VENABLE LLP

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Issue Editors

Jeffrey D. Knowles
jdknowles@Venable.com
202.344.4860

Roger A. Colaizzi
racolaizzi@Venable.com
202.344.8051

Gary D. Hailey
gdhailey@Venable.com
202.344.4997

Gregory J. Sater
gjsater@Venable.com
310.229.0377

In This Issue

Jeffrey D. Knowles
jdknowles@Venable.com
202.344.4860

Leonard L. Gordon
lgordon@Venable.com
212.370.6252

Amy Ralph Mudge
amudge@Venable.com
202.344.4743

Gregory J. Sater
gjsater@Venable.com
310.229.0377

Randal M. Shaheen
rmshaheen@Venable.com
202.344.4488

Ralph S. Tyler
rtyler@Venable.com
410.244.7436

Robert P. Davis
rpdavis@Venable.com
202.344.4514

Jonathan L. Pompan
jlpompan@Venable.com
202.344.4383

News

Appeals Court Says First Amendment Trumps FDA Off-Label Marketing Rules

On December 3, the United States Court of Appeals for the Second Circuit overturned the 2008 conviction of Alfred Caronia, a former drug company sales representative, for violating the Food, Drug and Cosmetic Act (FDCA) by introducing a misbranded drug into interstate commerce.

In 2008, Caronia was convicted of promoting the use of Xyrem, a narcolepsy drug, to treat excessive daytime sleepiness, muscle disorders and chronic fatigue although the FDA had not approved the drug to treat those conditions.

Caronia and his attorneys maintained that it should not be a crime for drug companies and sales representatives to truthfully promote FDA-approved drugs for legal, off-label uses when doctors may engage in similar speech without penalty.

The court held that "the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug."

An attorney for Caronia told Reuters the decision "increases the marketability of drugs, and means consumers can be fully informed by sales representatives, manufacturers and their own physicians."

Click here to read Reuters' coverage of the decision.

Click here to read the Court's 82-page opinion.

FTC Announces 100th Do Not Call Enforcement Action

This week, the Federal Trade Commission (FTC) announced its 100th Do Not Call enforcement action since the founding of the National Do Not Call Registry in 2003. The FTC alleges that the company involved placed robocalls to numbers on the National Do Not Call registry. In these calls, the company allegedly impersonated the FTC and used the promise of help securing refunds connected to recent FTC enforcement actions to convince consumers to provide personal and bank account information.

The enforcement action demonstrates the FTC's continued attention to violations of Do Not Call regulation and the Telemarketing Sales Rule, as well as the FTC's efforts to stop illegal commercial robocalls.

It is also a good reminder for marketers to examine and, if needed, update their Do Not Call policies and procedures to ensure compliance.

Click here to read the FTC's press release announcing the enforcement action and to view the FTC's complaint.

Analysis

NuWave v. Emson Highlights Infomercial Copyright and Trademark Considerations

Honors and Awards

Top ranked in *Chambers USA* 2012

Law Firm of the Year, National Advertising, *U.S. News and World Report*, 2011-2012

Top-Tier Firm *Legal 500*

For more information about Venable's award-winning Advertising and Marketing practice, please visit our website at www.Venable.com/Advertising-and-Marketing

In the December 2012 edition of the *DRMA Voice*, Venable partner **Gregory J. Sater** analyzes a recent U.S. District Court decision in a lawsuit brought by Hearthware against Emson.

In the lawsuit, Hearthware claimed that Emson's infomercial for the Super Wave oven was too similar to Hearthware's pre-existing infomercial for the NuWave oven – a claim of copyright infringement. Hearthware also alleged that the name of Emson's product, Super Wave, was confusingly similar to the name of Hearthware's preexisting product, the NuWave – a claim of trademark infringement. Both claims were rejected by the court on summary judgment.

The reasoning behind the Court's decision, writes Sater, serves as a good refresher for marketers on the basic legal principles of copyright and trademark infringement, especially in the context of infomercial marketing.

Click here to read the full text of Sater's *DRMA Voice* column.

Click here to read the Judge's Order in the case.

There Are Warning Letters from the FTC, And Then There Are Other Warning Letters

On November 28, the FTC announced that it had sent warning letters to certain members of the travel industry concerning certain advertising practices and the disclosure of mandatory charges to consumers. The following day, the FTC announced that it had sent warning letters to makers of sports equipment over certain health claims related to concussion prevention.

Venable partners **Leonard L. Gordon**, **Amy Ralph Mudge** and **Randal M. Shaheen** write in a recent post to Venable's advertising law blog, **www.allaboutadvertisinglaw.com**, that while any letter from the FTC deserves serious scrutiny, one type of FTC warning letter should be especially alarming to marketers.

Under Section 5(m)(1)(B) of the FTC Act, if the FTC enters a final cease and desist order (other than a consent order) with respect to an act or practice, then it may seek civil penalties against any company that engages in such act or practice with actual knowledge that it is unlawful. The FTC sometimes sends warning letters to companies that cite such final cease and desist orders entered against other companies and set the recipients up potentially for a subsequent civil penalty action.

In one court case, the United States Court of Appeals for the Eighth Circuit refused to give the FTC carte blanche in terms of how closely the cease and desist order must match the practice of the party under notice. However, the Venable partners write, significant questions remain regarding how closely the acts or practices in the cease and desist order must match the acts and practices that form the basis for the civil penalty action.

Click here to read the full post on Venable's advertising law blog.

Fred Meyer Guides Go Back to the Future

The FTC recently announced that it is considering whether to revise or eliminate its "Guides for Advertising Allowances and other Merchandising Payments and Services," writes Venable attorney **Robert P. Davis** in a recent post to Venable's advertising law blog, **www.allaboutadvertisinglaw.com**.

The guides, otherwise known as the "Fred Meyer Guides" due to the Pacific Northwest retailer who got caught in an FTC case that ended up in the United States Supreme Court in the 1960s, attempt to give guidance for businesses on some specific aspects of the Robinson Patman Act. The Act was intended to help small retailers compete against the big chain stores.

Under the Act, sellers of goods for resale (for example, manufacturers) are prohibited from discriminating against certain customers in favor of others, such as charging different prices to different buyers, where that discrimination might harm competition between those customers.

What is interesting, Davis writes, is that the FTC has done little to enforce the act since a case in 2000. The Department of Justice, which also has enforcement authority under the Act, has likewise done little to enforce the Act.

Among the 14 questions the FTC posed in its announcement of the review, five were of special interest:

- Whether there is a continuing need for the Guides;
- Whether there have been changes in the case law that should now be reflected in the Guides;
- How, if at all, the Guides should be revised to account for new developments in commercial practices since 1990, such as the growth of the Internet as a means of promoting products;
- What costs and benefits the Guides provide to business; and
- What costs and benefits the Guides ultimately have for consumers.

The FTC will accept comments until January 29, 2013.

Click here to read Davis' full post on Venable's advertising law blog.

Upcoming Events

"Telemarketing, Email and Text Message Marketing: Tips to Avoid Lawsuits," LeadsCouncil Webinar
December 11, 2012
Venable attorney **Jonathan L. Pompan** will moderate this discussion with **Ari N. Rothman** and **Molly T. Cusson**, two Venable attorneys with extensive experience advising lead generators and affiliate marketers on legal and regulatory matters. The session will address the effective management of legal and regulatory risks when marketing via telemarketing or email and text messaging. It will also provide pointers on negotiating contract protections, shoring up due diligence, minimizing compliance gaps, and what to do when your company is involved in a lawsuit.

Please **click here** for more information.

"Mother Nature's Perfect Litigation Storm: 'Natural' Claims," American Bar Association's Section of Antitrust Law, Private Advertising Litigation Committee
December 11, 2012
"Natural," "All Natural" and "Sourced from Nature" are claims that we see every day. Products with these claims have come under attack in a tsunami of class action filings filed in California and elsewhere. This panel, featuring Venable partner **Amy Ralph Mudge**, will overview the regulatory landscape for natural claims, examine the current controversies surrounding use of "natural" in advertising of food, dietary supplements, cosmetics and household products, discuss the development of industry consensus standards and the role of self-regulation, and provide some suggestions for marketers considering such claims.

This webinar is free for section members and nonmembers. Please **click here** for more information.

Affiliate Summit West 2013 - Las Vegas
January 13-15, 2013
Join Venable attorneys at this conference which provides educational sessions on the latest affliliate-marketing industry issues and fosters a productive networking environment for affiliate marketers.

To register, please **click here**.

Electronic Retailing Association Network LA: Beach Access - Santa Monica, CA
January 16, 2013
Venable is a proud sponsor of this event. Please join us and our direct-to-consumer marketing colleagues for an evening of connections and cocktails.

For more information, please **click here**.

Click here to subscribe to Venable's Advertising and Marketing RSS feed and receive the Venable team's insight and analysis as soon as it is posted.

Visit Venable's advertising law blog at www.allaboutadvertisinglaw.com.

575 7th Street, NW, Washington, DC 20004