Shook, Hardy & Bacon L.L.P.

ISSUE 6 | JULY 12, 2013

LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

CONTENTS

INSIDE GOVERNMENT

ITA Revokes Antidumping Order for HEDP from India

The U.S. Department of Commerce's International Trade Administration (ITA) has determined that sales of a chemical used in cosmetics, detergents and pharmaceutical and water treatments—1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP)—"have not been made at prices below normal value," and thus ITA has "revoked the antidumping duty order, in part, with respect to HEDP produced and exported by Aquapharm." The revocation applies to subject merchandise produced and exported by India-based Aquapharm Chemicals Pvt., Ltd. for consumption on or after April 1, 2012. *See Federal Register*, July 3, 2013.

AHRQ Seeks Scientific Information on Vitamin D and Calcium

The Agency for Healthcare Research and Quality (AHRQ) has requested public scientific information submissions on vitamin D and calcium that it intends to use in its "Vitamin D and Calcium: A Systematic Review of Health Outcomes" project, a regulatory review conducted under section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and section 902(a) of the Public Health Service Act. Specifically, the agency seeks information from ongoing and completed studies that report on vitamin D and calcium, including those describing adverse events. AHRQ will accept submissions until August 2, 2013. *See Federal Register,* July 3, 2013.

CFDA Seeks Comments on New Cosmetic Ingredient

The China Food & Drug Administration (CFDA) has issued a notice inviting public comments on the approval of a new cosmetic ingredient, Elaeagnus Mollis Diel Oil, a moisturizing element that purportedly contains antioxidant and anti-aging properties, for use in skin care products. If approved, the oil will reportedly be the fourth new cosmetic ingredient approved by CFDA in two years (following Polymethacryloyl Lysine and Dimethoxytolyl Propylresorcinol in March 2012 and Phenylethyl Resorcinol in December 2012). *See Chemlinked.com*, July 5, 2013.

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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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LITIGATION & REGULATORY ENFORCEMENT

Court Grants Preliminary Approval to Labeling Claims Against L'Oréal

A federal court in the District of Columbia has given preliminary approval to class certification and a settlement in litigation alleging that L'Oréal USA falsely labeled several products as available exclusively in salons. *Richardson v. L'Oréal USA, Inc.*, No. 13-508 (U.S. Dist. Ct., D.D.C., order entered June 27, 2013).

If finally approved following an October 11, 2013, fairness hearing, the settlement will resolve the claims of a nationwide class of purchasers and require the company to remove the claims from the advertising and labeling of products intended for U.S. markets for at least five years. Thereafter, "it may resume using the claims in markets with a 60% reduction from 2012 levels of non-salon sales." The company is not required to destroy products or packaging in inventory.

According to the complaint, while the company's Matrix Biolage®, Redken®, Kératase®, and Pureology® products carried labels indicating that they were available in salons only—thus implying they were of superior quality—the products could be purchased in non-salon retail stores, such as Target, Kmart and Walgreens. The plaintiffs apparently acknowledged that the company had a campaign to address the diversion of its products to stores without salons, but the labeling was allegedly misleading because the products are available in non-salon establishments despite those efforts.

The court outlined the counsel's efforts to reach a settlement, as well as the risks of proceeding with the litigation, and concluded that a proposed settlement providing injunctive relief only "lies within the range of possible approval." The court also deemed, "not outside the range of possible approval," incentive payments of $1,000 for the lead plaintiffs and a maximum award of $950,000 for attorney's fees, costs and expenses

Court Rejects Certification of California Class in Flammable Hair Product Suit

A federal court in California has denied without prejudice a motion to certify a class of California consumers who were allegedly deceived by L'Oréal's failure to include a flammability warning on Garnier Fructis Sleek & Shine Anti-Frizz Serum®; the court, however, granted a motion to certify a class of New York consumers raising the same claims in a consolidated action. *Guido v. L'Oréal USA, Inc.*, Nos. 11-1067, -5465 (U.S. Dist. Ct., C.D. Cal., order entered July 1, 2013). The company contends that after denatured alcohol was removed from the product in 2006 to comply with California's volatile organic compound regulations, it no longer required a flammability warning. The plaintiffs allege that it remains flammable, and they would not have purchased the product had they known it was flammable.

The court agreed with L'Oréal that under *Comcast v. Behrend*, 133 S. Ct. 1426 (2013), the California class could not be certified because the plaintiffs had not shown that common questions predominate over individual issues as to damages. The plaintiffs have not yet produced expert testimony to demonstrate a connection between their theories of liability—violations of California's consumer fraud statutes and breach of the implied warranty of merchantability—and damages.

According to the court, "because plaintiffs have not submitted expert testimony actually demonstrating a gap between the true market price of Serum and its historical market price, they have not met their burden of demonstrating that common questions predominate over individual issues regarding classwide relief." The court did not close the door on the plaintiffs, however, indicating that they could make a renewed motion for class certification after presenting expert testimony on the issue. The court did not find the same infirmity as to the proposed New York class of purchasers, noting that they were seeking statutory damages and no expert testimony was required to award relief to the New York class.

Other aspects of the court's ruling include a determination that one of the named plaintiffs did not have claims typical of the putative class because she purchased a bottle of Serum before 2007 when it had a flammability warning and thus had been exposed to a warning label; accordingly, the court ruled that she was not an appropriate class representative. The court rejected L'Oréal's argument that one of the named plaintiffs was subject to the defense of *laches* because she learned about the facts underlying her claim only after speaking with counsel. The court found no authority to defeat the typicality requirement of class certification on this ground.

Similarly, the court rejected claims that the named plaintiffs are not adequate representatives of the class because they lacked personal knowledge about the litigation, "and only sought to become plaintiffs after being contacted by counsel." In this regard, the court stated, "While they may have first learned about Serum's alleged flammability from plaintiffs' counsel, this is not disqualifying, especially in light of counsel's explanation that the key facts underlying this case were only uncovered after costly testing[, and] the fact that plaintiffs were solicited by counsel does not undermine a finding of adequacy. There is nothing inherently improper with the recruitment of class representatives, and where existing named plaintiffs become unavailable or unsuitable, allowing the recruitment of replacements is even recommended."

MDL Court Grants P&G Motion to Compel Discovery in Denture Cream Litigation

A multidistrict litigation (MDL) court in the District of Columbia has granted the motion of the Procter & Gamble (P&G) defendants to compel a third party to produce documents relating to a study commissioned by the plaintiffs in litigation alleging "that excessive use of the denture cream product, Fixodent, blocks copper absorption and ultimately leads to neurological injury." *In re*

Denture Cream Prods. Liab. Litig., MDL No. 13-384 (U.S. Dist. Ct., D.D.C., order entered July 3, 2013). Conducted by Salim Shah and his companies, the "Sarfez Entities," the study was designed "to determine how much copper, if any, is blocked during exposure to Fixodent." The plaintiffs intended to use the study to prove causation.

While the Sarfez Entities apparently produced some 1,500 pages of documents in response to P&G's discovery request, many emails were evidently missing attachments or were produced in a manner that did not allow them to be matched with their attachments, and parts and versions of documents were withheld without explanation. P&G sought the missing documents and also requested an order requiring the Sarfez Entities to submit their computers for forensic imaging, finding them in contempt and imposing monetary sanctions.

The court determined that the requested discovery was relevant, and, in the absence of any contrary evidence, that its production would not unduly burden the third party. Accordingly, the court granted the motion to compel in part, but refused to order forensic imaging, finding that this would increase the costs associated with production, or sanctions, because it was inappropriate at this stage to find the Sarfez Entities in contempt. If they fail to produce the requested documents, the court invited P&G to renew its requests for forensic imaging and a finding of contempt and monetary sanctions.

Among other matters, the Sarfez Entities resisted the motion by arguing that the relevance of the documents should be raised before the transferring court in Florida as part of a motion in limine and suggesting that the defendants must first depose the custodian of records before filing a motion to compel. The court noted that it need not determine whether the discovery sought will be admissible at trial; "[r]ather, the issue is whether the discovery sought is potentially relevant," and because the plaintiffs might rely on the study to make a showing of causation, the related materials were relevant and discoverable. The court also opined as to the suggested deposition, "the Sarfez Entities provide no case law to support the notion that the defendants must conduct a deposition in advance of seeking documents, and the Court can find none. … There is no requirement that any particular type of discovery be sought before another."

EMERGING TRENDS

British Cosmetics Company Offers Annual Prize to Support Worldwide Ban on Animal Testing

The U.K.-based Lush cosmetics company will accept nominations until July 15, 2013, for its second annual £250,000 ($376,000) "Black Box" prize that rewards individuals working in the fields of cruelty-free scientific research, awareness-raising and lobbying for their efforts to end animal testing.

A collaboration between Lush and the U.K.-based, non-profit research and consulting firm Ethical Consumer, this year's prize aims to inspire an international focus on toxicity testing of cosmetic products and ingredients in a manner that "complements the many projects already addressing the use of animals in medical testing."

Lush plans to offer the prize every year until all animal testing of cosmetics has been eliminated. The prize will be awarded either as a lump sum for a major breakthrough or distributed across five categories (science, training, lobbying, public awareness, and young researcher) at an annual awards ceremony each November. *See Lush.com.*

INTERNATIONAL DEVELOPMENTS

UK Agency Issues Warning About Unlicensed Herbal Dietary Supplement

The U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) has warned diabetics that they cannot give up their prescribed medication and rely on the alleged false advertising for an herbal remedy—Vedagrin, also known as Vedanate—sold with the claim "say goodbye to your diabetes medication forever." "While the patient information leaflet for this unlicensed medicine tells people to seek medical advice before stopping their insulin intake, the advertising claims for this product break advertising regulations for medicines," said MHRA's Richard Woodfield. "If these claims are followed they could have dangerous consequences for people with diabetes."

The Alliance for Natural Health International, an organization founded in 2002 to support the use of herbal products in health care, recently expressed concerns about MHRA's apparent change in policy as to herbal medicine practitioners. Founder Robert Verkerk composed an open letter to Prime Minister David Cameron warning of the "disastrous situation for herbal medicine practitioners, their suppliers and—most importantly—the millions of British citizens who rely on these products for their health," if the regulation allowing herbalists to compound remedies at the request of individual patients is repealed.

Verkerk reportedly responded to MHRA's action on Vedagrin by noting that herbal food supplements are under threat and that the agency "is working through a long list of complaints about herbal medicines selling as food supplements that it has received mainly from companies who have registered herbs under" a European Union (EU) herbal medicine products directive. He claimed that effective supplements have been delisted under the directive which apparently allows regulators "to classify almost anything as an unlicensed medicine. Effectiveness, it seems, is their main sin, and the reason given for classifying them as medicines," Verkerk said. "Perhaps anti-inflammatory diets will be next on the MHRA hit list." *See Alliance for Natural Health News Release*, May 3, 2013; *MHRA Press Release*, July 3, 2013; *NUTRAingredients.com*, July 8, 2013.

India Bans Animal Testing for Cosmetics

The Bureau of Indian Standards (BIS) has reportedly announced that it will implement a ban on animal testing for cosmetics, making it the first South Asian country to do so. The action follows an intense public campaign led by advocacy group Humane Society International (HSI) that garnered support from Indian Members of Parliament and State Assemblies.

In what was evidently a rare unanimous decision, BIS approved the removal of any mention of animal tests from the country's cosmetics standard so that any manufacturer interested in testing new cosmetic ingredients or finished products must now seek approval from India's Central Drug Standards Control Organisation, reported a news source. BIS also made alternative non-animal tests mandatory in an apparent effort to prevent companies from finding loopholes to continue testing on animals.

"India's decision shows the way for all countries that are still undecided about whether to ban cosmetics animal testing. Those countries should take action now, follow India's lead and end cruelty for beauty," said HSI Director of Research and Toxicology Troy Seidle.

Member of Parliament Baijayant 'Jay' Panda said, "This is a great day for India and for the thousands of animals who will no longer suffer, yet more work must be done. Our government must go a step further by banning cosmetics products that are tested on animals abroad and then imported and sold here in India."

Although the ban is considered a major victory, an HSI news statement noted that the next step for the Indian government is to enact a follow-up ban on selling cosmetics tested on animals in other parts of the world to prevent companies from outsourcing testing to other countries and importing the animal-tested products back into India. Currently, only Israel and the 27 European Union (EU) countries have both testing and sales bans in place. *See VicharVimarsh.com,* July 4, 2013; *HIS News Release,* July 9, 2013.

Meanwhile, during a recent visit to China, EU Health Commissioner Tonio Borg reportedly urged Chinese authorities to follow the European example, rid the cosmetics arena of animal testing and turn to alternative methods instead. "I have encouraged the Chinese authorities to avoid unnecessary testing for cosmetics," said Borg. "I see first signs of acceptance of alternative methods in China which I welcome very much. Acceptance of validated alternative methods … is clearly key to limit animal testing for cosmetics internationally." *See Cosmetics Design Europe,* June 26, 2013.

ECHA Seeks Comments on Synthetic Fragrance

The Swedish European Chemicals Agency (ECHA) has announced a public consultation for the classification and labeling of hydroxyisohexyl 3-cyclo-hexene carboxaldehyde, also known as Lyral, a synthetic fragrance commonly used in cosmetics, soaps, perfumes, and deodorants.

According to the agency, the public consultation will be open for 45 days and is set to end August 16, 2013. Comments will be published regularly on the ECHA Web site during the consultation period.

CTPA Says Preservative MI Is Safe Despite Growing Concerns

In response to rising concerns that the cosmetic preservative methylisothiazolinone (MI) may be linked to increasing cases of the skin allergy contact dermatitis among the general population in Europe, the Cosmetic, Toiletry and Perfumery Association (CTPA) has issued a **statement** affirming that MI is on the list of approved preservatives for use in cosmetic products and that the ingredient's safety has been confirmed by the European Commission's independent experts.

According to a news source, CTPA issued the statement after a group of dermatologists revealed that it plans to present MI patch-test findings at an upcoming medical conference. Although MI is reportedly considered safe and non-toxic, European regulations now permit stronger concentrations than previously allowed, and experts reportedly claim that since MI concentrations have increased, a sharp rise in cases of contact dermatitis has been observed.

John McFadden, a dermatologist at St. John's Institute of Dermatology in London, said "We are in the midst of an outbreak of allergy to a preservative which we have not seen before in terms of scale in our lifetime. Many of our patients have suffered acute dermatitis with redness and swelling of the face. I would ask the cosmetics industry not to wait for legislation but to get on and address the problem before the situation gets worse."

"We look forward to hearing about the studies in full at the conference," said CTPA Director General Chris Flower. "Patch testing, although important for an individual, does not reflect the real life scenario in the general population. Neither does it always mean that a person would react to the substance when it is used at a much lower, safe level in a cosmetic product."

"Human safety is the cosmetic industry's number one priority; in fact it is the law," Flower added. "Every cosmetic product must undergo a rigorous safety assessment before it is placed on the market. The assessment covers all of the ingredients, the final product, how and where the product is to be used, how often and by whom and must be carried out by qualified assessors." *See The Telegraph,* July 10, 2013.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

New Study Alleges Link Between Fish Oil and Increased Risk of Prostate Cancer

A recent **study** conducted by scientists at the Fred Hutchinson Cancer Research Center in Seattle has reportedly revealed that high concentrations

of omega-3 fatty acids—derived from fatty fish and fish-oil supplements—are associated with a 71-percent increased risk of high-grade prostate cancer. Theodore Braskey, et al., "Plasma Phospholipid Fatty Acids and Prostate Cancer Risk in the SELECT Trial," *Journal of the National Cancer Institute,* July10, 2013. The findings, which apparently confirm a 2011 study published by the same scientific team, also showed a 44-percent increase in the risk of low-grade prostate cancer and an overall 43-percent increase in risk for all prostate cancers. The current study examined 834 men from the Selenium and Vitamin E Cancer Prevention Trial (SELECT) and 1,393 randomly chosen others who did not have cancer.

"We've shown once again that use of nutritional supplements may be harmful," said Alan Kristal, the study's senior author and member of the Fred Hutchinson Public Health Sciences Division. Noting that it is unclear why high levels of omega-3 fatty acids would increase prostate cancer risk, the scientists suggest that one potentially harmful effect of omega-3 fatty acids is "their conversion into compounds that can cause damage to cells and DNA, and their role in immunosuppression."

"What's important is that we have been able to replicate our findings from 2011 and we have confirmed that marine omega-3 fatty acids play a role in prostate cancer occurrence," said co-author Theodore Brasky. "It's important to note, however, that these results do not address the question of whether omega-3's play a detrimental role in prostate cancer prognosis." According to Kristal, the findings in both studies were surprising "because omega-3 fatty acids are believed to have a host of positive health effects based on their anti-inflammatory properties." *See Fred Hutchinson Cancer Research Center News Release,* July 10, 2013. ■

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