is not" a prescription drug.[13] Moreover, the Court rejected Schering's argument that the "Rx only" statement on defendants' labels was literally false because it somehow related to *Schering's* OTC products. Instead, as the Court noted, the defendants' labels bore the individual manufacturer's name, not Schering's name.[14]

The Court observed that many literally false statements are not deceptive, citing a number of non-FDA examples. The Court also cited cases that have ruled that mere "puffery" does not lead to a proper Lanham Act claim. We can expect many other defendants in Lanham Act cases will argue that even if they have made statements that could otherwise be deemed to be literally false, a case should be dismissed because no one could be fooled or hurt by a statement that is a meaningless superlative.

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1 *See* 21 U.S.C. § 337. That provision *does* permit States to file actions to enforce certain provisions of the FDCA. However, it does not explicitly authorize private persons to enforce the Act. *See also* Buckman v. Plaintiffs Legal Committee, 531 U.S. 341, 349 n. 4 (2001).

2 15 U.S.C. § 1125(a)(1)(B), which forbids the use of any false or misleading representation of fact in commercial advertising or promotion. The Lanham Act permits a successful plaintiff to recover the defendant's profits, damages sustained by the plaintiff, and, in exceptional cases, reasonable attorneys' fees. 15 U.S.C. § 1117(a).

3 586 F.3d 500 (7th Cir., 2009). Hyman, Phelps & McNamara, P.C. represented Schwarz Pharma, Inc. and Kremers Urban, LLC in this case.

4 *Id*. at 505.

5 *Id*. The Court also concluded that the Lanham Act's prohibition of false and misleading representations in commercial advertising does not contain an exemption for labels. 586 F.3d at 503.

6 *Id*. at 505.

7 *Id*. at 508-509.

8 *Id*. at 510.

9 *Id*. at 505.

10 *Id*. at 508.

11 *Id*.

12 *Id*. at 509. The Opinion also contains an interesting discussion of when a seller of a drug can make changes to a product's labeling without seeking or obtaining FDA approval for the change. *Id*. at 509-510.

13 *Id*. at 508.

14 *Id*. at 513.