Shook, Hardy & Bacon L.L.P.

ISSUE 33 | OCTOBER 2, 2014

LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

CONTENTS

FIRM NEWS

McDonough and Henry to Lead ABA Food, Cosmetics and Nutraceuticals Committee

Shook, Hardy & Bacon Cosmetics & Personal Care Products Partners Madeleine McDonough and Laurie Henry have been appointed to lead the Food, Cosmetics and Nutraceuticals Committee of the American Bar Association's (ABA's) Section of Science & Technology Law as chair and vice-chair, respectively, for the 2014-2015 bar year. The committee seeks to educate its members on emerging legal issues related to food, cosmetics, dietary supplements, medical foods, and nutraceuticals, especially as to U.S. Food and Drug Administration regulation, potential class actions and trademark-infringement claims.

INSIDE GOVERNMENT

N.J. General Assembly Passes Microbead Legislation

The New Jersey General Assembly has unanimously approved legislation (A-3083) that would prohibit the manufacture, sale or promotion of cosmetic products containing microbeads. Companion legislation is pending before the state senate. The production and manufacturing prohibition would take effect January 1, 2015; the sales and promotion prohibition would take effect three years later. Those who violate the law would be subject to a penalty of not less than $1,000 and not more than $10,000 for each offense. The state's Department of Environmental Protection would have the authority to seek injunctive relief under the law.

Bill sponsor Patrick Diegnan (D-Middlesex) said, "I applaud the companies who have recognized the ill effects that polyethylene microspheres have on the environment and stand with us as we take steps to curb its use. By banning these products, we are preserving New Jersey's environmental heritage and protecting marine life." Co-sponsor Paul Moriarty (D-Camden

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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.

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and Gloucester) said, "New Jersey's marine life and fishing industry need our protection now. There are plenty of other ecologically friendly ingredients that can replace microbeads without endangering our ecosystem." *See Assembly Democrats News Release*, September 29, 2014.

LITIGATION AND REGULATORY ENFORCEMENT

Glucosamine and Joint Health Lawsuits Progress

A Maryland federal court overseeing multidistrict litigation (MDL) against GNC Holdings Inc. and Rite Aid Corp. has denied a motion to reconsider its dismissal of a case claiming that GNC deceptively advertises TriFlex and other glucosamine-based supplements as improving joint health without sufficient scientific evidence. *In re GNC Corp., Triflex Mktg. & Sales Practices Litig.*, MDL No. 14-2491 (U.S. Dist. Ct., D. Md., order entered September 9, 2014). The plaintiffs had alleged breach of express warranty, and violations of consumer-protection and deceptive-practices statutes because, they argued, studies had shown that glucosamine supplements did not improve joint discomfort or health in non-arthritic consumers any more reliably than placebos did. In its prior dismissal, the court found that the plaintiffs had failed to show that they relied on the allegedly deceptive advertising to make their glucosamine-based supplement purchases, and, in denying the motion to reconsider, confirmed that holding.

In a lawsuit with similar claims, Botanical Laboratories Inc. and Schwabe North America Inc. have agreed to pay $3.1 million to settle a putative class action filed in a California federal court. *Hazlin v. Botanical Labs. LLC*, No. 13-618 (U.S. Dist. Ct., S.D. Cal., motion for settlement approval filed September 15, 2014). The companies manufacture, distribute and advertise Wellesse Joint Movement Glucosamine Products, which they claimed could "protect and rebuild cartilage" and improve joint health despite, plaintiffs argued, scientific evidence that disputed such claims about glucosamine. The parties have asked the court to certify a nationwide class for the purpose of settlement distribution; consumers would be able to obtain up to $18 per bottle depending on the size they purchased, up to $100. In addition, $930,000 would be deducted from the settlement fund to pay attorney's fees, if the settlement is approved.

Settlement Reached in OxyELITE Pro Consumer-Fraud Class Action

GNC Holdings Inc. and USPLabs LLC have agreed to resolve claims that they failed to warn or misled consumers about their dietary supplements, which were recalled because they contained dimethylamylamine (DMAA) or aegeline, which can allegedly cause liver damage. *Velasquez v. USPLabs LLC*, No. 13-0627 (U.S. Dist. Ct., N.D. Fla., motion for preliminary approval filed

September 23, 2014). Additional information about DMAA products appears in Issue 7 of this *Report*. In April 2014, the U.S. Judicial Panel on Multidistrict Litigation refused to transfer actions relating to these dietary supplements to a single court for resolution of pre-trial proceedings, a matter discussed in Issue 23 of this *Report*.

If approved by the court, a $2-million fund would be established for a nationwide class of product purchasers who submit requests for reimbursement. Each would be able to recover $35 per container of OxyELITE Pro purchased, $20 per container of Jack3d purchased, and $20 per container of VERSA-1 purchased. Those purchasers with receipts would have no limit on reimbursements, while others could receive a maximum refund of $150. Unclaimed funds would be distributed *cy pres* to a charitable organization that is yet to be designated. The plaintiffs' motion for preliminary approval of the class settlement outlines the strengths and weaknesses of the claims, including that the "well-publicized nature" of the controversy over the products could have given many purchasers "actual knowledge" of the purported false advertising before making their purchases, a factor that can preclude class certification. The defendants continue to "deny all allegations of wrongdoing and of liability, and deny any causation of harm or damage to the Settlement Class."

FTC Approves Deceptive Advertising Claims Settlement with L'Oréal USA

After a public comment period, the U.S. Federal Trade Commission (FTC) has approved a final order settling claims that L'Oréal USA, Inc. deceptively advertised its Lancôme Genifique and L'Oréal Paris Youth Code anti-aging skincare products as clinically proven to reduce the effects of aging by targeting users' genes. I*n re L'Oréal USA*, No. 122 3016 (FTC, approval entered September 24, 2014). Under the agreement, L'Oréal cannot claim that any Lancome or L'Oréal Paris brand skincare product "boosts the activity of genes or targets specific genes, thereby [r]esulting in skin that looks younger or acts younger; or [c]ausing skin to respond five times faster to aggressors such as stress, fatigue, and aging." Additional information about the complaint and settlement appears in Issue 28 of this *Report*. *See FTC Press Release*, September 26, 2014.

FTC Bans Supplement Company Co-Founder from Weight-Loss Industry

HealthyLife Sciences and its co-founder John Dwyer have settled U.S. Federal Trade Commission (FTC) deceptive advertising claims involving Healthe Trim supplements which the defendants promoted as a product that consumers could use to "Get High School Skinny" by burning fat, increasing metabolism and suppressing appetite. *In re HealthyLife Sciences, LLC*, No. 122 3287 (FTC, agreement date unknown). Dwyer and HealthyLife reportedly claimed that Healthe Trim would suppress the appetites and boost the metabolisms of its users to help them lose weight without changing diet or exercise levels.

Under the agreement, HealthyLife cannot make such representations in advertisements about its products without reliable evidence to support them, and Dwyer is "permanently restrained and enjoined" from selling, distributing or marketing "any weight-loss product or program." *See FTC Press Release*, September 11, 2014.

FTC Settles Charges in Caffeine-Infused Shapewear Cases

The U.S. Federal Trade Commission (FTC) has settled with Norm Thompson Outfitters, Inc. (NTO) and Wacoal America, Inc. in cases alleging that the clothing companies falsely advertise their products—caffeine-infused undergarments—by claiming that they can slim wearers by up to two inches and reduce cellulite. *In re Norm Thompson Outfitters, Inc.*, No. 132 3094 (FTC, agreement date unknown). NTO and Wacoal allegedly claimed that their shapewear products, including Wacoal's iPants, could reduce thigh and hip measurements "without any effort" because their fabrics were infused with microencapsulated caffeine and retinol. Under the settlement agreements, neither company can claim that any garment can cause substantial weight or fat loss through the use of infused drugs or cosmetics, and they cannot claim that any drug or cosmetic reduces weight or cellulite without competent and reliable scientific evidence. Wacoal will pay $1.3 million and NTO will pay $230,000 to provide refunds to purchasers. *See FTC Press Release*, September 29, 2014.

SEC Charges Two for Alleged Insider Trading in Herbalife/Ackman Controversy

The U.S. Securities and Exchange Commission (SEC) has reportedly sued two individuals alleging that one of them capitalized on an insider tip that billionaire hedge fund manager William Ackman would bet against Herbalife in December 2012, attacking its business model as a pyramid scheme, and also bet that Herbalife stocks would fall, which they did, thus making a profit. The junior analyst responsible for the insider tip worked at Ackman's Pershing Square hedge fund; he has not been accused of wrongdoing, and he claims that his departure from Pershing was unrelated to the SEC investigation. His roommate and childhood friend, one of the alleged inside traders, has reportedly agreed to a $47,100 penalty, the amount that another friend, who traded on the information, apparently earned when Herbalife stock fell 39 percent.

Meanwhile, Ackman has apparently begun to see the fruits of his campaign against Herbalife. Since the U.S. Federal Trade Commission launched a formal investigation into the company this past winter, its stocks have lost significant value—falling nearly 50 percent this year. *The New York Times* put the penalty paid by one of the inside traders in the context of the "billion-dollar battle over Herbalife that has divided Wall Street. On one side is Mr. Ackman, who has staked his reputation on a belief that Herbalife is a pyramid scheme. The other group, led by the hedge fund magnate Carl C. Icahn, expects the

company to emerge from regulatory scrutiny unscathed." Additional details about the controversy and federal government's interest in the dietary supplement company appear in Issue 19 of this *Report*. *See The Wall Street Journal*, September 22, 2014; *The New York Post* and *The New York Times*, September 30, 2014.

U.S. Marshals Seize Products from Flawless Beauty

At the request of the U.S. Food and Drug Administration (FDA), U.S. Marshals seized unapproved and improperly labeled products that Flawless Beauty sold to individuals, retail outlets, health spas, and clinics. The seized items included injectable drug products such as Relumins Advanced Glutathione kits and Tatiomax Glutathione Collagen Whitening kits, as well as other products that claimed to treat scurvy and degenerative brain and liver disease. According to a press release, FDA has not received any reports of illness or injury from Flawless Beauty's products. "We have taken action to protect consumers and demonstrate our commitment to their safety by preventing these products from being distributed," said Melinda Plaisier, FDA's associate commissioner for regulatory affairs. *See FDA Press Release*, September 4, 2014.

Putative Class Action Alleges Male Performance-Enhancer Magna-Rx's Advertising Misleads

A proposed class action filed in a California federal court alleges that Magna-Rx, Inc. misleads consumers by advertising its male strength and performance-enhancing Magna-Rx+ product, without any clinical proof, as an aphrodisiac endorsed by doctors. *Dixon v. Magna-Rx, Inc.*, No. 14-7196 (U.S. Dist. Ct., C.D. Cal., filed September 15, 2014).

According to the complaint, Magna-Rx labels its product as "Dr. Aguilar's Original," despite having no affiliation with Dr. Aguilar, who owns a small "alternative medicine" clinic in Mexico and is not licensed to practice medicine in the United States. The plaintiff also claims that the "Real Doctors, Real Results" statement on MagnaRx+ packaging implies that the product is endorsed by at least two doctors, despite that no doctors have endorsed or recommended it. The plaintiff contends that the company has never sought and does not possess any scientific testing on the product's efficacy, so "Real Results" is also misleading. The complaint further alleges that none of the product's ingredients, individually or in combination, can "increase male strength and performance or are effective as an aphrodisiac." Alleging unfair competition, false advertising and violations of the Consumers Legal Remedies Act, the plaintiff seeks a corrective advertising campaign, disgorgement of money obtained by wrongful acts, destruction of misleading advertising materials, damages, and attorney's fees.

YouTube Beauty Blogger Files Counterclaims in Copyright-Infringement Case

Beauty blogger and designer of L'Oréal line em Cosmetics Michelle Phan has filed a countersuit against Ultra International Music Publishing (UIMP) and Ultra Records, which had sued Phan for allegedly infringing their copyrights by using their artists' music without permission in her YouTube videos. *UIMP v. Phan*, No. 14-5533 (U.S. Dist. Ct., C.D. Cal., counterclaim filed September 17, 2014). According to the counterclaim, Phan had an agreement with Ultra's senior new media manager allowing her, beginning in July 2009, to use the music in exchange for including links to purchase the songs via iTunes at the end of her videos. She also contends that through YouTube's Content ID system, the defendants had approved her use of their songs since 2009. Phan claims that Ultra and UIMP sent Digital Millennium Copyright Act notices to YouTube in bad faith in violation of that Act and intentionally interfered with a contract; she seeks declaratory judgments, damages and attorney's fees. Additional information about Ultra's complaint appears in Issue 30 of this *Report*.

Roca Labs Sues Website to Remove Negative Reviews

Dietary product manufacturer Roca Labs has filed a lawsuit alleging that Consumer Opinion Corp. and Opinion Corp., operators of PissedConsumer.com, hosted negative reviews of its products, including Gastric Bypass Alternative, in violation of the non-disparagement clause that many of its customers sign in exchange for a product discount. *Roca Labs, Inc. v. Consumer Opinion Corp.*, No. 14-2096 (U.S. Dist. Ct., M.D. Fla., defendant's opposition to temporary injunction filed September 18, 2014).

Roca claims that the defendants encourage Roca's customers to violate a non-disparagement clause that, according to the complaint, requires customers to "not speak, publish, print, blog or write negatively about [Roca] or its products in any forum" for a significant discount, averaging $800. The company alleges tortious interference, unfair trade practices and defamation and seeks declaratory judgments, damages, attorney's fees, and the names and addresses of alleged Roca customers who helped post negative content on the Website.

The Website operators have responded by claiming immunity under Section 230 of the Communications Decency Act, which protects service providers from liability for hosting content created by third parties. They contend that Roca is attempting to "force a cone of silence over each and every customer that discovers Roca Labs' product is not only a specious remedy for their weight issues, but a potential cause of additional health problems." In response to the growing number of non-disparagement clauses in consumer contracts, Reps. Eric Swalwell (D-Calif.) and Brad Sherman (D-Calif.) introduced the Consumer Review Freedom Act, which would prohibit the use of such clauses, in the U.S. Congress on September 15, 2014. *See Swalwell Press Release*, September 26, 2014.

NAD Chides Cerebral Success for SmartX Advertising

In response to a challenge by the Council for Responsible Nutrition, the National Advertising Division (NAD) of the Council of Better Business Bureaus has recommended that Cerebral Success discontinue several claims for its supplement SmartX, purportedly advertised as "an Adderall alternative for students who are taking the drug without a prescription." The advertising board found that the studies Cerebral Success provided "did not test SmartX products or formulas similar to SmartX's combination of ingredients and were limited to various findings on individual SmartX ingredients." It recommended that Cerebral Success discontinue claims that the product is an alternative to Adderall and that it was "[d]esigned to enhance memory, focus & mental agility; boost focus & concentration; stimulate mental energy & agility; enhance memory & recall; improve brain health & function; and reduce anxiety." NAD also took issue with a few of the company's claims about individual ingredients, including that L-Theanine "works to balance out the harsher effects of caffeine," but approved the claim that the ingredients "provide needed vitamins, nutrients & amino acids." *See NAD Press Release*, September 23, 2014.

INTERNATIONAL DEVELOPMENTS

Kroma EU Files Trademark-Infringement Suit Against the Kardashians

Kroma Makeup EU, the European distributor of By Lee Tillett's Kroma makeup, has filed a lawsuit against Kim, Khloe and Kourtney Kardashian as well as Boldface Licensing + Branding for allegedly infringing its Kroma trademark with their Khroma line of products. *Kroma Makeup EU LLC v. Boldface Licensing & Branding Inc.*, No. 14-1551 (U.S. Dist. Ct., M.D. Fla., filed September 23, 2014). The U.K.-based company also claims that its parent company, By Lee Tillett, failed to account for damages caused to Kroma EU when the company settled similar claims with the Kardashians in summer 2014.

Kroma accuses Boldface and the Kardashians of placing their Khroma cosmetics line on the market despite learning of Kroma's trademark in June 2012 and a September 2012 U.S. Patent and Trademark Office denial for Khroma trademark protection due to the likelihood of consumer confusion. The complaint describes the Kroma line as "high end," while the Khroma products are "of significantly lower quality," and it alleges that Khroma's trademark infringement caused Kroma EU to undergo "major instances of consumer confusion, severely impacting and effectively destroying its business." As an example, it cites an incident with "upscale British department store chain" Debenhams in which a store representative asked Kroma EU's head why the line had associated itself with the Kardashians and why the store should

carry a product that can be purchased at discount retailers, then ended its relationship with Kroma EU. The cosmetics company seeks compensatory and punitive damages for trademark infringement and tortious interference.

EMERGING TRENDS

Entrepreneur Creates Makeup Products with 3D Printing

Harvard Business School graduate Grace Choi has reportedly developed ways that women can make custom-colored makeup products at home, using either 3D printing equipment or a hacked 2D printer. Her technology uses a tool such as Photoshop to lift free hex color codes from the Internet, and then the printer adds a layer of U.S. Food and Drug Administration-approved inks to colorless eye shadow, face cream or moisturizer. Choi recommends a top layer of color, so that when the user is ready to change colors, the next layer of blank makeup is ready for a different color. She became interested in makeup because she believed that Asians were underrepresented in beauty industry marketing. Choi's initial products were skin creams made for this market. To develop options for a range of different skin tones, she decided that personalized colors and dyes were the key to inexpensive products.

Choi has apparently been reluctant to sell a branded printer, but believes that business opportunities can arise even when every young girl or woman makes her own makeup. Among other matters, she suggests that celebrities could have Internet video makeup pages that would provide inspiration for certain signature colors which could be downloaded and that her own company could supply the FDA-approved inks and raw makeup materials to be printed with color. According to Choi, "This is a very important social mission for me. I think of Mink [her company] as an educational tool for kids, and one that can get girls interested in technology. I don't need to be on some billionaires list. I'm aggressive and I'm going to make this happen. Before I die, this [beauty revolution] will happen." *See Business Insider*, September 15, 2014.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Study Suggests Link Between Children's Asthma and Prenatal Phthalate Exposure

In a study of 300 inner-city women and their children, ages 5-11, researchers have apparently observed a "significant association" between concentrations of phthalate metabolites in maternal urine collected during the third trimester of pregnancy and a diagnosis of current asthma among children participating

in a study cohort. Robin M. Whyatt, et al., "Asthma in Inner-City Children at 5-11 Years of Age and Prenatal Exposure to Phthalates: The Columbia Center for Children's Environmental Health Cohort," *Environmental Health Perspectives*, September 17, 2014.

While the researchers call for additional studies to replicate their findings, they found that prenatal metabolites of butylbenzyl phthalate (BBzP) and di-n-butyl phthalate (DnBP) were "associated with a history [of] asthma-like symptoms ($p<0.05$) and with the diagnosis of current asthma: RR 1.17 (95% CI: 1.01, 1.35) and RR 1.25 (95% CI 1.04, 1.51) per natural log-unit increase respectively." They also found that "[r]isk of current asthma was >70% higher among children with maternal prenatal BBzP and DnBP metabolite concentrations in the 3rd versus 1st tertile."

The Cosmetics, Toiletry & Perfumery Association (CTPA) responded to the study by distinguishing the phthalates used in cosmetic products from those associated with asthma, noting that "the two phthalates under scrutiny in the study are banned from cosmetic products in Europe." CTPA also observes that the study authors "state that no association was found between the prenatal exposure of several other phthalates and diagnosis of childhood asthma." In light of the demonstrated safety of the phthalates used in cosmetic products, CTPA suggests that pregnant women need not worry about the study's findings. *See CTPA News Release*, September 17, 2014.

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