Advertising Law @ manatt

June 7, 2010

In This Issue

FDA Warns Drug Company About Sponsored Sites

The Food and Drug Administration's Division of Drug Marketing, Advertising, and Communications issued a warning letter to pharmaceutical company Novartis about two disease-awareness sites sponsored by the company – even though the sites didn't mention the company's drugs by name.

As part of its monitoring and surveillance program, the DDMAC reviewed the sites (www.gistalliance.com and www.cmlalliance.com), which purported to be informational sites for those suffering from leukemia.

Novartis is the manufacturer of Gleevec, a drug approved to treat leukemia. But the DDMAC said the sites "are false and misleading because they promote the drug for an unapproved use, fail to disclose the risks associated with the use of Gleevec, and make unsubstantiated dosing claims," the letter said. Further, the company failed to submit the materials prior to dissemenination or publication.

Even though the sites do not actually name the drug Gleevec, they "effectively promote this drug product," the letter states, for several reasons:

- The sites were registered to Novartis and were "perceptually similar" to the Novartis Gleevec product website, incorporating similar color schemes, design layouts, and other presentation elements;
- Both sites were "clearly marked" with the Novartis Oncology name and logo, they discussed sponsorship by the company, and one page included a direct link to the Gleevec product website;
- Numerous references were made to a set of oncology clinical

Shortlisted for the CHAMBERS USA AWARDS for Excellence 2010

Recognized for Excellence in the areas of Advertising, Marketing and Media

The LEGAL 500 UNITED STATES

Named a Top Practice Nationally for Marketing and Advertising

THE BEST LAWYERS IN AMERICA

Practice leaders included among the prestigious *Best Lawyers* in the country

UPCOMING EVENTS

June 10-12, 2010

guidelines that recommend the use of Gleevec exclusively for first-line treatment of the type of cancer discussed on the sites; and Data from clinical studies included literature references that specifically named Gleevec.

"Based on this combination of factors, these websites are product-specific promotions for the drug Gleevec. Consequently, these websites are subject to regulation by the FDA, and are false or misleading," the letter said. Because the sites were subject to regulation by the FDA, the DDMAC then found that they promoted the drug for an unapproved use, made omissions about and minimized the risks of the drug, made unsubstantiated dosing claims, and failed to submit the information on the sites for prior approval. The DDMAC requested that Novartis immediately cease dissemination of the materials and submit a plan of action to disseminate truthful materials as well as corrective messages.

In a statement, a Novartis spokesperson said the company has stopped using all materials relating to the Web sites (both of which currently display a message that the site is unavailable) and would respond to the FDA to address its concerns. "One of our primary goals is to provide patients . . . access to accurate, timely and relevant disease information which is why we developed these unbranded disease awareness sites," the company said.

To read the letter, click here.

Why it matters: The FDA is currently considering whether – and how – to regulate drug marketing in the context of social media and Web 2.0. The warning letter serves as an example that the agency is already going above and beyond the traditional forms of marketing to enforce its regulations. Increased scrutiny of marketing via social media and sites like Twitter should be expected not just for company Web sites, but third-party and unbranded sites as well. The Web sites could be considered promotional materials by the FDA and therefore in violation of regulations if the agency finds too many connections between the company and the site, as it did with Novartis.

back to top

WHO Recommends Ban On Marketing Certain Foods To Kids

Concerned about increasing obesity rates among children, the World Health Organization outlined new recommendations for the marketing of certain foods, including a ban on marketing sugar-sweetened beverages and high-sodium foods at playgrounds and schools.

At the WHO's annual meeting, the ministers agreed to adopt the recommendations, which will serve as guidelines for the 193 member states. The recommendations are intended to "promote responsible

Natural MarketPlace 2010
Topic: "The Claim Game- Vegas Edition"
Speaker: Ivan Wasserman
Las Vegas, NV
Las Vegas Convention Center
for more information

June 10-12, 2010
American Advertising Federation
Topic: "Let's Get Digital"
Speaker: Linda Goldstein
Orlando, FL
for more information

June 10-12, 2010
American Advertising Federation
Topic: "Truth in Advertising: Can You Handle It?"
Speaker: Jeff Edelstein
Orlando, FL
for more information

June 15-16, 2010
American Conference Institute Litigating and Resolving Advertising Disputes
Topic: "The Realities of Bringing and Defending a Lanham Act case in Federal Court Part 2: Litigating and Proving the Case"
Speaker: Tom Morrison
New York, NY
The Helmsley Park Lane Hotel
for more information

marketing . . . of foods and nonalcoholic beverages to children, in order to reduce the impact of foods high in saturated fats, trans-fatty acids, free sugars, or salt, in dialogue with all relevant stakeholders, including private-sector parties, while ensuring avoidance of potential conflict of interest."

Specifically, the recommendations include a ban on the marketing of foods high in saturated fats, trans-fatty acids, free sugars, or salt at "settings where children gather," including nurseries, schools and school grounds, preschool centers, playgrounds, family and child clinics, pediatrics services, and during any sporting or cultural activities held on such premises. Member states are also urged to "consider the most effective approach to reduce marketing to children" of foods high in saturated fats, trans-fatty acids, free sugars, or salt.

The WHO recommendations also encourage member states to put in place a monitoring system to evaluate the effectiveness of its policy, include a system for sanctions and reporting complaints, to create an enforcement mechanism, and to conduct further research in the area, focused on reducing the impact on children of marketing such foods. And the WHO emphasized that although television remains an important advertising medium, the recommendations should apply to all forms of marketing, including the use of brand mascots or popular characters, Web sites, point-of-purchase displays, e-mails and text messages, viral marketing, word-of-mouth marketing, and other forms of social media.

To read the WHO's recommendations on the marketing of food and nonalcoholic beverages to children, click here.

Why it matters: U.S. Surgeon General Regina Benjamin endorsed the plan. "The set of recommendations on marketing of food and nonalcoholic beverages to children should play a significant role in helping member states promote healthier patterns of eating as part of efforts to reduce the growing epidemic of childhood obesity," she said in a speech.

The WHO noted that its recommendations could be implemented in a variety of formats, from statutory regulation to industry self-regulation. Some form of action by the U.S. government is possible between the support of the Surgeon General and the fact that the Obama Administration has tackled childhood obesity as an important issue. Earlier this month a Task Force created by the White House issued a plan for reducing childhood obesity that included similar recommendations to limit the marketing of unhealthy foods to children.

back to top

June 15-16, 2010

American Conference Institute

Litigating and Resolving Advertising Disputes

Topic: "Pushing the Envelope: Case Studies Examining Advertising that has been the Focus of Recent Adversarial Proceedings"

Speaker: Linda Goldstein

New York, NY

The Helmsley Park Lane Hotel

for more information

Newsletter Editors

Jeffrey S. Edelstein
Partner
jedelstein@manatt.com
212.790.4533

Linda A. Goldstein
Partner
lgoldstein@manatt.com
212.790.4544

Terri J. Seligman
Partner
tseligman@manatt.com
212.790.4549

Our Practice

Whether you're a multi-national corporation, an ad agency, a broadcast or cable company, an e-commerce business, or a retailer with Internet-driven promotional strategies, you want a law firm that understands ... more

Practice Group Overview
Practice Group Members

Info, Resources & Links

Subscribe
Unsubscribe
Newsletter Disclaimer
Manatt.com

NFL Fumbles Licensing Deal

In a closely watched case, the U.S. Supreme Court ruled that the National Football League's exclusive licensing agreement with Reebok violated antitrust laws, opening the door to allow individual NFL teams to independently license their trademarks.

Although the teams of the NFL formed the National Football League Property to develop, license, and market their intellectual property in 1963, the individual teams granted nonexclusive licenses to various vendors. That changed in 2000, when the NFLP entered into an exclusive 10-year deal with Reebok to manufacture and sell headwear for all 32 teams.

American Needle, a former licensee, filed suit, claiming that the deal violated the Sherman Act, the federal antitrust law. Lower courts disagreed, letting the deal stand. But in a unanimous opinion by the U.S. Supreme Court, the justices disagreed. The Court determined that although the teams operated as a single unit through the NFLP, they remained separate economic actors with independent centers of decision making.

"The fact that NFL teams share an interest in making the entire league successful and profitable, and that they must cooperate in the production and scheduling of games, provides a perfectly sensible justification for making a host of collective decisions. But the conduct at issue in this case is still concerted activity under the Sherman Act," the Court said.

Recognizing that some collective decisions are necessary and appropriate, the Court limited its holding to the NFLP's joint marketing venture. "The teams compete with one another, not only on the playing field, but to attract fans, for gate receipts, and for contracts with managerial and playing personnel. Directly relevant to this case, the teams compete in the market for intellectual property. To a firm making hats, the Saints and the Colts are two potentially competing suppliers of valuable trademarks," Justice John Paul Stevens wrote. But because each of the teams is a "substantial, independently owned, and independently managed business," they do not have common objectives, the justices said. "Decisions by NFL teams to license their separately owned trademarks collectively and to only one vendor are decisions that 'depriv[e] the marketplace of independent centers of decision making,' and therefore of actual or potential competition," the Court said.

The case will continue in the lower courts, as the justices did not determine whether the NFL actually violated antitrust law. A lower court will now determine whether the League's licensing practices actually harmed competition.

To read the decision in *American Needle v. National Football League*, click here.

Why it matters: The ruling's impact will be felt far beyond the goalposts of the football field, with implications for other sports leagues as well as other industries that engage in joint ventures. While Major League Baseball has an antitrust exemption dating back to 1922, the other sports leagues – the National Basketball Association, the National Hockey League, the National Collegiate Athletic Association, NASCAR, professional tennis, and Major League Soccer – had filed an amicus brief in support of the NFL before the U.S. Supreme Court, seeking similar protection. The Court's decision opens the door for more brands to create lucrative marketing deals with individual teams.

back to top

Coach Sues Chicago Over Counterfeits

Coach, Inc. filed a multimillion-dollar lawsuit against Chicago, alleging that the City's failure to crack down on vendors who sell counterfeit goods at an outdoor market amounts to a violation of the Lanham Act. The lawsuit, filed in Illinois federal court, seeks $2 million per violation, an injunction halting the sale of fake Coach products, and punitive damages.

According to the complaint, a Coach investigator visited Maxwell Street, a local market, in August 2009. Within plain view he observed roughly 300 vendors selling counterfeit Coach products, the suit claims. City police officers later returned to the market with the investigator, who purchased an $18 fake Coach bag at one booth and a fake Chanel bag for $24 at another booth. The two vendors were arrested and 351 fake Coach products were found in the two booths.

Coach sent a cease-and-desist letter to the City, asking it to curb activity at the market, but the City did not respond, the complaint alleges. Another investigator returned to the market earlier this year and found that little had changed from the prior visit. The suit names the two vendors who were arrested along with 100 John Does and the City of Chicago as defendants.

Over the last year Coach has filed almost 200 lawsuits as part of a nationwide program called Operation Turnlock, the company's attempt to use civil litigation to fight the distribution and sale of fake products. The suit against Chicago is the only one against a municipality. The City is named because vendors pay a $50 annual license fee in order to display their goods at the New Maxwell Street Market, two miles from the well-known downtown Loop. The City's inaction to stop the sale of knock-offs constitutes trademark and trade dress infringement under the Lanham Act, trademark dilution, and unfair competition under state law and copyright infringement, the suit alleges.

To read the complaint in *Coach v. City of Chicago*, click here.

Why it matters: The suit is unusual in its attempt to hold a municipality responsible for the sale of counterfeit products. Coach will argue that by issuing licenses to the vendors who made the allegedly illegal sales, the City can be held liable. The company will rely upon the arrests of vendors and the cease-and-desist letter it sent, claiming that it put the City on notice that the illegal activity was taking place.

back to top

EU To Search Engines: Still Breaking The Law

European authorities sent a letter to Google, Microsoft, and Yahoo! at the end of May informing the companies that their data-retention practices violate European Union law. European data-protection directives require that search engines delete all traceable links to individual computer users completely after six months.

The three search engines had previously been informed by the EU authorities that they were not in compliance. Although the companies updated their policies in response, the letter from the Article 29 Working Party, a group of 27 European national privacy chiefs, alleged that the search engines still do not adequately anonymize information about their users.

"An individual's search history contains a footprint of that person's interests, relations, and intentions and should rightly be treated as highly confidential personal data," the letters said. "Pursuant to the data-protection directive, the retention period should be no longer than necessary for the specific purposes of the processing, after which the data should be deleted." Each of the search engines has its own issues, according to the letter.

Google keeps its users' information for nine months, past the six-month limit, and deletes only a section of the users' IP address, which does not prevent the identification of data subjects, the EU authorities allege. Google also retains cookies for 18 months, which makes for "easy retrieval of IP addresses, every time a user makes a new query within those 18 months," according to the letter.

Although Yahoo! deletes IP addresses after three months, the EU authorities expressed concern about the company's techniques of hashing, specifically with regard to user identifiers, and cookies. And Microsoft – which has said it will delete IP addresses after six months – should also delete users' cookies and other session identifiers after that same time period, the letter said.

Based on the search engines' practices, the Working Party "cannot conclude that your company complies with the European data-protection directive," the letter said.

The letters requested that the three companies appoint outside auditors to verify that their practices have truly eliminated all links to users and their data.

To read the letter to Google, click here.

To read the letter to Yahoo!, click here.

To read the letter to Microsoft, click here.

Why it matters: In a separate letter, the EU authorities also encouraged the Federal Trade Commission to probe the search engines' data-retention practices in the United States, and investigate whether their data-retention policies constitute a violation of the FTC Act. "The concerns of the [Working Party] are focused on the retention and anonymization policy of the three providers with regard to the search query logfiles," the letter said, offering the FTC assistance in finding a "constructive solution to protect the private life of everybody who conducts searches on the Internet."

back to top