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FDA proceeding takes precedence over Lanham Act in drug labelling case **Unfair use**
United States - McDermott Will & Emery LLP

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In *Schering-Plough Healthcare Products Inc v Schwarz Pharma Inc* (Cases 09-1438, 1462, 1601, October 29 2009), in an extensive discussion of the interplay between Food and Drug Administration (FDA) procedures and the Lanham Act, the US Court of Appeals for the Seventh Circuit has affirmed the district court's dismissal, without prejudice, of a Lanham Act claim for false advertising because the plaintiff had "jumped the gun by suing before the FDA addressed the misbranding issue". The district court was thus correct in dismissing a Lanham Act claim without prejudice pending the FDA's decision on whether a generic drug should be pulled from the market or relabelled due to misbranding.

The case involved a claim of false advertising under §43(a) of the Lanham Act brought by Schering-Plough Healthcare Products Inc against four defendants. The parties are all manufacturers of an oral laxative with the chemical name of polyethylene glycol 3350. Schering sells its over-the-counter drug under the trademark MIRALAX. The four defendants sell the generic version under its chemical name, and two of the defendants also use the name GlycoLax. The defendants' version is sold as a prescription drug with the required symbol "RX only".

Originally, Schering's MiraLAX product was a prescription drug. After the patent expired, the FDA approved the defendants' abbreviated new drug applications, which authorized them to sell the generic version. Subsequently, the FDA approved the over-the-counter MiraLAX sold by Schering, but required that the label contain a warning to "use no more than 7 days". FDA regulations require that the labelling of the generic version be the same as that of the original drug (ie, the prescription-only version of MiraLAX). FDA law also requires that the label of a generic drug approved as a prescription drug must bear the symbol "RX only".

The district court dismissed the case without prejudice, suggesting that Schering could refile it if and when the FDA decided that the defendants' drugs were misbranded. Schering appealed, arguing that no reasonable trier of fact could fail to conclude that the terms "RX only" and "a prescription only laxative" on the labels of the defendants' drugs were literally false, and thus violated the Lanham Act regardless of the Federal Food, Drug, and Cosmetic Act.

Schering argued that the labels and package inserts stated that polyethylene glycol 3350 is sold only by prescription. However, since Schering's over-the-counter MiraLAX does not require a prescription, not all polyethylene glycol 3350 may be sold only by prescription.

The Seventh Circuit noted that the FDA was simultaneously conducting a proceeding to determine whether the defendants' drugs were misbranded in view of the over-the-counter version of the drug. Because the Food, Drug and Cosmetic Act does not permit both by-prescription-only and over-the-counter versions of the same drug to be sold at the same time, the FDA proceeding encompasses whether there is a "meaningful difference" between the pioneer drug and the generic drug or whether they are really "the same" drug (the defendants argued they were not selling the same drug because they did not use the warning "use no more than 7 days").

If the FDA determines that they are "the same", the result will be that the generic drug can no longer be sold. If it determines that they are different, it may decide that the labelling of the generics must be changed. The Seventh Circuit observed that:

> "*maybe the FDA doesn't care whether the labelling of the generic products obscures the existence of an over-the-counter equivalent; maybe all it cares about is that the labelling leads consumers to use the product safely*."

The FDA also wrote letters to the defendants stating that their drugs were misbranded because the label says "RX only", even though polyethylene glycol 3350 can also be sold without a prescription. However, the Seventh Circuit noted that a hearing had not yet been scheduled by the FDA.

Procedurally, the Seventh Circuit confirmed that dismissals without prejudice are appealable when the case comes to an end in the district court, unless the reason for dismissal is an easily fixable problem.

On the merits, the Seventh Circuit set aside the letters from the FDA, indicating that these were not final agency action binding on the district court. The Seventh Circuit also set aside any argument by Schering that the defendants' drugs were misbranded because they were labelled as prescription drugs, finding that "they are prescription drugs, so their labels have to say that, even if a close substitute (over-the-counter

MiraLAX) is not". The Seventh Circuit went on to note as follows:

> "*Nor do we think that just because the provision of the Lanham Act… is intended to protect competitors from the effects of false advertising or labelling, while the misbranding provision of the [Food, Drug and Cosmetic Act] is intended to protect the consumers of drugs, there can be no conflict between the statutes, hence no occasion for delaying this litigation to let the FDA weigh in*."

The Seventh Circuit also found merit in the defendants' contention that the district court was correct to deny Schering's motion for partial summary judgment on its Lanham Act claim regardless of how the FDA rules, because Schering made no attempt to prove that anyone was misled. The Seventh Circuit also affirmed that "literal falsity" was insufficient to make out a Lanham Act claim on these facts.

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