

The IP Me i



POM Wonderful: the new prescription for false advertising
Frances M Jagla, Paul D Swanson and Gregory F Wesner
Lane Powell PC

Pharmaceutical Trademarks 2015/2016

**World
Trademark
Review**[™]

A Global Guide



WE PROTECT OUR CLIENTS'
INTELLECTUAL PROPERTY RIGHTS
with some devastating rights of our own!

Lane Powell offers one of the Pacific Northwest's most comprehensive intellectual property practices. The Firm's Intellectual Property and Technology Practice attorneys are recognized for providing counsel across all key areas. Experience why so many clients trust the attorneys of Lane Powell for counseling and litigation in intellectual property rights matters.



Your Pacific Northwest Law Firm®

1.800.426.5801 • Visit us at www.lanepowell.com.

***POM Wonderful*: the new prescription for false advertising**

Authors

Frances M Jagla, Paul D Swanson and Gregory F Wesner

The ability of private parties to pursue mislabelling claims depends on whether allowing such claims to proceed would conflict with the purpose and intent of federal labelling laws and implementing regulations, such as those promulgated pursuant to the Food, Drug and Cosmetic Act of 1938, the Nutrition Labelling and Education Act of 1990 or the Dietary Supplement Health and Education Act of 1994. These federal laws do not allow private lawsuits to enforce their provisions.

In its groundbreaking *POM Wonderful v Coca-Cola* decision the Supreme Court paved the way for private competitor lawsuits over false and misleading food and beverage labels. Lower courts had previously ruled that federal Lanham Act false advertising claims are precluded by the detailed Food and Drug Administration (FDA) regulations governing the content of fruit juice labels. This meant that misleading labels were solely managed by administrative oversight. In *POM Wonderful* the Supreme Court unanimously rejected that preclusive result by holding that Lanham Act false advertising claims and FDA regulations serve different but complementary purposes. The former provide a private remedy for unfair competition, while the latter focus on quality and safety issues.

***POM Wonderful* decision**

The *POM Wonderful* facts are intriguing. POM Wonderful contended that Coca-Cola's

labelling of its Minute Maid Pomegranate Blueberry juice label was misleading and deceptive because the product contained only 0.3% pomegranate juice and 0.2% blueberry juice. The majority of the product (more than 99%) was cheaper apple and grape 'filler' juices. The brand label prominently displayed the Pomegranate Blueberry name and featured a colourful fruit vignette with a split ripe pomegranate, a sliced apple and a handful of blueberries, raspberries and red grapes. The label included the legend "Pomegranate Blueberry Flavored Blend of 5 Juices". Although not at issue in the case, Minute Maid's label also touted the fortified inclusion of an omega-3 fatty acid nutrient, docosahexaenoic acid, with the tagline of how its inclusion would "help nourish your brain".

According to POM, the Minute Maid juice should have been labelled as a "grape/apple" juice, since those ingredients constituted more than 99% of the fruit juice product. Further, the fruit vignette was misleading because the fruits depicted were out of proportion with the actual ingredients. To support its claim, POM developed expert witness survey evidence showing that more than one-third of those surveyed believed that the juice mainly contained pomegranate and blueberry juice – not the minuscule amounts actually present in the product.

POM contended that it had created the existing US market acceptance and demand for pomegranate juice. Because POM's



A party's compliance with FDA labelling requirements under the Food, Drug and Cosmetic Act is no defence to an unfair competition claim based on the content of the label

products were generally made with 100% pomegranate juice, POM had to invest in pomegranate orchards to source its product consistently and had to educate the consumer marketplace about the potential health benefits of pomegranate juice consumption. Its lawsuit against Coca-Cola and other juice manufacturers was intended to prevent free-riding on the demand which POM had created for pomegranate juice through its extensive marketing efforts.

The *POM Wonderful* case required the Supreme Court to decide what effect to give to two broad federal statutes – the Lanham Act and the Food, Drug and Cosmetic Act – when they potentially conflict with each other. Courts are instructed to give as much effect to both statutes as possible. This guiding principle is easy to state, but much harder to apply.

Balancing these principles, the Ninth Circuit had barred POM's federal Lanham Act claim because it viewed FDA regulations as effectively authorising the name that Coca-Cola had chosen for its juice. Under FDA regulations, a manufacturer may use the name of a flavouring juice that is not predominant by volume (see 21 CFR § 102.33).

The Supreme Court rejected the Ninth Circuit's reasoning in its entirety: "When two statutes complement each other, it would show disregard for the congressional design to hold that Congress nonetheless intended one federal statute to preclude the operation of the other" (*POM Wonderful* slip op at 11). "[I]f Lanham Act claims were to be precluded then commercial interests – and indirectly the public at large – could be left with less effective protection in the food and beverage labeling realm than in many other, less regulated industries" (*id* at 12).

Lexmark decision amplifies POM Wonderful

The effect of the *POM Wonderful* Supreme Court decision is particularly potent when considered in light of another Supreme Court decision that preceded it by only a few months – *Lexmark International v Static Control Components*. Taken together, the decisions could accelerate the pace of the Lanham Act claims in the medical, biotech, pharmaceutical and other regulated industries, and should provide even more incentive for producers to vet product claims carefully.

Lexmark softens standing requirements under Lanham Act

On March 25 2014 the Supreme Court handed down its decision in *Lexmark International v Static Control Components* (572 US ___ (2014)), which established that a federal Lanham Act unfair competition claim may be brought by a party which is only an indirect competitor with the alleged unfair competitor. Specifically, the court held that "[t]o invoke the Lanham Act's cause of action for false advertising, a plaintiff must plead (and ultimately prove) an injury to a commercial interest in sales or business reputation proximately caused by the defendant's misrepresentations" (*id*). Previously, direct competition was typically required for a party to have standing to sue for unfair competition under the Lanham Act.

The court's test for whether standing exists to sue under the Lanham Act takes account of the facts of a particular situation (ie, whether one suffers an injury that is proximately caused by the defendant). However, this definition appears to be broad enough to encompass the advertising practices of businesses that merely operate in the same industry. The pharmaceutical industry presents a competitive

environment where the implications of *Lexmark* could be strongly felt. It is certainly the case that head-to-head competition (eg, drugs marketed to treat the identical condition) is no longer required for Lanham Act standing.

Lanham Act claims not necessarily barred when another federal statute addresses same subject matter

As explained above, *POM Wonderful* established that a party's compliance with FDA labelling requirements under the Food, Drug and Cosmetic Act is no defence to an unfair competition claim based on the content of the label. In its holding, the court rejected Coca-Cola's argument that the doctrine of federal pre-emption (where a federal statute pre-empts the application of, for example, a state statute covering the same subject matter) applies to bar Lanham Act claims on product labelling. The court also rejected the government's position that a Lanham Act claim against a product label should be allowed only to the extent that the label content was not addressed by the Food, Drug and Cosmetic Act.

In holding that the Lanham Act and the Food, Drug and Cosmetic Act can co-exist, the court potentially opened the door to much more litigation over product labelling – an unusual move for a court that has tended to restrict, rather than open, private rights of action. When *POM Wonderful* is read in light of *Lexmark*, the implications for increased litigation could be profound.

“

It is important to counsel clients that many elements of their packaging and advertising can contain product claims that may be open to challenge

***POM Wonderful* plus *Lexmark* equals new playing field for pharmaceutical companies**

With *Lexmark* holding that indirect competitors have standing to sue under the Lanham Act, and *POM Wonderful* holding that an FDA-approved label can be challenged on false advertising and unfair competition grounds, things could get interesting. There are, for example, a myriad of pharmaceutical products directed towards cardiovascular health. It would likely be easy to draw a causal connection between sales of one drug for treating a cardiovascular condition and the sales of many other drugs directed to the cardiovascular system. Because direct competition is no longer required, provided that sales of one drug could affect the overall sales of another drug used to treat a cardiovascular condition, the standing requirement among these indirect competitors would seem to be met. This would allow any drug maker in the cardiovascular treatment field free rein to police the labels used on potentially all of the other drugs used to treat cardiovascular conditions. The fact that the FDA approved the label is no longer a defence to suit. Given the sizes of the markets for blockbuster drugs, anyone in this position would be highly motivated to assess its litigation options. In short, if a company sees another business in its commercial space with questionable label statements, it may well be able to bring a false advertising claim.

Moreover, the rationale in *POM Wonderful* seems readily applicable to other federal labelling regimes (eg, those under the Federal Insecticide, Fungicide and Rodenticide Act, which governs the labelling on agricultural and other products). Companies must be prepared for greatly increased litigation in this area.

Proactive clearance and counselling

What can be done? The *POM Wonderful* decision, particularly when read in light of *Lexmark*, serves as a reminder of the importance of clearing trademarks and reviewing the packaging and advertising of regulated products. Based on the new realities for regulated businesses, there are many opportunities to counsel clients

proactively in both trademark clearance and packaging and advertising review. This holds true across multiple industries: food and beverage, alcohol, tobacco, healthcare and medical products. In the pharmaceutical world, for example, one high-risk area for false advertising claims appears to be associated with over-the-counter preparations, including vitamins, supplements and nutritional foods and beverages.

While the FDA already investigates and evaluates claims made for ethical (prescription-based) preparations, it does not necessarily do the same for those nutritional or dietary supplements. Prescription products receive closer scrutiny,

including detailed review by the Office of Prescription Drug Promotion (OPDP, formerly the Division of Drug Marketing, Advertising and Communications). The OPDP provides written comments on proposed promotional materials, reviews complaints regarding alleged violations and monitors ongoing promotional activity. Under the Dietary Supplement Health and Education Act of 1994 (www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcaact/significantamendmentstothefdaact/ucm148003.htm), manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from



Frances M Jagla

Shareholder

jaglaf@lanepowell.com

Frances Jagla is a shareholder in Lane Powell's IP and technology practice group, and focuses her practice on trademarks, copyright, domain names and unfair competition. She has extensive US and international experience in name development, clearance filing, registration, maintenance and enforcement of trademarks and copyrights for Fortune 100 companies, as well as for start-ups and emerging businesses. Ms Jagla possesses in-depth knowledge of trademark-related acquisitions, divestitures, licensing, domain names and regulatory issues relating to healthcare trademarks, as well as other regulated industries. She has more than 20 years' in-house counsel experience and has her Yellow Belt certification in Legal Lean Sigma® and project management.



Paul D Swanson

Shareholder

swansonp@lanepowell.com

Paul Swanson is chair of Lane Powell's food, beverage and hospitality practice group and a member of the IP and technology practice group. His practice is devoted to litigating patent, trademark, copyright, unfair competition, software development and trade secret law disputes. Through his representation of various agribusinesses, Mr Swanson has litigated a number of cutting-edge issues arising in the field of plant patent, copyright and trademark law. The cases he has worked on have helped to shape and highlight the legal issues in this expanding area of law. He is a primary contributor to the firm's *Earth and Table* food blog, which concentrates on IP and unfair competition issues arising in the food, beverage, hospitality and agribusiness industries.

marketing products that are adulterated or misbranded, and are also responsible for evaluating the safety and labelling of their products before marketing to ensure that they meet all requirements of the Dietary Supplement Health and Education Act and FDA regulations. However, they are not required to obtain FDA approval before producing or selling dietary supplements. Manufacturers and distributors must ensure that all claims and information on the product label and in other labelling are truthful and not misleading.

In conjunction with the FDA, the Federal Trade Commission (FTC) is charged with preventing unfair competition and protecting

consumers from unfair or deceptive practices in the marketplace, including the marketing of unproven cures or treatments for various health conditions. “The FTC and the FDA have concurrent jurisdiction over dietary supplements and other health and nutrition products. The two agencies work closely to police the marketplace for false or unsubstantiated claims and for products or marketing practices that present safety concerns” (Deceptive Marketing of Dietary Supplements FTC Enforcement Activities, Prepared Statement of the Federal Trade Commission, May 26 2010, pages 2-3). The FTC has primary authority over the advertising aspects, while the FDA has primary authority for the labelling of health and nutrition products.

POM Wonderful adds another enforcement layer – a private lawsuit for false advertising and unfair competition. Even if a manufacturer or distributor has met FDA and FTC standards, *POM Wonderful* indicates that it may also face a court challenge by a third party or a potential competitor. As such, the attorney’s role should be to review product trademarks, taglines and labelling to make sure that the promotion and advertising of the product meet FDA and FTC guidelines and standards, and will also hold up to challenges by consumers or competitors.

Under this regime, it is important to counsel clients that many elements of their packaging and advertising can contain product claims that may be open to challenge. While it is unlikely that a legal practitioner would clear a name such as ‘Curecancer’ or ‘Enddiabetes’, the proposed name should be reviewed for more subtle promises or claims. In general, if the name suggests that the product will cure or physiologically change a health condition, such as ‘Lowchol’, those names should be considered to be adopted at a higher risk. Puffery, on the other hand – such as ‘Happyheart’ or ‘Brainfood’ – would be considered to be at a lower risk for false advertising claims (either administrative or through private action).

Whether drafting or reviewing advertising and labelling claims, legal professionals should demand that clients provide a reasonable level of substantiation of the



Gregory F Wesner
Shareholder
wesner@lanepowell.com

Gregory Wesner is a shareholder in Lane Powell’s IP and technology practice group and focuses his practice on patent, trademark and other IP litigation and related counselling. His patent litigation experience includes work with pharmaceuticals and medical devices, laser telemetry, wireless infrastructure technology, high-speed scanning radio technology, algorithms for video and image compression, as well as sports equipment and hand tool designs. He also has substantial experience litigating trademark and internet and technology law cases. A registered patent attorney, Mr Wesner also counsels clients in IP matters, including patent due diligence and freedom to operate, brand development and enforcement and trade secret protection.

claim. While the level of proof may not necessarily extend to clinical trial results, there should be strong justification for the statement. For example, if a statement about a product and its effects on the “structure or function” of the body includes an implied claim that the product is helpful for the treatment of disease, there is a need for substantiation. The stronger the statement, the more proof one should have regarding the accuracy of the claim.

To ensure compliance with FTC and FDA law, and to avoid the threat of a private Lanham Act suit, manufacturers of supplements should follow three important steps:

- careful consideration of the product name to ensure that it is not making an inadvertent health claim;
- careful drafting of advertising claims, with particular attention to how claims are qualified and what express and implied messages are actually conveyed to consumers; and
- careful review of the support for a claim to make sure it is scientifically sound, adequate in the context of the surrounding body of evidence and relevant to the specific product and claim advertised

(Dietary Supplements: An Advertising Guide for Industry, Bureau of Consumer Protection, <http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry>).

*POM Wonderful and Lexmark will change the way in which companies engaged in regulated industries look at their competitors’ naming, packaging and advertising. It should also serve as a reminder that a company’s own product lines should be reviewed and made compliant. **WTR***



Lane Powell PC
1420 Fifth Avenue, Suite 4200
PO Box 91302
Seattle WA 98111-9402
United States
Tel +1 206 223 7000
Fax +1 206 223 7107
Web www.lanepowell.com