Shook, Hardy & Bacon L.L.P.

ISSUE 23 | APRIL 17, 2014

LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

CONTENTS

INSIDE GOVERNMENT

Physician Calls for Regulatory Overhaul of Dietary Supplements

In a "Perspective" published in the April 9, 2014, issue of the *New England Journal of Medicine*, Pieter Cohen, a physician who is board certified in internal medicine, explains how the current system for regulating dietary supplements is inadequate and led to a cluster of cases of severe hepatitis and liver failure in Hawaii among OxyElite Pro users. Under current law, supplements do not require premarket approval, and half of U.S. adults consume them, spending more than $32 billion annually on more than "85,000 different combinations of vitamins, minerals, botanicals, amino acids, probiotics, and other supplement ingredients." The U.S. Food and Drug (FDA) Administration is charged with identifying and removing dangerous supplements after they have allegedly caused harm.

With hundreds of supplements sold as "all natural" containing potentially dangerous ingredients, including pharmaceuticals, stimulants, anabolic steroids, and new analogues of methamphetamine, Cohen states that "the agency has its work cut out for it." He claims that MedWatch, on which FDA relies for adverse event information, "suffers from significant underreporting and incomplete reports, which hamper its ability to detect harms even from prescription medications." He contends that the most recent clusters of serious adverse effects linked to supplements were not found through the MedWatch system, noting that clinicians can be unfamiliar with supplement ingredients and may turn to poison centers for help. In fact, "[a]n investigation by the Government Accountability Office revealed that between 2008 and 2010, more than 1000 supplement-related adverse events were reported to poison centers but not reported to the FDA."

Cohen calls for "sweeping changes" to create an effective surveillance system, including shared reports among key organizations, a "supplement response team" and a requirement that supplement manufacturers "provide complete manufacturing details and additional samples as requested." He also recommends that every supplement ingredient "undergo rigorous safety testing

SHB offers expert, efficient and innovative representation to clients targeted by plaintiffs' lawyers and regulators. We know that the successful resolution of health, wellness and personal care product-related matters requires a comprehensive strategy developed in partnership with our clients.

For additional information on SHB's Health, Wellness & Personal Care Products capabilities, please contact

Debra Dunne
215-278-2555
ddunne@shb.com

Laurie Henry
816-559-2421
lhenry@shb.com

Madeleine McDonough
816-559-2342
mmcdonough@shb.com

If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

before marketing. Until that happens, consumers and physicians cannot be assured that the pills, powders, and potions labeled as dietary supplements are safe for human consumption."

FDA Warns Company That Its Beverage Products Are Misrepresented as Dietary Supplements

The U.S. Food and Drug Administration (FDA) has issued a warning letter to Dewmar International BMC Inc., alleging that the company misbrands its Lean Slow Motion…Potion beverage as a dietary supplement, when the product is in fact represented as a conventional food in marketing materials. This is reportedly the first warning letter of its kind since FDA issued its final guidance on liquid dietary supplements in January 2014.

"Your use of the term 'dietary supplement' below the Nutrition Facts panel on your product labels does not make your products dietary supplements, because your Lean Slow Motion…Potion products are represented for use as conventional foods," wrote FDA District Director Patricia Schafer. Citing Dewmar's description of its products as beverages on the cans' information panels and referencing the company's Website, which refers to the products as the "#1 relaxation beverage" and "the most potent relaxation drink," FDA noted that Dewmar's products (i) "have the appearance and packaging of carbonated soft drinks"; (ii) include a Nutrition Facts label; (iii) are sold in single-serving pop-top aluminum cans and appear to be carbonated soft drinks; and (iv) contain "typical ingredients for carbonated soft drinks," such as citric acid, carbonated water and sugar.

The agency has also called into question Dewmar's use of melatonin, a neurohormone predominantly used as a sleep aid to treat sleep-related disorders. According to the agency, because Lean Slow Motion…Potion is effectively marketed as a beverage, and melatonin is an unapproved food additive under Section 409 of the Federal Food, Drug, and Cosmetic Act, the product is considered an adulterated food and should be removed from the market.

LITIGATION AND REGULATORY ENFORCEMENT

Court Certifies Nationwide Class Challenging Efficacy of Homeopathic Remedy

A federal court in California has certified a nationwide class in litigation alleging that the makers of homeopathic products advertised as fast, safe and effective relief from children's cold and flu symptoms mislead consumers because "homeopathy is pseudoscience" and the products are "nothing more than sweetened, flavored water with . . . highly diluted concentrations of the products' so-called 'active ingredients.'" *Forcellati v. Hyland's, Inc.*, No. 12-1983 (U.S. Dist. Ct., C.D. Cal., order entered April 9, 2014).

At the outset the court ruled that the defendants failed, as previously ordered, to sufficiently discuss why California law should not be applied to the claims of out-of-state purchasers under a choice-of-law analysis, choosing instead to "rely on conclusory assertions and citations to cases in which defendants met their burdens in different factual circumstances." In this regard, the court observed, "Given that *Mazza* did not 'categorically rule out application of California law to out-of-state class members,' simply citing *Mazza* in no way relieves Defendants of their burden."

The approved class definition excludes California consumers to prevent overlap with claims certified in a California state-court action. While the court certified a monetary damages class under Federal Rule of Civil Procedure 23(b)(3), it refused to certified a class seeking injunctive relief under Rule 23(b)(2) because "Plaintiffs have no reason to re-purchase cold and flu products that they consider to be completely worthless and ineffectual." So ruling, the court disagreed with other Ninth Circuit district courts which have concluded that representative plaintiffs have the Article III standing to pursue their Rule 23(b)(2) claims under similar circumstances to further the purpose of California's consumer-protection laws.

Among other matters, the court also disagreed with the Third Circuit which has found proposed classes insufficiently ascertainable when no records were available to confirm class membership: "purchasers likely have not retained proof of purchase for such low-cost products, and Defendants do not have any records identifying the consumers who purchased their products via retail intermediaries." According to the court, facilitating small claims is the policy at the very core of the class-action mechanism. The plaintiffs precisely identified their class based on objective criteria—purchase of specific products within a prescribed time frame—and this is enough to satisfy the implied ascertainability requirement of Rule 23(a). The court was untroubled by the defendants' argument that inaccurate or fraudulent claims would dilute the relief available to "true" class members. In the court's view, "with so little money at stake, class members may lack any incentive to pursue claims individually. Accordingly, even though some inaccurate or fraudulent claims may go undetected, a diluted recovery is surely preferable to absent class members' only realistic alternative: no recovery at all."

The court further ruled that the plaintiffs had sufficiently shown commonality. "Here, all of Plaintiffs' claims share the same fundamental premise: Defendants misrepresent that their products safely and effectively treat flu and cold symptoms when, in fact, they have no medicinal value whatsoever." While some consumers were satisfied with the defendants' products, the court found that the efficacy claims could still be proven misleading given the plaintiffs' allegations that the products are placebos and any "effectiveness arises solely as a result of the placebo effect." As to the predominance requirement, the court determined that individual decisions about buying the products, based on a

large number of factors, are "immaterial here given the objective materiality of the alleged misrepresentations. 'Defendant[s] cannot reasonably argue that a putative class member would purchase a product that does not work.' Accordingly, the particular circumstances under which each individual purchase was made cannot 'transform a common question' of whether the alleged misrepresentations were objectively material 'into a multitude of individual ones.'"

Court Dismisses Antitrust, Tortious-Interference and Lanham Act Claims Against Estée Lauder

A federal court in Florida has dismissed a duty-free store's claims against The Estée Lauder Companies, Inc. (ELC) for failure to state a valid claim, dismissing two of the three claims with prejudice and allowing the third to be amended. *Duty Free Americas, Inc. v. The Estée Lauder Cos., Inc.*, No. 12-60741 (U.S. Dist. Ct., S. Fla., decided March 31, 2014). Duty Free Americas, Inc. (DFA) alleged that ELC had acted inappropriately in its dealings with DFA and in association with several of DFA's proposals for business with various airports.

ELC and DFA had a business relationship until 2008, when ELC increased its prices for travel retail stores and DFA stopped buying ELC products to stock in its duty-free stores in airports. DFA alleged that following the end of that relationship, ELC interfered in DFA's proposals to four airports to establish duty-free stores in their international terminals. The court disagreed, dismissing each of DFA's attempted-monopolization, tortious-interference and false advertising claims against ELC.

The court first assessed DFA's attempted-monopolization claim. DFA argued that ELC had engaged in anticompetitive conduct because ELC had refused to do business with DFA, ELC had submitted false information to airport authorities about DFA, and ELC had required stringent conditions for the sale and display of its products when DFA and ELC had a business relationship. The court disagreed, finding no legal basis for the first assertion, no factual basis for the second and no standing for the third. Refusing to impute to ELC any statements to the airports by third-party DFA competitors, the court also dismissed the tortious-interference claim. Because both claims appeared in the original and amended complaints and had undergone extensive discovery, they were dismissed with prejudice.

DFA also alleged that ELC contributed to false advertising by DFA's competitors. After DFA submitted proposals to two airports, its competitors expressed doubts to the airports about the accuracy of DFA's projected sales based on ELC's confirmation to those companies that DFA was not authorized to sell ELC products in its stores. The court dismissed this claim as well, finding that each statement was opinion rather than a factual assertion and thus did not constitute false advertising under the Lanham Act. As this claim first appeared in DFA's amended complaint, the court dismissed the claim without prejudice.

No MDL for Dietary Supplement Class Actions

The Judicial Panel on Multidistrict Litigation (JPML) has issued an order denying the request of USPlabs, LLC to transfer nine actions pending before six federal district courts to a multidistrict litigation court (MDL) for pre-trial proceedings. *In re OxyElite Pro & Jack3d Prods. Liab. Litig.*, MDL No. 2523 (J.P.M.L., order entered April 2, 2014).

According to the panel, "[a]lthough all actions allege that various USPlabs products are unsafe, . . . it appears that the different formulations of the products will not give rise to substantially overlapping discovery, particularly in light of the differences in the health risks alleged and the distinct regulatory responses to the DMAA and aegeline products. Additionally, the three consumer class actions raise a unique threshold issue with respect to the alleged impact of a state court class settlement agreement reached in 2012." JPML encouraged the parties to "employ various alternatives to transfer which may minimize the potential for duplicative discovery and/or inconsistent pretrial rulings."

The lawsuits allege false advertising and personal injury from the use of OxyElite Pro and Jack3d products made with the stimulant dimethylamylamine (DMAA) and personal injury allegedly caused by OxyElite Pro with aegeline, a plant extract. The products at issue are no longer on the market since the U.S. Food and Drug Administration (FDA) took action in 2012 and 2013 advising consumers not to buy or use DMAA-containing products. Details about FDA's action and product forfeiture actions taken by federal prosecutors appear in Issue 5 of this *Report*.

Weight-Loss Pill Maker Pleads Guilty to Misbranding

According to the U.S. Department of Justice (DOJ), Balanced Health Products and owner Nikki Haskell have entered guilty pleas to misdemeanor counts of misbranding in the distribution of "StarCaps" weight-loss pills which failed to list a prescription drug as an ingredient.

Manhattan U.S. Attorney Preet Bharara said, "For years [the defendants] distributed weight-loss pills throughout the United States that they sold as 'all natural' when in fact the pills contained a prescription drug banned by the National Football League and other major sports organizations." The ingredient in question, Bumetanide, can apparently be used to mask the presence of steroids and other banned doping agents in the human body. Available by prescription only, Bumetanide is a diuretic used clinically to treat heart failure, acute renal failure, high blood pressure, and edema, DOJ reported.

Haskell faces a maximum one-year prison term and one-year term of supervised release, as well as a maximum fine of $100,000. The company faces a maximum fine of $200,000 or twice the gross pecuniary gain derived from

the offense. The defendants are scheduled for sentencing before a federal magistrate judge in New York on June 30, 2014. *See DOJ Press Release*, March 26, 2014.

Cosmetics & Clothing Companies Settle Trademark Dispute

Mary Kay Inc. has reportedly agreed to settle its claims that clothing and accessories company Michael Kors LLC violated a co-existence agreement involving use of the initials "MK" by filing applications with the U.S. Patent and Trademark Office to register "MK" for use on a charm attached to an Estée Lauder cosmetic gift bag; under the agreement, Mary Kay apparently has the exclusive right to use the mark to promote makeup. *Mary Kay Inc. v. Michael Kors LLC*, No. DC-13-01663 (Tex. Dist. Ct., Dallas Cnty., joint motion to dismiss filed April 2, 2014). Without indicating the terms of the agreement other than assuming their own litigation costs, the companies stated, "All matters in controversy between Mary Kay and Michael Kors have been fully compromised and settled, and those parties no longer desire to prosecute their respective claims and counterclaims." *See Law360*, April 4, 2014.

FTC Approves Consent Order in Case Against L'Occitane

Following a public comment period, the Federal Trade Commission (FTC) has unanimously approved a final consent order regarding its settlement with cosmetics manufacturer L'Occitane, Inc. First announced in January 2014, FTC accused L'Occitane of violating the FTC Act by making improper claims about the slimming properties of its Almond Beautiful Shape and Almond Shaping Delight skin creams. The order requires L'Occitane to refund $450,000 to consumers and prohibits the company from making false and deceptive weight-loss claims in the future. *See FTC News Release*, April 8, 2014.

Putative Class Claims Herbalife Violated Securities Laws

Shareholder litigation has been filed against Herbalife Ltd. and its CEO, CFO, COO, and president, claiming that they "made materially false and misleading statements regarding the Company's business, operational and compliance policies" in violation of securities laws. *Awad v. Herbalife Ltd.*, No. 14-2850 (U.S. Dist. Ct., C.D. Cal., filed April 14, 2014). Information about the company's efforts to lobby Congress in light of concerns over its direct-sales practices appears in Issue 21 of this *Report*.

Claiming that shareholder investments have lost value as various news stories have surfaced about accusations that the nutritional supplement and personal care products company operates as a pyramid scheme, the plaintiff alleges that the defendants deceived the investing public through a scheme that artificially inflated the market price of its securities. The complaint cites an April 11, 2014, *Financial Times* news item on a purported Department of

Justice and Federal Bureau of Investigation criminal probe of the company, after which Herbalife stock allegedly fell more than 13 percent. The company has released a statement indicating that it has no knowledge of any ongoing criminal investigation. *See Law360*, April 11, 2014.

Kanebo Faces First Group Action over Skin Whitening Product

According to news sources, 14 men and women have filed what is said to be the first group action against Kanebo Cosmetics, Inc. in the Shizuoka District Court. Seeking a total of ¥70 million (US$674,300) in damages, the plaintiffs, who range in age from their 30s to 70s, allege that company products containing Rhododenol have caused white blotches on their faces or other body parts. They seek compensation for the costs of medical treatment as well as psychological injury. Their complaint reportedly alleges that the products were defective and that Kanebo failed to take measures to ensure product safety. Information about other similar litigation facing the company appears in Issue 15 of this *Report*. *See The Japan Daily Press* and *The Borneo Post*, April 3, 2014.

EMERGING TRENDS

PCPC Launches Cosmetics Manufacturing Assessment Tool

The Personal Care Products Council (PCPC) has **launched** its personal care manufacturing assessment program designed to help companies assess manufacturing processes for cosmetics and personal care products. Developed jointly by PCPC and SAI Global, an independent legal, compliance and risk-management services provider, PCPC says that the voluntary program demonstrates the industry's "continued adherence to good manufacturing practices" and covers quality aspects relating to personnel, equipment, raw materials, production, subcontracting, complaints and recalls, waste management, control, and storage and shipment. *See PCPC News Release*, April 9, 2014.

L'Oréal and Shiseido Rated Among the "World's Most Ethical Companies"

International think tank the Ethisphere Institute has named global beauty companies L'Oréal and Shiseido Co., Ltd., among the winners of its 2014 "World's Most Ethical Companies" award. Recognized as companies that "go beyond making statements about doing business ethically and translate those words into action," the beauty brands joined 142 other companies awarded the same designation for "promot[ing] ethical business standards and practices internally," exceeding legal compliance minimums and "shap[ing] future industry ethical business standards." The World's Most Ethical Company assessment is based on the Institute's proprietary rating system, which ranks companies in the following categories: ethics and compliance

program; reputation, leadership and innovation; governance; corporate citizenship and responsibility; and culture of ethics. *See Ethisphere.com*, March 20, 2014.

INTERNATIONAL DEVELOPMENTS

Russian Patent Office Cancels Chinese Cosmetic Company's BBC Trademark Registration

The Russian Federal Service for Intellectual Property, Patents and Trademarks has reportedly removed Chinese cosmetic manufacturer Britain BBC International Cosmetics, Ltd.'s right to use the name "BBC" after an investigation revealed that some 60 percent of the brand's consumers thought the products were made with permission from the British Broadcasting Corporation (BBC), which they are not.

According to a news source, Britain BBC International Cosmetics is listed as a partner company in the Batel cosmetics network of Chinese brands in Russia, and its profile erroneously claims that the company's hair, skin and body care products are produced "under the control of Britain BBC Cosmetics International, UK." The BBC has blasted the beauty brand for its use of the three-letter initial branding and a logo that is apparently exceedingly similar to BBC's registered trademark. *See CosmeticsDesign-Europe*.com, April 3, 2014.

Ad Watchdog Upholds Complaint Against Dutch Joint Supplement Health Claims

The U.K. Advertising Standards Authority (ASA) has upheld a **complaint** alleging that Dutch joint supplement manufacturer Finitro International made and continues to make unsubstantiated joint health claims on its Website that are unauthorized by the EU Register of Nutrition and Health Claims for Foods.

With claims that its Finitro Forte Plus dietary supplement product is "the cure for osteoarthritis" and that after continuous use consumers "may expect the recovery of cartilage and a life free of pain," the company has been cited by ASA twice during the past three years.

In September 2011, ASA published an adjudication against product claims on Fintro's Website, to which the company did not respond. Following an ASA investigation, however, Finitro apparently indicated that it would amend its Website to comply with the adjudication. In April 2012, ASA published a second adjudication against claims for Finitro Forte Plus, and again Finitro submitted another assurance of future compliance. In June 2012, after continued non-compliance with the adjudications, the Committee of Advertising Practice (CAP) Compliance team placed details of the case on the ASA Website where, according to the agency, they will remain until Finitro amends

its Website claims. According to a news source, CAP is investigating the matter and will place Finitro's Website on its "enhanced name and shame list," as well as consider other measures, including (i) removing any paid-for ads via search engine agreement; (ii) advising trade associations to take action; (iii) shutting down Web domains; and (iv) referring the matter to the courts. *See Nuta-Ingredients.com*, April 10, 2014.

European Perfumery Industry Displeased with Fragrance Regulations

A group of more than 100 European perfume makers and cosmetic industry professionals gathered on April 7, 2014, in Paris, to voice concerns about European Commission (EC) Regulation No. 1223/2009, which seeks to tighten fragrance industry regulations with a series of bans, labeling requirements and research projects aimed at protecting consumers from allergens. The measures, which the EC proposed in response to recommendations from the Scientific Committee on Consumer Safety (SCCS), are currently subject to a public consultation that ends May 14.

At issue for beauty product and perfume manufacturers is the committee's proposal to prohibit certain substances, restrict the concentration of a series of others and add many substances to the list of allergens that must be labeled. Claiming that the proposed regulations would seriously damage the fragrance industry by forcing perfume makers to change many of their formulations and thus incur extra costs, members of the group also note that regulatory changes could compromise the European perfumery industry's reputation as a cultural asset. "Further restrictions of the type currently proposed will not only continue this destructive trend [], but will also send a message that Europe has turned its back on an important aspect of its own rich cultural heritage," states an online **petition** from industry group Perfumo International.

"With our signatures, we request that the decision-makers obtain a comprehensive perspective beyond the scope of the narrow confines of the [SCCS] opinion. This broad and complete perspective must include the following considerations and interests: consumer protection, cultural identity, economic considerations, and consumer interests above and beyond mere health and safety." *See Premiumbeautynews*.com, April 8, 2014.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Researchers Demonstrate DNA Damage from Nanoparticles

Using an innovative screening technology, MIT and Harvard School of Public Health researchers have been able to subject numerous samples to an improved "comet assay" and conclude that zinc oxide nanoparticles—used

in sunscreens—and nanoscale silver—added as an antimicrobial to toys, toothpaste, clothing, and other goods—produce substantial DNA damage. Christa Watson, et al., "High-Throughput Screening Platform for Engineered Nanoparticle-Mediated Genotoxicity Using CometChip Technology," *ACS Nano*, March 11, 2014.

Other nanoparticles (silicon dioxide, iron oxide and cerium oxide) tested on suspension human lymphoblastoid and adherent Chinese hamster ovary cell lines showed low genotoxicity. According to the researchers, occupational exposures and those affecting children and fetuses are of greatest concern. They claim that their screening-method efficiencies could help in the design of safer nanoparticle forms; partnering with industry, they have already apparently engineered safer UV-blocking nanoparticles by coating zinc oxide particles with a nanothin layer of amorphous silica, which reduces the particles' damaging effects on DNA. *See MIT News Release*, April 8, 2014.

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
Philadelphia, Pennsylvania
+1-215-278-2555
San Francisco, California
+1-415-544-1900
Seattle, Washington
+1-206-344-7600
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400