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Juice Labeling and *Pom Wonderful v. Coca-Cola*: A Legal Overview

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Summary

This report discusses two different federal statutes that regulate beverage labels. The Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations outline requirements for beverage labels reflecting the different ingredients of the juice. The FDCA also prohibits misbranded food and beverages when labels are false and misleading. The Lanham Act, the federal trademark statute that regulates unfair competition, also prohibits misleading labels and advertisements that may hurt a competitor's business and/or goodwill. While these two statutes both impact juice labels, the overall purpose and enforcement of these two statutes differ. Only the federal government can enforce the FDCA, while the Lanham Act allows competitors to enforce the act's principles in the courts. The Lanham Act prohibits unfair competition, while the FDCA seeks to ensure public health and safety. These similarities and differences raise questions regarding the legal options for businesses claiming harm from a misleading or misbranded beverage label, such as the negative impact on the market for their products. Such questions include whether a business can seek relief against a competitor's misleading juice label in court.

The courts and parties in *Pom Wonderful v. Coca-Cola* encountered this issue, specifically regarding Coca-Cola's allegedly misleading juice label. In 2008, Pom brought suit against Coca-Cola alleging that Coca-Cola's Pomegranate Blueberry beverage name and label violates the Lanham Act and California's unfair competition laws because it misleads consumers to believe that the beverage consists of primarily pomegranate and blueberry juices when it actually contains mostly apple and grape juices. The district court in California and the Ninth Circuit held that the FDCA precludes Pom's Lanham Act claim because of the Food and Drug Administration's (FDA's) exclusive authority to regulate food labels and the absence of any FDA action against Coca-Cola for this label. The U.S. Supreme Court held that Pom may bring a Lanham Act claim alleging unfair competition from misleading beverage labels regulated by the FDCA because of the absence of anything in the text, legislative history, or structure of the FDCA or the Lanham Act that shows congressional intent to preclude such Lanham Act claims.

The two legal issues before the courts in *Pom Wonderful* focused on the interaction of federal statutes with both state and federal laws. On remand, the lower courts will have to consider again the issues of preemption, specifically whether the FDCA preempts Pom's California state law claims when the state law provisions are not identical to the federal law. Additionally, the Supreme Court's preclusion analysis in *Pom Wonderful* adds to the case history addressing the preclusion of Lanham Act claims by the FDCA. However, as consumers appear increasingly concerned about how food products are labeled, further litigation may be needed to clarify how the Supreme Court's holding in *Pom Wonderful* applies to Lanham Act food and beverage claims that are dissimilar to Pom's Lanham Act claim. Similarly, it is unclear how *Pom Wonderful* may apply to other FDA-regulated products such as drugs and cosmetics. Despite the possibility for further litigation, *Pom Wonderful* provides a useful opportunity to observe and understand the interplay between two federal statutes that can be applied to the wider federal regulatory context.

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In *Pom Wonderful v. Coca-Cola*, Pom first brought a suit in 2008 against Coca-Cola, claiming that Coca-Cola's Pomegranate Blueberry beverage name and label violates the Lanham Act and California's unfair competition laws because it misleads consumers to believe that the beverage consists of primarily pomegranate and blueberry juices when it actually contains mostly apple and grape juices. The district court in California and the Ninth Circuit held that the Food, Drug, and Cosmetic Act (FDCA) precludes Pom's Lanham Act claim due to the Food and Drug Administration's (FDA's) exclusive authority to regulate food labels and the absence of any FDA action against Coca-Cola for this label. The U.S. Supreme Court granted certiorari and in an 8-0 decision[1] held that Pom Wonderful may bring a Lanham Act claim alleging unfair competition from false or misleading product descriptions on food and beverage labels regulated by the FDCA.

Pom Wonderful v. Coca-Cola presents several significant legal issues, including the enforcement of the statutory requirements for food and beverage labeling and the complex relationship among the FDCA, the Lanham Act, and the state laws involved in this regulatory scheme. When such an overlap among various statutes occurs, questions regarding the relationship among federal statutes and state laws arise among the different actors involved, such as the federal government, beverage manufacturers, and consumers. This report explores these various legal issues in the context of *Pom Wonderful v. Coca-Cola* and beverage labeling.

The two legal issues before the courts in *Pom Wonderful* focused on the interaction of federal statutes with both state and federal laws. On remand, the lower courts will have to consider again the issues of preemption, specifically whether the FDCA preempts Pom's California state law claims when the state law provisions are not identical to the federal law. Additionally, the Supreme Court's preclusion analysis in *Pom Wonderful* adds to the current case law addressing preclusion of Lanham Act claims by the FDCA. However, further litigation may be needed to clarify how the Supreme Court's holding in *Pom Wonderful* applies to Lanham Act food and beverage claims that are dissimilar to Pom's Lanham Act claim as well as other FDA-regulated products like cosmetics.

The report begins with an overview of the statutory and regulatory background of beverage labeling, including affirmative requirements for beverage labels, the FDCA and Lanham Act provisions for misbranding, and the enforcement of these two federal statutes. Next, the report discusses the procedural history of *Pom Wonderful v. Coca-Cola* and the legal arguments made by both parties. The report then concludes by analyzing legal issues presented in the *Pom Wonderful* case concerning preemption and preclusion in the context of the U.S. Supreme Court's analysis in its *Pom Wonderful* decision.

Statutory and Regulatory Background

Both the FDCA and the Lanham Act impact the content of juice labels, including Coca-Cola's Pomegranate and Blueberry beverage. The following section examines the provisions in these two federal statutes on which the parties and the courts in *Pom Wonderful* relied for their legal analysis. The section begins with an overview of the FDA requirements for the content of beverage labels. Next, the section discusses the misbranding provisions in both the FDCA and the Lanham Act. The section then concludes by highlighting the different enforcement mechanisms for these two federal statutes.

[1] Justice Breyer took no part in the consideration of this case.

FDA Requirements for Beverage Label Content[2]

FDA regulations outline several affirmative requirements for juice labels, such as Coca-Cola's Pomegranate Blueberry, reflecting the ingredients, flavors, and production of the beverage.[3] The FDA promulgated these rules to implement the Nutrition Labeling and Education Act of 1990.[4] During the notice and comment period of the rulemaking, FDA noted that a multiple-juice beverage named for a represented flavor would not necessarily be misleading if "consumers [are] given enough accurate information to easily ascertain the nature of the juices represented to be present in a multiple-juice beverage."[5] Unlike other types of labels, such as those for drugs,[6] the FDA does not preapprove juice labels under these regulations.

The regulations first distinguish between "juices" and other beverages. Only beverages that are 100% juice may be called juice.[7] Beverages diluted to less than 100% juice must have the word "juice" qualified with another term such as "beverage," "drink," or "cocktail."[8] For example, a beverage containing less than 100% cranberry juice may be labeled "Cranberry Juice Cocktail."

If the beverage contains a mixed combination of fruit or vegetable juices, then the name of the beverage must be the name of the juices in descending order of predominance by volume unless the label indicates that the named juice is used as a flavor.[9] For example, "Apple, Pear and Raspberry Juice Drink" or "Raspberry-Flavored Apple and Pear Juice Drink" addresses the differences in volume of the various juices. If the label presents one or more but not all of the juices, then the name must indicate that more juices are present.[10] For example, "Apple Juice Blend" signifies that the beverage contains other juices than the predominant apple. If one or more juices are named (but not all) and the named juice(s) is not the predominant juice, the name of the beverage must either state that the beverage is flavored with the named juice or state the amount of the named juice in a 5% range.[11]

If the juice has been modified, then the common name shall include a description of the modification, such as "Acid-reduced Cranberry Juice."[12] If juices in the beverage are made from concentrate, the name must indicate that fact using terms such as "from concentrate" or "reconstituted."[13]

[2] The following section provides an overview of the relevant regulations in *Pom Wonderful v. Coca-Cola*, but does not discuss all regulations that impact juice labels in any context.

[3] FDCA defines "label" as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. §321(k).

[4] P.L. 101-535.

[5] Food Labeling, 56 Fed. Reg. 30452-01 (July 2, 1991).

[6] 21 U.S.C. §355(d).

[7] 21 C.F.R. §102.33(a).

[8] *Id.*

[9] 21 C.F.R. §102.33(b).

[10] 21 C.F.R. §102.33(c).

[11] 21 C.F.R. §102.33(d).

[12] 21 C.F.R. §102.33(e).

[13] 21 C.F.R. §102.33(g).

Misbranding under the FDCA and the Lanham Act

Food, Drug, and Cosmetic Act (FDCA)

Both the FDCA and the Lanham Act prohibit the "misbranding" of food and beverage labels. Under the FDCA, a food is misbranded if the "labeling is false or misleading in any particular."[14] As Congress enacted the FDCA to protect the health and safety of the public,[15] FDCA's misbranding provision protects the consumer from negligent or false labeling that may cause physical harm, by, for example, not disclosing the correct information and preventing the consumer from making the right health choices.[16]

At its most basic meaning, courts have interpreted FDCA's misbranding provision to target a label that characterizes the food or beverage to be something other than it is. In the seminal case *U.S. v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar,* the Court found the vinegar labeled "Excelsior Brand Apple Cider Vinegar Made from Selected Apples" to be something other than indicated.[17] The vinegar at issue was made from dehydrated apples and not from apple cider "as [is] generally known" for this type of beverage.[18] Therefore, the Court found the product was misbranded due to this misrepresentation of the beverage's production and content.

Courts have noted the significance of "or" in the FDCA's misbranding provision ("false *or* misleading"), signaling that a label of misbranded food may be misleading without it being false and vice versa.[19] Deception from a misbranded food label may arise due to the use of statements that are not technically false or may be literally true.[20] Similarly, statements may be technically accurate, but can still mislead the consumer. To determine whether a label is false or misleading, courts generally look at the ordinary meaning of words and not necessarily the trade or commercial meaning.[21] A misleading label could potentially deceive the "unthinking and credulous" consumer, not necessarily a "reasonable" consumer.[22] However, it is not necessary to show that a consumer was actually misled or deceived or that the intent to deceive was present.[23]

The entire label does not need to be deceptive in order to violate FDCA's misbranding prohibition. Food is "misbranded" if it appears that any single representation on the label is false or misleading. In *U.S. v. An Article of Food ... "Manischewitz ... Diet Thins,"* the court found that a label for matzo crackers was misleading as the use of the phrase "Diet-Thins" encourages consumers to assume, incorrectly, that the food would lead to weight loss.[24] The court held that the government did not need to prove that the entire label was misleading, just one section.[25] Moreover, a court may also consider certain segments of the label within the context of the entire

[14] 21 U.S.C. §343(a).

[15] *See generally* U.S. v. Sullivan, 332 U.S. 689 (1948).

[16] Developments in the Law - The Federal Food, Drug, and Cosmetic Act, 67 Harv. L. Rev. 632, 649 (1954).

[17] U.S. v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar, 265 U.S. 438, 444-45 (1924).

[18] *Id.* at 444.

[19] *See, e.g.,* Van Liew v. U.S., 321 F.2d 664, 673 (5th Cir. 1963).

[20] Ninety-Five Barrels, 265 U.S. at 443.

[21] *See, e.g.,* Libby, McNeill & Libby v. U.S., 210 F.148, 149 (4th Cir. 1913).

[22] U.S. v. An Article of Food ... "Manischewitz ... Diet Thins," 377 F.Supp. 746, 749 (E.D.N.Y. 1974).

[23] *Id.*

[24] *Id.*

[25] *Id.*

label.[26] The court in *U.S. v. An Article of Food Consisting of 432 Cartons, More or Less, each Containing 6 Individually Wrapped Candy Lollipops of Various Flavors* concluded that although the labeling on the inside of the candy box may be misleading, a jury may find the label not to be misleading when read together with the description of the contents listed on the outside of the carton.[27]

Lanham Act

While the FDCA focuses on public health, the Lanham Act, also known as the Trademark Act of 1946, seeks to "protect persons engaged in ... commerce against unfair competition."[28] Congress intended the act to protect a business's reputation whose goodwill may be diverted by deceptive advertisements or labels and to encourage consumers to purchase products in confidence by reassuring consumers that a specific mark designates the product that they expect and wish to buy.[29] The Lanham Act's false and misleading advertising provision, Section 43(a),[30] enables those who claim to be damaged by another's false or misleading advertisement to bring suit against this entity and seek civil damages.[31]

Courts have broken down Section 43(a) into five main elements. For a successful Lanham Act claim, the plaintiff must prove that (1) the defendant made false or misleading statements about the product; (2) there is actual deception or at least the tendency to deceive a substantial portion of an intended audience; (3) the deception was material to the consumer's purchasing decisions; (4) the product traveled in interstate commerce; and (5) there is a likelihood of injury to the plaintiff (such as declining sales or loss of goodwill).[32]

To demonstrate that a statement is false under the Lanham Act, the plaintiff must show that it is literally false, or that it is literally true but likely to mislead or confuse consumers.[33] Generally, puffery in advertising is not actionable under Section 43(a) as "no one would rely on its exaggerated claims" and, therefore, it is not deceptive.[34] Similarly, unsupported or unsubstantiated claims are not per se violations of Section 43(a).[35] For literally true but misleading statements, a plaintiff must produce evidence that the target audience, rather than the general public, was or is likely to be misled.[36]

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[26] U.S. v. Article of Food Consisting of 432 Cartons, More or Less, Containing 6 Individually Wrapped Candy Lollipops of Various Flavors, 292 F.Supp. 839, 841 (S.D.N.Y. 1968).

[27] *Id.*

[28] 15 U.S.C. §1127.

[29] S. Rept. 79-1333, at 3 (1946).

[30] "Any person who ... uses in commerce any word, term, name, symbol, or device ... or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which ... in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such an act." 15 U.S.C. §1125(a).

[31] 15 U.S.C. §1125(a).

[32] *See, e.g.*, Warner-Lambert Co. v. Breathasure, Inc., 204 F.3d 87, 91-92 (3d Cir. 2000) (internal citations omitted).

[33] *See, e.g.*, Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1139 (9th Cir. 1997).

[34] Toro Co. v. Textron, Inc., 499 F.Supp. 241, 253, n.23 (D.Del. 1980) (internal citation omitted).

[35] *See* Sandoz Pharms. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 228 (3d Cir. 1990).

[36] Johnson & Johnson Merck Consumer Pharms. Co v. Smithkline Beecham Corp., 960 F.2d 294, 301 (2d Cir. 1992).

Enforcement

The Lanham Act and the FDCA have different enforcement mechanisms. Only the federal government may enforce the provisions under the FDCA.[37] The FDCA prohibits private litigants from suing to enforce compliance with the FDCA and its implementing regulations. To remedy alleged mislabeling violations, the FDA may send out warning letters to firms and facilities that the agency believes are violating the FDCA. The agency also has seizure authority to remove misbranded products from the marketplace.[38] Immediately after the seizure, a hearing occurs where the owner of the misbranded food has the right to object to the seizure as an exercise of his due process rights.[39] However, due process principles are generally applied narrowly during post-seizure hearings because of the public health and safety concern.[40] At the hearing, the court will decide whether to condemn the product or whether to release the goods if the government has failed to provide sufficient evidence to justify the seizure. The court may allow the owner to correct the defects of the product, such as through relabeling, after condemnation.[41]

Unlike the FDCA, the Lanham Act offers private enforcement remedies. While the Lanham Act states that "any person who believes that he or she is or is likely to be damaged by"[42] a false or misleading representation may seek civil damages, courts have not found standing for consumers under this provision of the Lanham Act, but instead require some commercial injury for standing.[43] The circuit courts are split as to whether a plaintiff must be a competitor of the defendant in order to have standing. The Third Circuit has stated that a non-competitor may have sufficient standing under Section 43(a).[44] The Ninth Circuit has held, however, that the plaintiff must allege a commercial injury that limits the plaintiff's ability to compete with the defendant in order to qualify for standing.[45]

The Lanham Act provides for injunctive[46] and monetary relief.[47] For injunctive relief, a plaintiff must show that the defendant's representations about its product "have a tendency to deceive consumers."[48] While this standard requires less proof than actual deception, a plaintiff must show that at least some consumers were misled by the advertisement. Once a violation of Section 43(a) has been established, a district court may exercise broad discretion in awarding monetary relief to the plaintiff.[49] The plaintiff may recover lost profits, the defendant's profits gained as the result of the false advertising, and attorney's fees at the discretion of the court in exceptional cases.[50]

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[37] 21 U.S.C. §337(a) ("all such proceedings for the enforcement ... of this chapter shall be by and in the name of the United States.")

[38] 21 U.S.C. §334.

[39] Juici-Rich Prods, Inc. v. Lowe, 735 F.Supp. 1387, 1392 (C.D. Ill. 1990).

[40] *See* U.S. v. Article of Device "Theramatic," 715 F.2d 1339 (9th Cir. 1983).

[41] *See, e.g.,* U.S. v. 43 ½ Gross Rubber Prophylactics Labeled in Part "Xcello's Prophylactics," 65 F. Supp. 534 (1946).

[42] 15 U.S.C. §1125(a).

[43] *See, e.g.,* Seven-Up Co. v. Coca-Cola Co., 86 F.3d 1379, 1383, n.5 (5th Cir. 1996) ("we have found no case which suggests that 'consumers' as such have standing under §43(a).")

[44] *See* Joint Stock Soc'y v. UDV N. Am., Inc., 266 F.3d 164, 180 (3d Cir. 2001).

[45] Barrus v. Sylvania, 55 F.3d 468, 470 (9th Cir. 1995).

[46] 15 U.S.C. §1116.

[47] 15 U.S.C. §1117.

[48] *See, e.g.,* Pizza Hut, Inc. v. Papa John's Intern., Inc., 227 F.3d 489, 497-98 (5th Cir. 2000).

[49] 15 U.S.C. §1117(a).

[50] *Id.*

While the Lanham Act permits courts to increase the damages, the statute does not permit courts to award punitive damages for violations of Section 43(a).[51]

Pom Wonderful v. Coca-Cola

Pom Wonderful LLC produces, markets, and sells bottled pomegranate juice and pomegranate juice blends. The Coca-Cola Company produces, markets, and sells bottled juices and juice blends under the Minute Maid brand. In September 2007, Coca-Cola began promoting its new juice blend, "Pomegranate Blueberry." This juice blend contains approximately 99.4% apple and grape juices, 0.3% pomegranate juice, 0.2% blueberry juice, and 0.1% raspberry juice. The label of Pomegranate Blueberry depicts a fruit vignette of the five fruit ingredients in the juice. Below the fruit vignette reads "Pomegranate Blueberry" and "Flavored Blend of 5 Juices." The back of the bottle reads "Minute Maid Enhanced Pomegranate Blueberry Is Made With A Blend of Apple, Grape, Pomegranate, Blueberry, and Raspberry Juices From Concentrate and Other Ingredients."[52]

Source: Minute Maid's "Pomegranate Blueberry Juice Blend" as pictured in Pom Wonderful LLC v. Coca-Cola Co., 679 F.3d 1170, 1173 (9th Cir. 2012).

In 2008, Pom sued Coca-Cola, alleging that Coca-Cola misled consumers to believe that the Pomegranate Blueberry beverage contains mostly pomegranate and blueberry juices when it actually contains mostly apple and grape juices.[53] Specifically, Pom claimed that Coca-Cola violated the false-advertising provision of the Lanham Act (§43(a)), in addition to California's Unfair Competition Law and False Advertising Law, which prohibit misleading advertising, and California's Sherman Law,[54] which includes language materially identical to FDCA's misbranding

[51] 15 U.S.C. §1117(b).

[52] Pom Wonderful LLC v. Coca-Cola Co., 727 F.Supp.2d 849, 853 (C.D. Cal. 2010).

[53] *Id.* at 1174.

[54] Cal. Health & Safety Code §110660.

provision, Section 343(a)(1). Coca-Cola responded that the beverage's name and label complied with FDA regulations,[55] which, therefore, precludes Pom's Lanham Act challenge.[56] Coca-Cola also moved to dismiss Pom's state law claims on the basis that the FDCA preempts state law obligations not identical to the federal law.[57]

Lower Court Decisions

The District Court for the Central District of California partially granted summary judgment to Coca-Cola, holding that the FDCA's regulations barred Pom's Lanham Act challenge of the Pomegranate Blueberry name and labeling.[58] The court reasoned that the FDA had already spoken directly on the issue of identifying beverages with non-primary juices through its regulations.[59] The court also emphasized that the beverage name complies with these regulations. Additionally, the court held that Pom lacked statutory standing to pursue the state law claims.[60] Pom's interest in the expectancy of consumer profits did not qualify, for the court, as injury under the doctrine of standing.

Pom appealed the district court decision to the Ninth Circuit, which affirmed the district court's holding that the FDCA and its regulations bar Pom's Lanham Act claim for both the Pomegranate Blueberry name and label.[61] While the Ninth Circuit refrained from stating that compliance with the FDCA or FDA regulations will always insulate a defendant from Lanham Act liability, the court deferred to Congress's decision to delegate beverage juice labeling to the FDA and to FDA's expertise in the area.[62] The Ninth Circuit remanded the case to the district court to reconsider issues of standing in connection with Pom's state law claims.[63]

Supreme Court Decision

The U.S. Supreme Court granted petition for a writ of certiorari in January 2014.[64] The issue before the Court was whether a private party may bring a Lanham Act claim challenging a food label that is regulated by the FDCA. In its brief before the Court, Pom argued that neither the FDCA nor the Lanham Act contains a provision limiting the application of the Lanham Act in the context of misleading food labels.[65] If Congress had intended to preclude Lanham Act claims in this instance, according to Pom, Congress could have added an express preclusion provision, when it added the state law preemption provision to the FDCA in 1990.[66] Moreover, Pom further argued that Coca-Cola's label could have complied with both the FDCA and the Lanham Act, but the company chose not to label its product in such a manner.[67] Pom also stated that the Ninth

[55] 21 C.F.R. §101.22(i)(1)(i); 21 C.F.R. §102.33(d).

[56] Pom Wonderful LLC v. Coca-Cola Co., 727 F.Supp.2d 849, 871 (C.D. Cal. 2010).

[57] *Id.* at 859.

[58] *Id.* at 872.

[59] *Id.* at 871. *See* section of this report "FDA Requirements for Beverage Label Content."

[60] *Id.* at 870.

[61] Pom Wonderful LLC v. Coca-Cola Co., 679 F.3d 1170, 1179 (9th Cir. 2012).

[62] *Id.* at 1178.

[63] *Id.* at 1179.

[64] Pom Wonderful LLC v. Coca-Cola Co., No. 12-761, slip op. (2014).

[65] Brief of Petitioner at 15, Pom Wonderful LLC v. Coca-Cola Co., No. 12-761, slip op. (2014).

[66] *Id.* at 16.

[67] *Id.* at 15.

Circuit's holding would leave the entire regulation of misleading food labels with the FDA, an agency that does not have the necessary resources to fulfill this task.[68]

In response, Coca-Cola argued that Congress has demonstrated its intent to preclude Lanham Act claims and thus to create a uniform national scheme for food labeling regulation through the FDCA and the act's bar against a private cause of action.[69] The specificity of the FDCA and the Nutritional Labeling and Education Act (NLEA) compared to the broad language in the Lanham Act, according to Coca-Cola, demonstrates Congress's intent to preclude a Lanham Act claim in these circumstances. Coca-Cola continued that a "specific" federal law (one with multiple, precise requirements), such as the FDCA, can narrow the scope of a general federal law even if the specific law does not expressly indicate this intention.[70] In Coca-Cola's view, the FDCA's exclusive delegation of enforcement authority to the federal government and NLEA's express preemption clause signal Congress's intent to do so.[71]

In an 8-0 decision,[72] the Supreme Court held that the Ninth Circuit's ruling that Pom's Lanham Act claim is precluded by the FDCA was incorrect, as the text, legislative history, and structure of the two acts do not support preclusion for this type of claim.[73] Congress, according to the Court, did not intend the FDCA to preclude Lanham Act claims, such as Pom's.[74] Further analysis of the Supreme Court's decision is provided in the following discussion on select legal issues.

Select Legal Issues

The primary issue before the Supreme Court in *Pom Wonderful v. Coca-Cola* was whether the FDCA precludes Pom's Lanham Act claim. Additionally, the lower court on remand is likely to consider the issue of preemption (the displacement of state law requirements for federal law) for Pom's state law claims. The following section provides an overview of these two legal issues, preemption and preclusion, in the context of *Pom Wonderful v. Coca-Cola* and juice labeling.

Preemption

Preemption occurs when federal law displaces state law requirements. As the legal basis for preemption, the Supremacy Clause of the Constitution states that the "Laws of the United States" made in pursuance of the Constitution are by definition "the supreme Law of the Land" "notwithstanding" "the Constitution or the Laws of any State to the Contrary."[75] Federal preemption occurs when: "(1) Congress enacts a statute that explicitly pre-empts state law; (2) state law actually conflicts with federal law; or (3) federal law occupies a legislative field to such an extent that it is reasonable to conclude that Congress left no room for state regulation in that field."[76]

[68] *Id.* at 18.

[69] Brief of Respondent at 15, Pom Wonderful LLC v. Coca-Cola Co., No. 12-761, slip op. (2014).

[70] *Id.* at 18-21.

[71] *Id.* at 23-24.

[72] Justice Breyer took no part in the case.

[73] Pom Wonderful LLC v. Coca-Cola Co., No. 12-761, slip op., at 2 (2014).

[74] *Id.* at 17.

[75] U.S. CONST. Art. VI, §1, Cl. 2.

[76] Bruton v. Gerber Prods. Co., 961 F.Supp.2d 1062, 1078 (N.D. Cal. 2013).

When first considering a preemption case, the Supreme Court has instructed courts to "start with the assumption that the historic police powers of the States were not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress."[77] The Court regards this presumption against preemption as heightened when "federal law is said to bar state action in fields of traditional state regulation."[78] For over a century, the Court has found food labeling, as part of the effort to protect consumers from fraud and to ensure food safety, to be an area of traditional state regulation.[79] For lower courts in recent cases, this presumption does not necessarily bar further analysis of a preemption claim as they explore the various types of preemption discussed below.[80]

Courts generally consider express preemption first, specifically whether Congress has enacted an express preemption provision indicating its intent to preempt some state law. In 1990, Congress passed the Nutrition Labeling and Education Act (NLEA) amending the FDCA to prescribe national uniform nutrition labeling for foods.[81] NLEA included an express preemption provision, Section 343-1(a), which states that "... no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce"[82] certain misbranding labeling requirements already established by the FDCA such as food identity,[83] imitation food,[84] and prominence of information on the label.[85] The express preemption provision does not address the false or misleading label provision (§343(a)(1)). One California district court has remarked that the absence of the false or misleading provision (§343(a)(1)) from the express preemption provision means that the FDCA does not preempt any state law claims arising from false or misleading labels.[86] NLEA's Section 6(c) also states that the act "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. §343-1]."[87]

In addition to an express provision, preemption may also occur when state law conflicts with federal law, such as when it is impossible for a party to comply with both state and federal requirements. Such conflict occurs when compliance with both federal and state regulations is a "physical impossibility."[88] The Supreme Court rarely invokes this doctrine, but provides a hypothetical example in *Florida Lime & Avocado Growers, Inc. v. Paul.* In this case, the Supreme Court referred to a situation in which federal law prohibited the marketing of any avocado with

[77] U.S. v. Locke, 529 U.S. 89, 107 (2000)(quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

[78] N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995).

[79] Plumley v. Com. of Mass., 155 U.S. 461, 472 (1894)("If there be any subject over which it would seem the states ought to have plenary control ... ,it is the protection of the people against fraud and deception in the sale of food products."); Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 144 (1963)("States have always possessed a legitimate interest in 'the protection of (their) people against fraud and deception in the sale of food products' at retail markets within their borders.") *See also* In re Farm Raised Salmon Cases, 175 P.3d 1170, 1176 (Cal. 2008).

[80] *See, e.g.,* Bruton, 961 F.Supp.2d at 1078-80.

[81] P.L. 101-535.

[82] 21 U.S.C. §343-1.

[83] 21 U.S.C. §343(g).

[84] 21 U.S.C. §343(c).

[85] 21 U.S.C. §343(f).

[86] *See, e.g.,* Chavez v. Blue Sky Natural Beverage Co., 268 F.R.D. 365, 370 (N.D. Cal. 2010).

[87] P.L. 101-535, §(6)(c)(1).

[88] Florida Lime, 373 U.S. at 142-43.

more than seven percent oil, while California law excluded from the state any avocados measuring less than eight percent oil.[89]

An implied field preemption may occur when state law regulates conduct in a field that Congress intended to occupy exclusively.[90] A court may infer field preemption unless the field includes areas traditionally occupied by the states. In these cases, the court must find "clear and manifest" congressional intent to supersede state laws.[91] For preemption cases regarding state misbranding laws similar to FDCA's false and misleading provision, defendants claiming preemption have pointed to the FDCA's enforcement provision as congressional intent that FDCA should supersede state laws.[92] In *Chavez v. Blue Sky Natural Beverage Co.,* the defendant argued that the FDCA's bar against private litigants bringing suits for noncompliance with the FDCA signals congressional intent that the FDCA serves as the only authority in food labeling cases.[93] However, the court found that this did not demonstrate "clear and manifest" intent to occupy the entire field of food labeling.[94] Defendants also claim preemption is warranted when state law requirements are not identical to federal requirements or when Congress has so broadly regulated the field that there is no room left for state regulation in that particular issue area.[95] The defendant in *Holk v. Snapple Beverage Corp.* argued that as the FDCA so extensively regulates food beverage labeling, the federal statute should preempt similar state laws.[96] However, the Third Circuit disagreed, stating that the mere existence of a federal regulatory scheme, even such an extensive one as FDCA's, does not imply preemption of state laws by itself.[97]

Pom Wonderful and State Law Claims

While the Supreme Court did not consider Pom's state law claims, the district court on remand will likely consider these claims and the issue of preemption. Pom initially brought several state law claims against Coca-Cola under California's Unfair Competition Law[98] and California's False Advertising Law,[99] which prohibit deceptive practices and misleading advertising. The district court initially ruled that the FDCA preempted Pom's state law claims, according to Section 343-1(a) of the FDCA, to the extent that the California laws imposed obligations that are not identical to those imposed by the FDCA and its implementing regulations.[100] The court specifically pointed to the FDA regulations outlining the affirmative requirements for beverage labels,[101] which the California Unfair Competition and False Advertising Laws do not address. However, the district court did not find preemption on implied field preemption grounds, emphasizing the lack of

[89] *Id.* at 143.

[90] English v. Gen. Electric Co., 496 U.S. 72, 79 (1990).

[91] *Id.*

[92] *See, e.g.*, Brazil v. Dole Food Co., Inc., 935 F.Supp. 2d 947, 954 (N.D. Cal. 2013).

[93] Chavez, 268 F.R.D. at 371.

[94] *Id.* at 371-72.

[95] *See, e.g.*, U.S. v. Locke, 529 U.S. 89, 111 (2000); Brazil, 935 F.Supp. 2d at 958.

[96] Holk v. Snapple Beverage Corp. 575 F.3d 329, 337 (3d Cir. 2009).

[97] *Id.* at 339.

[98] California Business & Professions Code §17200 *et seq.*

[99] California Business & Professions Code §17500 *et seq.*

[100] Pom Wonderful LLC v. Coca-Cola Co., No. CV 08-06237SJO, 2009 WL 7050005, at *6 (C.D. Cal. 2009).

[101] *See* section of this report "FDA Requirements for Beverage Label Content."

evidence signaling congressional intent that the FDCA should occupy exclusively the food labeling and advertising field.[102]

Pom later amended its initial complaint to include claims under California's Sherman Law, which includes language that is materially identical to FDCA's misbranding provision.[103] Ultimately, the district court found that Pom did not have standing to assert the state law claims as Pom did not lose money or property as a result of the unfair competition.[104] Pom's "lost business opportunity" in the pomegranate juice market was not sufficient to give it standing, according to the court, as it did not show that Pom was entitled to restitution from the defendant.[105]

The Ninth Circuit disagreed with the district court's standing analysis insofar as it based its decision on Pom's eligibility of restitution. The circuit court remanded the case to the district court to rule on the state law claims. While the Supreme Court did not address the merits of Pom's state law claims, the Supreme Court did note that it is significant that the FDCA's preemption provision distinguishes among different FDCA requirements.[106] For example, the preemption provision forbids state law requirements that are of the type but not identical to specific food and beverage labeling provisions.[107] If the district court finds that Pom has standing to bring the state law claims, it is likely that the district court will consider this preemption provision when reviewing the case on remand.

Preclusion

When two federal statutes regulate a similar area, the courts, "absent a clearly expressed congressional intention to the contrary, [should] regard each as effective."[108] The alternative approach of giving maximum effect to each statute is to preclude one statute for the other, when the court finds that the statutes conflict and otherwise cannot effectively operate together. Such an interpretation can occur on a broad scale or more narrowly in a specific instance. In either context, courts generally examine whether such a conflict exists and whether one statute has impliedly repealed the other.

Repeals by implication are generally not favored and tend not to be based on perceived conflict alone.[109] "When there are two acts upon the same subject, the rule is to give effect to both if possible.... The intention of the legislature to repeal 'must be clear and manifest.'"[110] Congressional intent to repeal a statute or part of a statute should be clear and present in the text. Repeal by implication generally is allowed only where "(1) provisions in the two acts are in irreconcilable conflict, the later act to the extent of the conflict constitutes an implied repeal of the earlier one; and (2) if the later act covers the whole subject of the earlier one and is clearly intended as a substitute, it will operate similarly as a repeal of the earlier act."[111] Creating a corollary to the second part of this rule, the Supreme Court has stated that absent a clear intention

[102] *Id.* at *7.

[103] Pom Wonderful LLC v. Coca-Cola Co,, 679 F.3d 1174 (9th Cir. 2012).

[104] Pom Wonderful LLC v. Coca-Cola Co., 727 F.Supp.2d 849, 869 (C.D. Cal. 2010).

[105] *Id.*

[106] Pom Wonderful LLC v. Coca-Cola Co., No. 12-761, slip op., at 10 (2014).

[107] 21 U.S.C. §§343-1(a)(1)-1(5).

[108] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 143-44 (2001).

[109] 1A Sutherland Statutory Construction § 23:9 (7th ed.).

[110] U.S. v. Borden Co., 308 U.S. 188, 198 (1939) (internal citation omitted).

[111] Radzanower v. Touche Ross & Co., 426 U.S. 148, 154 (1976).

otherwise, "a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment."[112]

Interplay Between Lanham Act and FDCA

Prior to *Pom Wonderful*, courts have both permitted and denied a plaintiff to pursue a food or beverage Lanham Act claim in particular circumstances. Generally, courts allow a Lanham Act claim if the claim does not depend on the direct or indirect interpretation of the FDCA or FDA regulations. The court in *Grove Fresh Distributors, Inc. v. Flavor Fresh Foods, Inc.* permitted the plaintiff's Lanham Act claim, which turned on the definition of orange juice from concentrate.[113] The plaintiff alleged that the defendant's representation that the product was 100% orange juice from concentrate was false because the product contained additives and adulterants.[114] Even though the plaintiff referred to the FDA regulation's definition of orange juice in its claim, the court still permitted the Lanham Act claim to continue because the plaintiff did not have to rely on the FDA regulations to meet the elements of the Lanham Act. According to the court, the plaintiff could have used other alternatives, such as the market definition of orange juice, in order to show that the defendant's representation was "false" under the Lanham Act.[115]

Before *Pom Wonderful,* courts generally did not permit a Lanham Act claim if the claim required an original interpretation of FDA regulations and the FDA had not yet ruled or acted upon that particular product. Permitting such a claim would, according to the courts, usurp FDA's interpretive authority and undermine Congress's decision to limit FDCA enforcement to the federal government.[116] The court in *Summit Technology, Inc. v. High Line Medical Instruments* extended deference to the FDA for the same reason. In this case, the plaintiff's Lanham Act claim alleged that the defendant falsely implied that the importation of the defendant's laser system was legal.[117] The FDA had not yet determined whether to take action against the defendant for its importation of the product. In order to assess the validity of the plaintiff's falsity claim, the court would have had to perform an "original interpretation" of the FDA regulations before the FDA had a chance to interpret and act upon its own regulations. The court refused to perform such an interpretation, which would have preempted the FDA before it had acted.[118]

Similarly, courts tend not to permit a Lanham Act claim related to whether a defendant's conduct violates the FDCA. In *PhotoMedex, Inc. v. Irwin,* the plaintiff claimed that the defendant made false representations under the Lanham Act about FDA clearance to market the defendant's device.[119] For this particular device, the manufacturer can obtain FDA clearance, according to the FDA regulations, if the product is sufficiently similar to a device that has already received clearance.[120] The court did not permit the Lanham Act claim in this case, as it required the court

[112] Morton v. Mancari, 417 U.S. 535, 550 (1974).

[113] Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc., 720 F.Supp. 714, 715 (N.D. Ill. 1989).

[114] *Id.*

[115] *Id.* at 716.

[116] *See, e.g.*, Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1139 (4th Cir. 1993); Sandoz, 902 F.2d at 231-32.

[117] Summit Tech., Inc. v. High-Line Med. Instruments, Co., 933 F.Supp. 918, 934 (C.D. Cal. 1996).

[118] *Id.* at 933-34.

[119] PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 921-22 (9th Cir. 2010).

[120] *Id.* at 922.

to interpret whether the defendant qualified for FDA clearance and not whether the FDA had or had not granted the clearance.[121]

Courts generally do not permit Lanham Act claims concerning false or misleading use of terms defined by FDA regulations. The plaintiff in *Eli Lilly & Co. v. Roussel Corp.* alleged that the defendant's use of "generic" and "safe and effective" in an FDA application was false.[122] Because the claim required the court to interpret the FDA regulations' definition of these terms to determine their falsity, the court denied the Lanham claim.[123] Similarly, in *Healthpoint v. Ethex Corp.,* the plaintiff claimed that the defendant's advertising of the safety and effectiveness of its drugs violated the Lanham Act, specifically the inappropriate use of FDA terms "equivalent to" and "alternative to."[124] The court dismissed the Lanham Act claim because it determined that the correct use of these terms in the context of drug marketing required the interpretation and application of the FDCA and FDA regulations.[125]

Supreme Court's Preclusion Analysis in *Pom Wonderful v. Coca-Cola*

In *Pom Wonderful v. Coca-Cola,* the Supreme Court held that "[c]ompetitors, in their own interest, may bring Lanham Act claims like Pom's that challenge food and beverage labels that are regulated by the FDCA."[126] In reaching that conclusion, the Supreme Court first looked at the text of both statutes and noted the absence of any provision in either statute that forbids or limits Lanham Act claims.[127] This absence, according to the Court, is "'powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring' proper food and beverage labeling."[128] For the Court, even FDCA's preemption provision supported finding no preclusion in this case. Instead, the provision indicated that Congress intended the FDCA to preempt state law in particular contexts only, according to their interpretation of Section 343-1(a).[129]

The Supreme Court further commented on the relationship between the Lanham Act and the FDCA. According to the Court, these two federal statutes complement each other in food and beverage labeling, with the Lanham Act protecting commercial interests and the FDCA protecting health and safety.[130] Similarly, the Court pointed to the opportunity, offered by the Lanham Act, for private companies that have market expertise to enforce the Lanham Act, which in turn provides incentives for manufacturers to "behave well" in the context of food and beverage labeling.[131] Because the FDA does not preapprove food and beverage labels under its regulations, precluding Lanham Act claims in this context, according to the Court, would leave commercial

[121] *See id.* at 924-25.

[122] Eli Lilly and Co. v. Roussel Corp., 23 F.Supp.2d 460, 470 (D.N.J. 1998).

[123] *Id.* at 477.

[124] Healthpoint, Ltd. v. Ethex Corp., 273 F.Supp.2d 817, 838 (W.D. Tex. 2001).

[125] *Id.* at 839.

[126] Pom Wonderful LLC v. Coca-Cola Co., No. 12-761, slip op., at 2 (2014).

[127] *Id.* at 9.

[128] *Id.* at 10 (quoting Wyeth v. Levine, 555 U.S. 555, 575 (2009)).

[129] Pom Wonderful LLC v. Coca-Cola Co., No. 12-761, slip op., at 11 (2014).

[130] *Id.* Lower courts have also recognized the different purposes of the Lanham Act and the FDCA (commercial interests compared to public health and safety, respectively). *See, e.g.*, Mylan Labs, 7 F.3d at 1139; Sandoz, 902 F.2d at 231-32.

[131] Pom Wonderful LLC v. Coca-Cola Co., No. 12-761, slip op., at 12 (2014).

interests with less effective protection regarding enforcement.[132] The Court reasoned that it is unlikely that Congress intended this result.

As of the date of this report, the scope of *Pom Wonderful's* holding as applied to all food/beverage Lanham Act claims is unclear. The Supreme Court, in its decision, emphasized that the FDCA does not preclude Lanham Act claims *like* Pom's. However, the case history, as discussed in the previous section, reveals that the courts have distinguished between Lanham Act claims that require courts to interpret FDA regulations and those, like Pom's, that permit a court to consider the Lanham Act "independently" from the FDA regulations. Further litigation requiring the courts to apply the *Pom Wonderful* holding is necessary to determine whether "like Pom's" is read broadly (to all food/beverage Lanham Act claims) or more narrowly. Similarly, it is also unclear whether the *Pom Wonderful* holding applies to other FDA-regulated products such as drugs and cosmetics. A legislative response may also clarify this relationship between the Lanham Act and the FDCA in other cases. However, the Supreme Court's opinion in *Pom Wonderful* does elucidate how two federal statutes may interact with each other, not only in the context of food labeling, but also in the greater federal regulatory framework.

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[132] *Id.*