FISH & RICHARDSON

TrademarkThoughts

Trademark and Copyright Group

Winter 2010

Published by
Fish & Richardson

Trademark use in strategic business policy

fr.com
800-818-5070
info@fr.com

Plaintiff Beware: Perils of Bringing False Advertising Claims Against FDA-Regulated Products

Patent litigation cases involving million-dollar blockbuster drugs and medical devices seem to routinely make the news. Trademark cases involving such products are rarer, and false advertising cases under the federal Lanham Act involving FDA-regulated products are *really* news.

There were several such false advertising cases in 2010 involving medical devices, food, drugs, and sunscreens. However, there is tension between false advertising claims under the Lanham Act and compliance with FDA regulations. On the one hand, Section 43(a) of the Lanham Act provides a cause of action against any person who uses in commerce any "false or misleading description of fact" in commercial advertising that misrepresents the nature, characteristics, qualities, or geographic origin of his or another person's goods or services. This provision allows claims for false advertising to be brought by competitors for ads that are either literally false on their face or that, while not literally false on their face, are nonetheless misleading. On the other hand, Section 337(a) of the federal Food, Drug, and Cosmetic Act states that only the United States may bring actions to enforce the Act (i.e., there is no private cause of action for violation of FDA regulations).

Thus, a plaintiff bringing a false advertising claim under the Lanham Act involving a product regulated by the FDA may find itself constrained by the prohibition against private enforcement of the FD&C Act, depending on the nature of the claim and the particular circumstances of the marketing of the defendant's product. While it may be too soon to tell if trends are emerging, in today's tough economic climate some companies may be looking for any edge they can get, whether by aggressive advertising or aggressive action in court challenging such advertising.

Medical Devices

In *PhotoMedex Inc. v. Irwin,* 601 F.3d 919 (9th Cir. 2010), the defendant sold a version of its excimer laser that had been modified from what the FDA had authorized. FDA regulations permit modifications without further authorization if the changes cannot significantly affect the safety or effectiveness of the device. It is up to the manufacturer to make an initial assessment as to whether this standard has been met, and if a manufacturer concludes in good faith that no further FDA authorization is required, it may sell the modified device, subject to potential future FDA enforcement action.

"A plaintiff bringing a false advertising claim under the Lanham Act involving a product regulated by the FDA may find itself constrained by the prohibition against private enforcement of the FD&C Act, depending on the nature of the claim and the particular circumstances of the marketing of the defendant's product."

The defendant advertised its modified version of the device as "FDA approved." The plaintiff brought suit, claiming that the modified version was not FDA approved or otherwise authorized. The judge ruled that because the federal Food, Drug, and Cosmetic Act does

not allow for private causes of action for violation of the Act, the plaintiff's claim was barred. Where the FDA itself had not concluded that the modified device at issue was not unauthorized, a Lanham Act claim alleging such unauthorized marketing could not be sustained. However, the court cautioned that a claim could be pursued if a company falsely claims that FDA authorization had been obtained for a device when no such authorization had been issued for any version, unlike the situation in the present case where authorization for at least the original version had been issued and where the FDA had taken no enforcement action to stop the marketing of the modified version.

Food

In *Pom Wonderful LLC v. The Coca-Cola Company,* ___ F. Supp.2d ___ (C.A. No. 08-06237, C.D. Cal. 2010), Pom, the producer of pomegranate juice and juice blends, sued Coca-Cola (owner of the MINUTE MAID brand of juices) for advertising a "Pomegranate Blueberry Flavored Blend Of 5 Juices." In the ranking of ingredients by volume as required by FDA labeling regulations, blueberry ranked fourth, behind apple, grape, and pomegranate, and one above raspberry. A vignette depicting each of the five fruit ingredients also appeared on the label.

"...the court cautioned that a claim could be pursued if a company falsely claims that FDA authorization had been obtained for a device when no such authorization had been issued for any version..."

Pom claimed that the name "Pomegranate Blueberry Flavored Blend of 5 Juices" and the vignette showing pomegranates and blueberries constituted false advertising under the Lanham Act and state law. The court ruled that the claims were precluded as a matter of law because the label complied with all applicable FDA regulations. The FDA had directly spoken on the issues that formed the basis of the claims and had already determined what was permissible. Indeed, the FDA had spoken on several occasions, and each time it had concluded that manufacturers of multiple-juice beverages could identify such beverages with the name of a nonprimary, characteristic juice. The name "Pomegranate Blueberry Flavored Blend Of 5 Juices" complied with the requirements. Coca-Cola was permitted to name the juice a pomegranate "blend" or "flavor" even if pomegranate was merely used as flavoring rather than as a primary juice.

As for the fruit vignette, Pom argued that because it included a large, half-open pomegranate, consumers would incorrectly believe that the juice consisted primarily of pomegranate juice. This claim was also precluded, as the vignette was related to and/or part of the label and complied with FDA regulations.

However, Pom's claims regarding Coca-Cola's specific advertising and marketing of the juice—as distinct from the labeling—were allowed to go forward. The survey presented by Pom provided at least some evidence of consumer deception, though the court noted that the survey was seemingly unreliable because it did not appear to relate to Coca-Cola's advertising and marketing, but instead only implicated the name and labeling of the juice. At a minimum, triable issues of material fact remained as to these claims.

Drugs

In *Bayer v. Mouratidis* (Trademark Trial and Appeal Board, Opp. No. 91185473, May 21, 2010), the U.S. Trademark Office considered an opposition by Bayer to a trademark application for ORGANIC ASPIRIN

*Though this case [*Bayer v. Mouratidis*] did not involve a claim of false advertising* per se, *it is a reminder that trademarks themselves can be deceptive and a form of false advertising.*

These recent cases show that, despite the lack of private cause of action under the federal Food, Drug, and Cosmetic Act, not every claim alleging false advertising involving an FDA-regulated product is automatically doomed to fail.

for a "dietary supplement." Relying on a dictionary definition of "aspirin" as meaning acetylsalicylic acid (which the applicant admitted), Bayer argued that identifying a product as "aspirin" that did not contain acetylsalicylic acid was both deceptively misdescriptive and deceptive under the Lanham Act.

The U.S. Trademark Office agreed, finding that consumers would be likely to mistakenly believe that ORGANIC ASPIRIN was a type of aspirin (i.e., the mark was deceptively misdescriptive) and that consumers would base their purchasing decision at least in part on this mistaken belief (i.e., the mark was also deceptive). The Trademark Office also noted that the applicant's website created the misimpression that there are two types of aspirin, synthetic and organic. Although aspirin is clearly a drug subject to regulation by the FDA, the Trademark Office did not rely on any FDA definitions or regulations, citing instead Bayer's reference to a standard English dictionary definition of aspirin.

Though this case did not involve a claim of false advertising *per se*, it is a reminder that trademarks themselves can be deceptive and a form of false advertising. In essence, the Trademark Office ruled that if it isn't aspirin, you can't call it aspirin in your trademark.

In another recent drug case, *Ferring Pharmaceuticals, Inc. v. River's Edge Pharmaceuticals LLC,* ___ F.Supp.2d ___ (C.A. No. 09-02601-AW, D. Md. 2010), the court denied defendant's motion to dismiss and allowed Ferring's claims alleging misleading marketing claims to proceed. Ferring, maker of the urinary antiseptic drug PROSED, claimed that River's Edge's marketing of its product as having the same amounts of the same active ingredients misled drug data publishing services to list the River's Edge product as a generic equivalent for PROSED, further misleading doctors.

The court found that only claims that require interpretation of a matter that is "exclusively" within the jurisdiction and expertise of the FDA are precluded as "improper attempts to use the Lanham Act as a backdoor to private enforcement." In examining Ferring's specific claim, the court stated that "the case law is relatively consistent in holding that claims that a competitor has falsely advertised its product as the generic of another drug, especially where the drugs are not subject to FDA approval, are permissible Lanham Act claims." The court also allowed Ferring's related claim to proceed, alleging that River's Edge's marketing of its product as having the same active ingredients in the same amounts as PROSED was false and misleading.

"Understanding how a product is regulated by the FDA and its current state of compliance is time well invested, and even then it is best to study the case law regarding the particular claim at issue."

Sunscreens

In *Schering-Plough Healthcare Products Inc. v. Neutrogena Corp.,* ___ F.Supp.2d ___ (C.A. No. 09-642-SLR, D. Del. 2010), Schering, owner of the COPPERTONE brand of sunscreens, brought suit alleging that Neutrogena's advertisements for its ULTIMATE SPORT sunscreens contained various false claims regarding the Sunburn Protection Factor (SPF). FDA regulations require sunscreens to be labeled with the SPF, informing potential purchasers how well the product protects against ultraviolet B sunlight.

The court denied Schering-Plough's motion for a preliminary injunction, ruling that the contested claims were not unambiguously literally false. Notably, the court did not discuss whether Neutrogena's claims were inconsistent with FDA labeling requirements. In the absence of an issue of the consistency of the claims with FDA requirements, the Lanham Act claims, though denied at the preliminary injunction stage, were at least allowed to proceed to trial.

These recent cases show that, despite the lack of a private cause of action under the federal Food, Drug, and Cosmetic Act, not every claim alleging false advertising involving an FDA-regulated product is automatically doomed to fail. A claim that would require the plaintiff to prove noncompliance with the Act, in the absence of prior FDA determination of the issue at hand, may face some challenges, as would a claim based on labeling that complies with FDA regulations. However, if there is an unambiguous requirement that a defendant has failed to comply with, or if an advertisement (or trademark) makes implied claims that are not subject to express FDA regulation, a complaint is more likely to survive.

Plaintiffs considering bringing a false advertising claim against a competitor involving a product regulated by the FDA would be wise to consider carefully how the FDA's regulations might influence the outcome of the case. Understanding how a product is regulated by the FDA and its current state of compliance is time well invested, and even then it is best to study the case law regarding the particular potential claim at issue. Plaintiffs should also keep in mind that the scope of products subject to FDA regulation is wide and includes what may be unexpected to some, such as dandruff shampoo, anti-cavity toothpaste, and some computer software with medical applications.

By Keith A. Barritt
barritt@fr.com

Keith A. Barritt is a member of Fish's Trademark and Copyright group and the Regulatory and Government Affairs group. He specializes in all aspects of trademark law and FDA regulation.

Fish & Richardson regularly publishes the *Trademark Thoughts* newsletter series to keep clients informed on important changes in the law and trademark use in strategic business policy. To subscribe to this publication, please visit www.fr.com/trademarkthoughts.