Proskauer

newsletter

# False Advertising Litigation in 2009: Year End Review

February 2010
**in this issue**



Numerous recent media articles have reported an increase in false advertising disputes in 2009, both in federal and state court litigation and in proceedings before the National Advertising Division (NAD), the advertising industry self-regulatory body. Whether the rise in false advertising cases is the result of advertisers having to fight harder for market share in a diminished economy, a statistical blip, or other reasons, the fact is that in 2009, many noteworthy decisions were handed down in Lanham Act false advertising cases, state law-based consumer class actions and by NAD. In this newsletter, Proskauer's False Advertising Litigation practice has sought to provide concise descriptions of some of the year's most important decisions. We hope that you find them interesting and informative.

## Significant NAD Decisions in 2009

### Speed of Relief Cases

*This year NAD examined product "speed of relief" claims in an effort to provide clearer and more accurate messages to consumers who evaluate over-the-counter medicine performance. NAD emphasized that a claim's substantiation must match real-world conditions, and that advertisements should reflect the actual result for the average consumer. Among the more notable cases on this topic from 2009 are the following:*

*Novartis, Novartis Excedrin, Case Report # 4973 (February 2009)*.[1] This NAD matter concerned a television advertisement for Novartis' Extra Strength Excedrin, featuring a digital clock in the background with a woman seated at an outdoor café wincing in pain and rubbing her head due to a headache. The background and the time on the clock then warped ahead, after which a voice-over asks: "What's the only gel tab . . . to start relieving your headache in just fifteen minutes?" After the clock in the background reaches the 15-minute mark the woman exhales, smiles, and walks away from the table. Wyeth, the maker of Advil, challenged the advertisement, arguing that a reasonable person would interpret that Extra Strength Excedrin begins to work within 15 minutes for all people. Wyeth further alleged that, based on the woman's demeanor during the simulated 15-minute sequence, the commercial implied a claim of total relief after 15 minutes.

In defense of its commercial, Novartis submitted a confidential and proprietary clinical trial that studied the speed and efficacy of Extra Strength Excedrin in relieving headaches

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1 From 2009 Client Alert.

*as compared to a placebo*. According to Novartis, the study showed that, 15 minutes after dosage, "a statistically significant percentage" of people who took Extra Strength Excedrin began to feel relief from their headache compared to those taking the placebo. Novartis argued that based on the clinical trial it was accurate to inform consumers that Extra Strength Excedrin "start[s] relieving your headache in just 15 minutes." Similarly, Novartis rejected the existence of the alleged implied claim, arguing that it was not reasonable to conclude that a consumer would ignore the commercial's clear audio message that Extra Strength Excedrin "*starts*" to relieve a headache after 15 minutes.

NAD noted that the claim must reflect the real-world performance for the average consumer, and, therefore, scientific substantiation must accurately fit and reflect the advertiser's claim. NAD stated that, while statistical significance is an important consideration in determining a product's efficacy, it often does not reflect the experience of the average consumer using the product. Indeed, where the statistical comparison is between an active product and a control, which by definition is not efficacious, a statistically significant result can be shown even when the percentage of people for whom the test product works at a particular point in time is small. NAD determined that the commercial could reasonably be viewed as communicating that the average consumer would obtain some relief within 15 minutes. However, Novartis' study actually showed that only a small (though statistically significant) percentage of the Extra Strength Excedrin users began to feel relief at 15 minutes. Therefore, NAD determined that Novartis should alter its commercial to reflect the actual result of the test for the average consumer; namely, that "some people will experience relief in as little as fifteen minutes." Finally, NAD found an implied claim of complete relief, noting that despite the commercial's "starts relieving" audio message, reasonable consumers could view the woman's actions in the commercial as depicting complete relief within 15 minutes. Novartis stated its intention to appeal the decision to the National Advertising Review Board (NARB).

An appeal was presented in November 2009 (NARB Panel #152) on the single issue of whether Novartis had provided "sufficient substantiation to support its express claim that Extra Strength Excedrin "[s]tart[s] relieving your headache in just fifteen minutes." Novartis submitted a proprietary clinical study on a confidential basis, from which the NARB Panel concluded that only a very small percentage of test subjects indicated that there was less headache pain, or that there had been some headache pain relief, at the 15-minute point. The NARB Panel determined that "Novartis [should] discontinue its claim that Extra Strength Excedrin '[s]tart[s] relieving your headache in just fifteen minutes,' or modify the claim to accurately reflect the results of its clinical study in a manner that does not state or imply that typical consumers can reasonably expect a reduction in headache pain within fifteen minutes after taking Extra Strength Excedrin."

*Schering-Plough Healthcare Products, Inc., Claritin® RediTabs®, Case Report # 4998 (April 2009)*. In this case, McNeil Consumer Healthcare challenged a commercial by Schering-Plough Healthcare Products Inc. for its Claritin RediTabs allergy relief medication. Schering-Plough's commercial took place on a race car track with a NASCAR driver narrating that "speed is important" to him and that he uses Claritin RediTabs – "the fastest dissolving allergy medicine" – while a super (i.e., small text) is shown on the screen stating: "[s]peed of dissolution does not imply speed of relief." As race cars speed around a track, the driver states, "just touch it to your tongue and like magic it's gone" and ends by declaring that "there's no better way to live than Claritin clear."

McNeil argued that this commercial, with its race car themes and statements, sent a false message to consumers that Claritin RediTabs provide fast allergy relief and that it is the fastest working allergy medicine. McNeil provided a consumer perception survey that it argued demonstrated that this commercial conveyed a superiority claim on speed of allergy relief and that the super did not correct this message. McNeil further noted that studies concerning the active ingredient in Claritin demonstrated that Claritin could take anywhere from 90 minutes to three hours to start relieving allergy symptoms.

The advertiser argued that the commercial only communicated that Claritin RediTabs were the "fastest dissolving" allergy medication, and that any speed references were to dissolution. The advertiser contended that there were many flaws in McNeil's survey, including, among other things, that there was an inadequate control, that the results were overstated and that leading and biased questions were asked. The advertiser also argued that it had reliable substantiation to support its fast relief claim, if that claim were, indeed, communicated by the commercial.

NAD noted that, although McNeil's consumer survey contained leading questions, the majority of responses did indicate that consumers had a rapid *relief* takeaway. NAD recognized, however, that it did not need to limit itself to the survey and could interject its own independent judgment to determine the message conveyed. NAD determined that because consumers are all seeking quick allergy relief, the imagery of the commercial and the driver's statements communicate not only that RediTabs dissolve quickly, but that they also relieve symptoms quickly. Moreover, NAD found that the super on the screen contradicted the main message of the commercial, and even had the super not been found contradictory, it was still "insufficient to qualify the claims because the race car imagery and sounds are loud and distracting and the super, consequently, is not easy for the consumers to notice, read or understand." NAD did not need to address whether the advertiser could make a "fast relief" claim because the commercial communicated a superiority claim on speed of relief. NAD recommended that the commercial be permanently discontinued, and that future advertisements avoid imagery and claims that implied the product provided very fast or instantaneous relief; the advertiser was free, however, to advertise the rapid dissolution benefits of Claritin RediTabs.

**Green Cases**

*In 2009, NAD continued its rigorous evaluation of "green" advertising claims in order to ensure that clear and truthful messages are communicated to environmentally conscious consumers in their purchasing decisions. Among the more notable cases from this past year are the following:*

*Dispoz-o Products, Enviroware Plastic Utensils and Tableware, Case Report # 4990 (March 2009)*.[2] In this "green" advertising challenge, NAD held that in order to make advertising claims about the environmental impact of a product, an advertiser must use the actual product in its substantiation testing and must comply with Federal Trade Commission (FTC) standards. The advertiser was Dispoz-o Products, a manufacturer of disposable food service products. A competitor, Solo Cup Operating Corporation, challenged the advertiser's biodegradability claims, including: "Enviroware is formulated to degrade in months when buried or discarded in a landfill"; "Enviroware will degrade in

[2] From 2009 Client Alert.

as little as 9 months"; and "Enviroware cutlery, straws, hinged containers, plates, bowls and trays are 100% biodegradable and come with a certificate of biodegradability." The challenger argued that these claims misled environmentally conscious consumers into believing that the products fully degrade in a short amount of time, when there is no evidence that the products did so. The challenger also asserted that Dispoz-o did not meet the FTC standards for making environmental claims in advertising, in that Dispoz-o did not provide "competent and reliable scientific evidence" to substantiate its biodegradability claims.

NAD found in favor of the challenger. Because consumers are not usually capable of verifying the truthfulness of advertising claims about a product's environmental impact, NAD found it particularly important that this type of advertising be carefully regulated. NAD emphasized that, in reviewing environmental advertising claims, it will rely heavily on the FTC standards set forth in that agency's Green Guides. NAD noted that the advertiser's products were not subject to clinical testing. Indeed, the report on which the advertiser relied for substantiation only tested concentrated substance pellets, which NAD explained were structurally different from the utensils and tableware being advertised. Further, NAD found that it was unclear whether the report on which the advertiser relied adequately simulated landfill conditions. NAD explained that the proffered testing had used heavily controlled conditions that were not typical of most landfills and, therefore, would cause different degradation than in natural landfill conditions. Even though the advertiser provided a certification from a supplier that the products are biodegradable, NAD did not accept this as a substitute for scientific testing sufficient to substantiate environmental claims.

NAD concluded that the advertiser had not established, by competent and reliable scientific evidence, that its products would completely break down within a short period of time after customary disposal, nor had the advertiser provided competent and reliable scientific evidence that the products would biodegrade when disposed of under landfill conditions. NAD recommended that the advertiser discontinue its advertising statements that claimed that the products were formulated to degrade in months when buried or discarded in a landfill, and that the products are 100 percent biodegradable. NAD further recommended that the advertiser should "significantly" qualify its other statements about the products' ability to degrade in order to prevent misleading consumers about the rate and extent of degradation. This case is another example of NAD's continued focus on properly substantiated "green" product advertising, including: (1) its demand for testing conditions that replicate the products' actual degradation qualities and (2) reliance on FTC standards to hold advertisers accountable.

*Southern Diversified Products, LLC, Mythic Paints, Case Report # 5009 (April 2009).* In this case, advertising claims made by Southern Diversified Products, LLC for its Mythic Paint products were challenged by Valspar Corporation, another producer of paint products. Among the many claims Valspar challenged were Southern Diversified's statements that: (1) its Mythic Paint contains "zero VOC" (volatile organic compounds) and "zero carcinogens"; (2) it was the "only zero VOC, zero carcinogenic premium quality line of latex paints available"; (3) Mythic Paint was the "first non toxic high performance paint that is safe for all members of the family . . . no toxins or VOCs that can off-gas into the home environment"; and (4) Mythic Paint was a "safe alternative to traditional paint . . . a safe atmosphere for ourselves, our family and our environment."

The challenger argued that the advertiser had made unsupported superiority and exclusivity claims, and that Mythic Paint did contain some VOCs and carcinogens. Because the advertiser's claims of "zero" Voc or carcinogens were based upon the assurances of its suppliers, which, in turn, were based on a regulated threshold that *did* allow certain de minimis amounts of VOCs and toxins, the challenger argued that the advertiser's "zero" claim was false. The challenger also submitted its own internal testing that allegedly demonstrated that Mythic Paint did contain recognized VOCs. Further, the challenger argued that the advertiser's campaign falsely communicated the message that all other paints are unsafe and unhealthy.

Southern Diversified argued that its suppliers' use of calculated tests to determine the presence of hazardous materials in Mythic Paint was the most accurate and reliable method, and that it was approved by the relevant regulatory authorities, such as the Occupational Safety and Health Administration (OSHA) and other state and federal labeling regulations. Southern Diversified further argued that the challenger's internal testing was flawed in several respects, including that it was conducted by an employee of the challenger and failed to test the paint prior to the addition of colorant. Southern Diversified maintained that its claims concerning traditional paints were truthful, that risks associated with traditional paints were recognized by health experts, and that the claims did not falsely disparage its competitors.

NAD acknowledged that "[t]he promise of products that are safer for individuals and the environment have a strong appeal among an increasingly environmentally conscious and health conscious consumer population." NAD relied on the regulatory scheme established by the Environmental Protection Agency and OSHA, among others, and determined that the bases Southern Diversified had used for its "zero" VOC claims were reasonable. On the zero carcinogen claims, NAD found that the alleged carcinogen contained in Mythic Paint (as identified by the challenger) was not proven carcinogenic based on risks associated with exposure in paint. NAD also determined that the testing submitted by the challenger was flawed, and that the evidence presented did not overcome or rebut the reasonable basis provided by the advertiser (relying on regulatory standards). NAD did recommend, though, that Southern Diversified clearly and conspicuously disclose that the "zero VOC" claim does not account for the addition of other manufacturers' colorants to Mythic Paint. NAD determined that Southern Diversified had a reasonable basis for its safety slogan, "Safe for People, Safe for Pets and Safe for Earth," although its comparative claims should be discontinued or modified to cease suggesting that all other paints pose severe health risks, or that traditional paints are dangerous. Finally, Southern Diversified was advised to discontinue its exclusivity claim that it is the *only* premium paint without VOC, toxins or carcinogens.

*Apple Inc., Apple Notebooks, Case Report # 5013 (June 2009).* Dell, Inc. challenged express and implied "green" claims made by Apple, Inc. for its MacBook laptops. Among the express claims made in Apple's MacBook advertisements were statements that the MacBook's "advanced aluminum and glass enclosure is completely recyclable," that it is "engineered to be so efficient, it runs on a quarter of the power of a single light bulb," and that "it's made without many of the harmful toxins found in computers like mercury." Apple's advertisements also proclaimed its MacBooks to be "the world's greenest family of notebooks," and that "[t]he highly recyclable, even more energy efficient MacBook family has been designed with the environment in mind." Dell challenged the express claim, "[t]he New MacBooks. . . [t]he world's greenest family of notebooks," as well as the implied claim that Apple notebooks are "greener" than competing notebooks.

Dell argued that the claim "world's greenest family of notebooks" was a broad superiority claim as against all manufacturers' laptop notebooks, and that "family" actually referred to a particular model (or group of models) and not to *all* laptop notebooks made by another manufacturer. Dell also contended that Apple's claims concerning recyclability, reduced packaging, less toxic materials and increased energy efficiency should all be considered superiority claims because those claims are read in the context of Apple's "world's greenest family of notebooks" statement, and that Apple had not established superiority over all of its competitors on all four of those characteristics. Apple, in turn, argued that its use of the word "family" in the claim referred to *all* notebooks made by a competing manufacturer, and, in the case of Apple, whose MacBook is its *only* line of notebooks, this claim was supported by the "gold" ratings it had received from the Electronic Product Environmental Assessment Tool (EPEAT). Apple also argued that its specific "green" characteristics were separate from its "world's greenest family of notebooks" claim, and that these characteristics were monadic claims that were fully substantiated by, among others things, its EPEAT ratings, its ENERGY STAR compliance and the FTC's Green Guides.

NAD identified the issues in this dispute as: (1) whether "the world's greenest family of notebooks" was a superiority claim as to all competing notebooks; and (2) whether "family" referenced a notebook *product line* or *all* notebooks produced by a manufacturer. NAD found that, in these advertisements, consumers could "reasonably take away the message that Apple's MacBooks are the most environmentally benign notebooks on the market and that [the specific characteristic claims formed] the basis for a superiority claim" due to the juxtaposition of the "world's greenest family of notebook" claim with those four specific characteristic claims discussed above. NAD determined that, indeed, "while other manufacturers may have subcategories of lines with similar [high EPEAT] ratings, none has comparable high ratings for all of the notebooks it produces." However, NAD found that consumers could reasonably take away the message that a "family" of notebooks is a particular *line* of laptops and not *all* of the laptops produced by a manufacturer. NAD recommended that the advertiser modify its "world's greenest family of notebooks" claim to clarify that the basis for the comparison is between all *MacBooks* to *all* of the notebooks manufactured by any given competitor. NAD also recommended that Apple avoid claiming the "world's greenest" given the "potential for overstatement caused by 'world's,'" including that some notebooks in the Toshiba Portégé line have a higher gold EPEAT rating than MacBooks.

NAD's Apple decision is noteworthy not only as an example of NAD's increased focus on monitoring potential consumer perception of "green" advertising claims, but also because NAD found that "EPEAT is a recognized industry methodology to identify the 'green' characteristics of a computer product," and that laptop manufacturers, such as Apple, should be free to communicate this information to consumers, especially as consumers continue to place importance on a product's "green" characteristics in making their purchasing decisions.

*The Clorox Company, Green Works Cleaning Wipes, Case Report # 5099 (September 2009)*. Method Products, Inc. challenged Clorox Company's advertising claims for its Green Works Natural Cleaning Wipes (Wipes). Discussed here is Method's challenge to Clorox's claim that its Wipes are "biodegradable," including claims that the Wipes are "99% natural and biodegradable."

Method argued that Clorox's biodegradable claim was false and misleading because the Wipes did not meet the FTC definition of biodegradability. Method argued that Clorox's product instructions presume disposal in a landfill. Because FTC Green Guides explain that degradation is extremely difficult in a landfill environment, Method argued that it was very unlikely that the Wipes would biodegrade under customary disposal conditions. Indeed, the Wipes' label states that "biodegradability [is] validated in typical *compost* conditions" (emphasis added), indicating that the Wipes would not biodegrade in a landfill. Although Clorox had since modified the packaging of its Wipes to change to a "compostable" claim, Method argued that this claim also was misleading because claims of biodegradability and compostability are distinct product qualities that should not be used interchangeably.

Clorox argued that its Wipes are biodegradable, and that the packaging disclosure was clear as stated: "Green Works natural biodegradable* cleaning wipes," with the asterisk leading to a statement on the back label that "[b]iodegradability validated in typical compost conditions." Clorox also provided separate disposable instructions for composting the wipes. Although Clorox argued that this issue was moot because it was now making a "compostable" claim, Clorox maintained that its biodegradable claim was supported by lab testing under both industrial and home compost conditions.

NAD noted that "[t]he promise that a product will return to nature holds a strong appeal for consumers who are concerned about sustainability." Relying on the FTC Green Guides definition of "biodegradability" and its use in advertising, NAD concluded that the particular qualification used by Clorox on its biodegradability claim did not "clearly and adequately communicate to consumers the degree to which the product is, or is not, biodegradable," and that the disclaimer statement used by the asterisk was confusing. Moreover, "a product that is compostable may or may not be biodegradable" under the FTC definitions. For these reasons, NAD agreed with Clorox's decision to discontinue its "biodegradable" claim in favor of a more refined compostable claim. This case is noteworthy as yet another example of NAD's continued reference and reliance upon those standards and definitions promulgated in the FTC Green Guides.

**Nutritional Cases**

*Consistent with consumers' increased purchasing of health-conscious food products, NAD also continued its review of advertising that made various claims of beneficial nutritional content. Among the more notable cases on this topic from 2009 are the following:*

*The Dannon Company (Light & Fit 0% Plus Yogurt), NAD Case # 4953 (January 2009)*. This case demonstrated the importance of being clear and conspicuous in disclosures concerning the nutritional content of food products. Dannon claimed on the front of its product packaging for its Light & Fit 0% Plus Yogurt that it contained "50 Percent More Fruit." This claim was followed by an asterisk that referred to a disclaimer found on the back of the packaging that read "*50% MORE FRUIT than Regular Light & Fit 6 oz. Nonfat Yogurt." NAD noted that disclaimers must be "clear and conspicuous," and that they are effectively communicated when they are "displayed in a manner that is readily noticeable, readable and/or audible, and understandable to the audience to whom it is directed."

Applying this standard and considering a number of factors, NAD held that the disclaimer here was inadequate to properly limit a claim so prominently featured on the front of the packaging. Specifically, NAD found that the disclosure was too far removed in proximity

to the claim it sought to qualify. NAD also found that the disclosure appeared within a column of copy containing various other claims and/or disclosures such that the consumer would have to wade through a lot of other information (all in a relatively small and similar typeface) before arriving at the qualifying information.

NAD further held that, even if the disclosure had been sufficiently clear and conspicuous, the evidence in the record did not provide a reasonable basis for the claim. The advertised Light & Fit 0% Plus Yogurt is packaged in eight individual four-ounce cups (four ounces constituting a "serving"). Thus, according to NAD, the literal message conveyed by the claim was that "the new Light & Fit 0% Plus yogurt (which comes in 4-ounce containers) has 50% more fruit than [Dannon's] regular Light & Fit Nonfat yogurt (which comes in 6-ounce containers)." The evidence supporting this claim comprised a lone sentence in a declaration submitted by Dannon, stating that the new Light & Fit 0% Plus Yogurt "contains 50% more fruit per 6 ounces than Dannon's regular Light & Fit yogurt." Or put simply, six ounces (or one and one-half servings) of Light & Fit 0% Plus Yogurt purportedly contains 50 percent more fruit than six ounces of Dannon's Regular Light & Fit Nonfat Yogurt – a claim different from the claim at issue. Rather, the claim here is that Dannon's four-ounce Light & Fit 0% Plus Yogurt contains 50 percent more fruit than its six-ounce Regular Light & Fit Nonfat Yogurt, a claim which remained unsupported by any evidence in the record. Thus, NAD recommended that the claim and accompanying disclaimer be discontinued.

NAD also reviewed another claim on the back of the packaging representing that Dannon's "Light & Fit 0% Plus contains 12% of the recommended daily value of protein and 10% of the recommended daily value of Vitamin A per 8 oz." However, NAD noted that a single serving of Light & Fit 0% Plus Yogurt consists of one four-ounce container, and, thus, in order to obtain the claimed benefits, an individual would have to consume two serving size containers of the advertised product, and not one container, as might reasonably be understood from the claim. Accordingly, to avoid the potential for consumer confusion, NAD recommended that Dannon either discontinue the claim or modify it to clearly and conspicuously disclose that "two servings" of the yogurt contains the claimed percentages of protein and Vitamin A.

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Campbell Soup Company (Campbell's Select Harvest Soups), NAD Case # 4981 (March 2009) and General Mills, Inc. (Progresso® Soup), NAD Case # 5050 (July 2009). In this pair of disputes over canned soup advertising, NAD reiterated that, while an advertiser may have an accurate point of comparison between its product and a competitor's, not every potential depiction of that comparison is valid. NAD also emphasized the importance of reliable and well designed consumer perception surveys, if one is submitted to support the challenge.

In the first case, Campbell Soup Company attempted to differentiate its Select Harvest line of soups from General Mills' Progresso soups by highlighting that, unlike Progresso, Select Harvest contained no added MSG (monosodium glutamate). Campbell's commercials featured a simulated "blind tasting" where both brands were tasted by two blindfolded women. The woman tasting Progresso stated that she tasted "MSG" and other chemicals, while the woman tasting Select Harvest tasted natural ingredients. Campbell's print advertisements depicted a comparison of the labels of the soup brands, where for Progresso the "chemical-sounding" ingredients (including MSG) were highlighted, while for Select Harvest the natural ingredients were highlighted. Above the

Select Harvest product appeared the statement “Bring your Appetite,” while above the Progresso product appeared the statement “Bring Your Dictionary.”

General Mills alleged that Campbell’s advertisements misled consumers because, while Select Harvest did not contain added MSG, they did contain naturally occurring glutamates, which the USDA requires to be prominently noted on the product label. General Mills also argued that Campbell’s advertisements imply a “grossly exaggerated” level of MSG and other chemical-sounding ingredients in Progresso compared to the actual amounts. Lastly, General Mills alleged that the advertisements impliedly claimed that Select Harvest soups are more healthful and better tasting than Progresso due to the absence of chemical-sounding ingredients. In support of its claims, General Mills submitted a consumer perception survey, which allegedly found that 47 percent to 62 percent of those surveyed believed that Campbell’s advertisements communicated health superiority. However, NAD held that the survey was highly suggestive and materially flawed, and thus unreliable, because of the leading nature of its closed-ended questions. NAD stated that, while consumer perception surveys can be useful in determining whether an advertisement unfairly disparages a competitor’s product, the validity of their methodology must be assessed.

NAD then found that Campbell’s “No MSG” claims were substantiated because the USDA permits advertisers to make “No MSG” statements for products containing naturally occurring glutamates but no added MSG. However, NAD determined that Campbell’s advertisements did not display prominently enough the required USDA disclaimer identifying the presence of naturally occurring glutamates. Next, NAD agreed with General Mills that the television advertisements exaggerated the levels of MSG and other artificially sounding ingredients because those ingredients were “the very first ingredients detected by the women tasting [General Mills’] soups.” However, NAD found that Campbell’s print advertisements were proper in this respect because they merely highlighted an actual label from a can of Progresso. NAD held that, while a competitor may not unfairly disparage the competing product, it is permitted to highlight actual differences, which is what the print advertisements did. NAD also determined that the television commercial should be modified because the mock “taste test” reasonably could be viewed to convey that the Select Harvest tasted better than Progresso, a comparison for which Campbell’s had no substantiation. Similarly, NAD also found that the advertisements in context, including through the use of taglines such as “Bring Your Appetite,” misleadingly suggested that Progresso was less desirable in terms of flavor.

Finally, NAD noted that advertisements are allowed to convey “a high quality message,” but may not disparage a competitor’s product by falsely implying that it contains harmful chemicals or unwholesome ingredients. NAD found that the television commercial did not run afoul of this rule, but that the print advertisements unfairly questioned the wholesomeness of General Mills’ ingredients by suggesting that consumers should limit their MSG intake. NAD concluded that while Campbell’s had an accurate point of comparison, it did not allow Campbell’s to state it in every way that it wished.

In the second case, General Mills attempted to correct the alleged misinformation in Campbell’s advertising campaign by also focusing on the differences in the two soups’ MSG content. General Mills’ print advertising depicted side-by-side images of both companies’ chicken noodle soup cans, with “Campbell’s has 95 soups with MSG” appearing above the Campbell’s can and “Progresso has 26 soups with no MSG” appearing above the Progresso can. General Mills also launched an online banner

advertisement featuring the statement “95 Campbell’s Soups with MSG,” an image that fades into an image of a can of Progresso chicken soup, and the text “Take the Progresso taste challenge. Get started with $3 worth of coupons.”

Campbell’s alleged that the advertisements conveyed the message that large numbers of its soups are made with MSG, as compared with the number of Progresso soups that contain MSG. Thus, according to Campbell’s, they falsely implied that Progresso soups are a better choice for consumers looking for a soup without MSG, that Progresso soups do not have MSG, or that fewer Progresso soups have MSG than Campbell’s soups. Campbell’s argued that nearly two-thirds of all Progresso soups are made with MSG, the largest selling Progresso soup is made with MSG, and less than half of all Campbell’s soups are made with MSG. Moreover, Campbell’s argued that the advertisements suggested that the depicted Progresso chicken noodle soup does not contain MSG when it actually does.

In support of its claims, Campbell’s submitted a consumer perception survey, which allegedly found that, in response to certain open-ended questions, 43.7 percent of those surveyed believed that the advertisements communicated that all or most Campbell’s soups contain MSG, or that all and/or most Progresso soups do not. Notably, only 11 percent of those viewing the control advertisement reported this belief. Moreover, in response to certain closed-ended questions, 78 percent of those surveyed believed that the advertisements communicated that most or all Progresso soups do not contain MSG, and that most or all Campbell’s soups do.

NAD concluded that the survey submitted by Campbell’s was flawed in several respects. For example, NAD found that the closed-ended questions used in the survey were biased. Moreover, over half of the control group agreed with statements that were factually incorrect, a high noise level that NAD found troubling. NAD also had concerns about the nature of the control advertisement, which was identical to the test advertisement but with additional text that provided a more complete accounting of the numbers of soup varieties that contain MSG: “Campbell’s has 95 soups with MSG (and 124 that don’t)” and “Progresso has 26 soups with no MSG (and over 50 that do).” This control presented a problem because it did not appear any longer to be an advertisement for Progresso and, thus, was unrealistic and inappropriate.

NAD then determined that, while it was literally true that Campbell’s has 95 soups made with MSG, while Progresso has 26 made with no MSG, a consumer may reasonably understand the claim to communicate any number of messages about the brands and their relative MSG content. Such communications included the inaccurate message that Campbell’s soups are more likely to have MSG than Progresso soups, that most Campbell’s varieties have MSG, or that a greater percentage of Campbell’s soups than Progresso soups contain MSG. NAD found these implied messages unsupported by the underlying evidence.

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**Dietary Supplement Cases**

*In October 2006, the Council for Responsible Nutrition (CRN) launched a program with NAD to expand NAD’s visibility in the dietary supplement marketplace. A task force of the CRN regularly reviews dietary supplement advertising and recommends some of them for challenge to NAD. The challenges are an effort by CRN to encourage manufacturers to*

*provide substantiation for their advertising claims to an objective third party for review and evaluation and to assure that claims being promoted to consumers are truthful, not misleading, and are substantiated by credible scientific evidence. The following trio of cases are representative of NAD's continuing monitoring of the wide variety of claims being made concerning the efficacy of dietary supplement products, and emphasize the importance of valid and appropriate scientific evidence to support the claims.*

In *Nutrex, Inc., NAD Case # 4965 (February 2009)*, CRN challenged certain print and Internet advertisements disseminated by Nutrex, Inc. for its Vitrix Maximum Impact dietary supplement. Vitrix was being marketed to improve sexual performance, and the advertising generally made claims that Vitrix would: (1) increase testosterone; (2) increase libido; (3) increase sexual stamina; and (4) build muscle, based on its five key ingredients. In support of these claims, Nutrex relied on studies conducted on the ingredients in Vitrix.

NAD disagreed, determining that the articles and studies submitted by Nutrex were insufficient to support claims that Vitrix (or its ingredients) "increases testosterone," "produces testosterone-like effects," "boosts sexual libido and sexual stamina," and "builds muscle." Thus, NAD recommended that these claims be discontinued. Most notably, one set of studies had been conducted on rats and, in NAD's view, could not be used to support claims for humans, and, moreover, the studies themselves never clearly concluded that a particular ingredient increases "sexual interest," libido, or desire even in the subject rats. NAD also found a lack of support for claims that the product is "fast acting" because, even if the evidence submitted by Nutrex supported a claim that the ingredients were released rapidly, all of the ingredients are intended to have an effect over time, and, thus, rapid delivery was irrelevant to the product's intended benefits. In NAD's view, the advertisement "conveys a message that this product can be taken before sexual activity and will result in Viagra-like effects" – a message that was not supported by the evidence. Thus, NAD recommended that Nutrex discontinue all claims suggesting that Vitrix is "fast-acting" or "works quickly" or "instantly." Finally, NAD held that the claim "Have the Best Sex of Your Life" – in the context of an advertisement that also included the claim "Experience the best sex you ever had by increasing your testosterone levels with Vitrix dramatically" – was not puffery and recommended that it also be discontinued.

In *Schiff Nutrition, Inc., NAD Case # 4970 (February 2009)*, CRN challenged certain print advertisements disseminated by Schiff Nutrition Group for its MegaRed Omega-3 Krill Oil dietary supplement. MegaRed was being marketed as improving cardiovascular health, and, in particular, as comparatively superior to fish oil for that benefit. Reviewing the scientific evidence, NAD initially determined that C-reactive protein (CRP) is accepted as a "marker" for cardiovascular health and, furthermore, as an indicator of heart disease. Thus, NAD held that Schiff had provided a reasonable basis for claiming that krill oil had been clinically proven to provide a heart health benefit by reducing the levels of CRP in the blood and also by lowering cholesterol levels when taken in certain concentrations.

Like Nutrex, Schiff relied on various studies to support its claims. Specifically, the studies compared krill oil to fish oil, indicating that MegaRed lowers CRP more effectively and faster than fish oil supplements. NAD, however, held that none of the studies sufficiently supported the comparative superiority claims at issue. For example, while one study would support a claim that krill oil lowers CRP levels more than fish oil, Schiff was making broader, unqualified comparative superiority claims concerning cardiovascular health in general by representing that krill oil is "better, faster and more powerful than fish oil," or that krill oil is "3x better than fish oil for supporting cardiovascular health." Because krill oil and fish oil provide different cardiovascular benefits that currently could not be

quantitatively compared, NAD held that Schiff's claims were "likely to convey a message to consumers that there is a proven comparative efficacy of the two products," for which there was no evidentiary support. Thus, NAD recommended that the claims be discontinued. Furthermore, because there was no established dosage that was optimal for supporting cardiovascular health, and all of the studies tested different amounts of the oils, NAD recommended that Schiff discontinue its claim that "just One MegaRed™ softgel = three fish oil softgels for supporting Cardiovascular Health." With respect to the claim that MegaRed helps "[m]aintain healthy cholesterol levels already within the normal range," NAD recommended that Schiff modify the claim to clearly communicate the results of the research supporting the claim; namely, that the studies have shown that dosages higher that 3 MegaRed capsules have been shown to "[m]aintain healthy cholesterol levels already within the normal range."

By contrast, because both CRP levels and lowered cholesterol are significant markers for cardiovascular health, NAD held that one of the studies, coupled with other evidence suggesting that lower CRP levels also will improve health, provided a reasonable basis for Schiff's claim that MegaRed has been "[c]linically shown to support cardiovascular health." Similarly, NAD held that one of the studies provided sufficient support for the general claim that MegaRed "[p]romotes joint health and flexibility."

Lastly, *Herbal Groups, Inc., NAD Case # 5005/5005R (April 2009, July 2009)* involved a CRN challenge to certain Internet advertisements disseminated by Herbal Groups, Inc. for its Prostalex Plus dietary supplement. The principal claims related to improving prostate function and reducing frequent urination and other urinary dysfunction. NAD also focused on testimonials featured in the advertising extolling the virtues of the product, as well as a "Prostate Health Blog" linked to Herbal Groups' Web site. In response to NAD's inquiry, Herbal Groups submitted a study on Prostalex, but then declined to participate in the NAD process. Accordingly, NAD referred the matter to the FTC and the FDA for possible enforcement action. Thereafter, Herbal Groups decided to participate in the NAD process, submitting additional materials (including other research) and addressing the specific concerns raised by NAD.

After reviewing Herbal Groups' submissions, NAD held that, while the Prostalex Plus study indicated that the product helped reduce the size of the prostate, there was no evidence to support the claim, "regain your youthful prostate function," and NAD therefore recommended that the claim be discontinued. Moreover, NAD held that, while there was evidence that this product can help reduce prostate size and, in turn, help relieve some of the symptoms associated with an enlarged prostate, the claim that the product will "solve" your urination problems overstated the performance capability established by the evidence. Similarly, NAD held that the claim that "you'll finally be able to sleep through the night without any trips to the bathroom" was overly broad and recommended that it be modified to more accurately reflect the evidence; namely, that Prostalex Plus will reduce the size of the prostate and, in turn, reduce the number of nightly trips to the bathroom. Likewise, NAD held that the absolute claim that Prostalex Plus will "stop your constant need to urinate" was overly strong and not supported by the research.

NAD also held that, while the claim that Prostalex Plus can "improve your ability to urinate" can be supported by the research, the claim needed to more clearly connect this benefit to the product's ability to help reduce prostate size. Similarly, NAD held that there was insufficient evidence to support the claim that one of the benefits of Prostalex Plus is that users will "no longer have trouble getting your stream to start" and recommended

that it also be modified to more accurately reflect the evidence. By contrast, NAD held that certain claims were supported by the study because they clearly connected the reduction of "the need to urinate" to the demonstrated effect of the product, i.e., reduction of prostate size.

As to the testimonials, NAD was concerned because, while the evidence indicated that Prostalex Plus helped reduce prostate size, there was insufficient evidence to support quantified claims stating that someone that "used to get up more than 6 times a night . . . [did not] have to get up even once," or that a truck driver "almost had to quit . . . but now . . . can go for hours and hours without having to look for a bathroom," or that "all" of someone's "urination problems [are] totally gone now." In NAD's view, "these are the types of claims that could be supported by studies and research, but have not been." Thus, NAD recommended that Herbal Groups discontinue these quantified testimonials or, alternatively, modify them to bring them into compliance with the FTC Guides (*i.e.*, disclose that the results are atypical or what results a consumer can generally expect based upon the results of the Prostalex Plus study).

**Miscellaneous Cases**

*Finally, we conclude with some interesting miscellaneous decisions.*

*The Procter & Gamble Company, Swiffer Dust & Shine Furniture Spray, Case Report # 4960 (January 2009)*. In this dispute, S.C. Johnson & Son, Inc. (SCJ), maker of Pledge furniture polish, challenged claims made by Procter & Gamble (P&G) in advertisements for its Swiffer Dust & Shine Furniture Spray (Swiffer DS). P&G claimed that its Swiffer product left "less greasy residue than the leading furniture polish" on "your wood surfaces." P&G argued that not all remaining residue could be considered a "positive product attribute" of furniture polishes, and, therefore, it was important to communicate to consumers that the ingredients in Swiffer DS were designed specifically to lessen the amount of residue.

SCJ alleged that P&G's advertisements unfairly denigrated Pledge furniture polish. SCJ also argued that claims concerning whether Pledge left a "residue" on surfaces were precluded because they had already been the subject of challenges in 2004 and 2006, in which NAD had concluded that the substance left behind by Pledge was actually a product benefit, and thus could not be described by the derogatory term "residue." However, since the prior cases had concerned only a comparison between a dry dusting product and a wet polish, NAD determined that it was appropriate to reexamine the residue claims in the context of these different products.

NAD concluded that the mere ingredient differences between the products "[did] not show that such differences are noticeable to the consumer, nor [did] it show that the differences actually result in a less 'greasy residue' for surfaces treated with Swiffer DS – as opposed to Pledge." NAD also reviewed the head-to-head testing submitted by P&G in support of its "less greasy residue claim" and found that, while there was a technical difference in the *amount* of residue left behind, the testing did not address whether this difference was noticeable to the consumer or whether the Pledge residue would be considered "greasy residue" by consumers. Even the consumer-use test submitted by P&G did not persuade NAD that its claim could be supported because it still did not establish that consumers could detect the difference in amount of residue, or that the residue was perceived negatively as "greasy residue." For these reasons, NAD recommended that P&G discontinue using the phrase "greasy residue" to describe the substance left by Pledge

on wood surfaces. Finally, concerning a split-screen product demonstration in the commercial purporting to show that Swiffer DS left behind less greasy residue, NAD determined that the Swiffer DS and Pledge comparison should be modified because the lighting and actions performed on each side (a finger swipe on polished wood surface) were not identically presented and thus presented a misleading impression of the products' relative performance.

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*S.C. Johnson & Son (Pledge™ Fabric Sweeper for Pet Hair), NAD Case # 5068 (August 2009)*. S.C. Johnson & Son also successfully defended a challenge to an advertisement for its Pledge Fabric Sweeper product. NAD applied the well-established burden-shifting analysis to claims that SCJ's product outperformed 3M Company's lint rollers in removing pet hair from upholstery. In doing so, NAD provided valuable guidance on both the quantum and quality of evidence that SCJ submitted.

In the challenged television commercial, as a white sofa is seen lowered into a clear glass box containing 15-20 black cats, an announcer states, "We've placed Leah's sofa in this glass box full of black cats to demonstrate the cleaning power of our newest Pledge product . . . ." As the announcer continues: "Meet the new Pledge Fabric Sweeper . . . it's quick and effective, removing as much pet hair as 145 sticky lint roller sheets," Leah is seen using the device, cleaning the pet hair from the sofa. The words "145 sticky lint roller sheets" appear simultaneously on the screen, and Leah is then depicted sitting on the clean sofa, expressing amazement at how well the products works and the amount of hair it removed.

Initially, NAD concluded that SCJ's selection of the lint rollers to be tested (specifically marketed for use on pet hair), along with the testing parameters used, were appropriate. SCJ had properly tested its Fabric Sweeper through an independent facility on both microfiber and chenile upholstery fabrics, and both parties' devices were used in accordance with their product use instructions. Both products were also treated in the same manner throughout the testing. Moreover, SCJ submitted consumer-use evidence demonstrating that the amount of pet hair used in the test was within the range of pet hair found in consumers' homes. NAD also affirmed SCJ's use of readily available Nielsen data in selecting the devices to be used in the testing.

Based on this testing, NAD held that the data confirmed, at the 95 percent confidence level, that one Fabric Sweeper unit picked up more pet hair than 145 lint roller sheets, thereby providing a reasonable basis for the claim in question. Moreover, NAD rejected 3M's position that objective weight measurements, rather than subjective observations, were the more appropriate means by which to measure when a lint roller sheet should be replaced. In NAD's view, "consumers can readily identify when a lint roller sheet has reached its capacity (that being when the device no longer continues to pick up the pet hair) and that it is time to replace the lint roller sheet – just as the technicians in the test did." According to NAD, "in ordinary use, that is precisely how consumers would determine when to use a new sheet." Having concluded that the testing replicated in-home use, and that the data established a reasonable basis for the claim, NAD noted that the burden shifted to 3M to show that it had more reliable evidence demonstrating a different result. In the end, NAD held that 3M had not met this burden.

NAD also rejected 3M's argument that the challenged commercial did not properly circumscribe the claim because it failed to disclose the material limitation that the Fabric

Sweeper is not effective on clothing, unlike 3M's lint rollers, which have greater applicability. NAD noted that the entire context of the challenged commercial concerns black cat hair removal from a white sofa and the comparative performance capabilities of the Fabric Sweeper and lint rollers in removing pet hair from upholstered furniture. Moreover, the device is only seen being used on upholstery, and there is no mention of clothing whatsoever. Thus, NAD found that nothing in the commercial led viewers to conclude that the Fabric Sweeper is effective (let alone just as effective) on clothing, and that SCJ need not further disclose that the advertised product was not intended for use on clothing.

Finally, NAD rejected 3M's claim that the product demonstration overemphasized the main feature of the Fabric Sweeper's capabilities, in that the final product shot depicted a Fabric Sweeper that is overstuffed with cat hair in a manner that is unlikely to be the result of the commercial's demonstration, and that, as such, consumers would take away an inaccurate message about the amount of pet hair that one Fabric Sweeper can pick up. Although agreeing that, when a product demonstration is used in an advertisement as visual proof of a product's performance capability, the advertiser must accurately depict the conditions under which the demonstration was conducted, NAD held that SCJ's commercial was not misleading, but, rather, representative of the product's demonstrated performance capability and storage capacity.

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*Sprint Nextel Corporation, 3G Network, Case Report # 5106 (November 2009)*. Verizon Wireless challenged a claim by Sprint Nextel Corporation that Sprint operates "America's most dependable 3G network." A 3G network typically refers to a carrier's data transmission capabilities over a cellular network. Verizon argued that Sprint's claim relied upon three flawed factors. The first two factors were Nielsen Mobile drive test data that measured success in connecting to the network (connection success) and success in downloading/uploading small and large files (session reliability), both of which Verizon acknowledged were relevant, except that Verizon argued Sprint had relied on outdated Nielsen data and/or a miscalculation of current Nielsen data. The third factor was signal strength, which Verizon maintained was inapplicable to "dependability."

Verizon argued that, for the most recent period of Nielsen data, it had actually received better scores than Sprint on connection success and session reliability. Sprint contended, though, that in the *two* most recent tests, combined scores demonstrated that Sprint's signal strength, session reliability and connection success *overall* were better than Verizon's scores. Sprint also argued that, even if only the most recent Nielsen test was considered, Sprint's large lead in signal strength overcame the fact that Verizon had led by small margins on connection success and session reliability. Sprint also pointed out that its advertisements disclosed that the claim was "based on independent, third-party drive tests for 3G data connection success, session reliability and signal strength for the top 50 most populous markets."

NAD determined that, due to the constantly evolving nature of 3G networks and providers' efforts to constantly improve performance, the best evidence to support a "most dependable" claim is the most recent Nielsen test drive data, not a compilation of past and recent Nielsen results. NAD found that, in the most recent testing, Verizon performed better than Sprint on connection success and session reliability, and, on that alone, it was clear that Sprint could not support a claim that it was the "most dependable" 3G network. On signal strength, NAD concluded that Sprint had not met its burden of

showing the extent to which signals degrade as they penetrate buildings and the level of signal strength that would be necessary for connecting and completing a task in a typical building. Indeed, "[m]ore generally, [NAD determined] that greater signal strength above that which is necessary to connect and complete a task does not yield greater reliability." NAD thus determined that Sprint lacked sufficient support for its claim as "America's most dependable 3G network."

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*Matrixx Initiatives, Inc. (Zicam Cold Remedy Products), NAD Case # 5008 (May 2009)*. Here, NAD held that an advertiser must exercise care when advertising a medical product that is similar, but not identical, to another product and may not assume that tests done on one product will apply to the other. The advertiser, Matrixx, is the maker of Zicam, a popular brand of products advertised to shorten the duration of the common cold. In 2005, in a decision that garnered unusual publicity, NAD reviewed Matrixx's advertising for Zicam nasal gel in spray form and concluded that the studies relied-upon substantiated Matrixx's claim that, when taken at the onset of a cold, Zicam nasal gel is clinically proven to shorten the cold's duration. NAD also concluded that those studies supported Matrixx's claims about Zicam nasal gel in swab form.

This time, a competitor, Quigley Corporation, challenged new Matrixx advertising about the efficacy of Zicam when taken orally. The new advertisements stated, "Taking Zicam Cold Remedy at the first sign of a cold: Reduces the duration of the common cold"; "Numerous physicians, including ear, nose, and throat specialists, general practitioners and internists have come forward in support of the science behind Zicam cold remedy"; and "Get over your cold faster with Zicam Cold Remedy!" These new claims were based on the same studies on which Matrixx relied in the 2005 challenge. Here, however, the challenger argued that none of those studies had tested the efficacy of the oral version of Zicam. The challenger also contended that Matrixx's "doctors have come forward" claim was the equivalent of a "Doctors Recommend" claim which, in this case, was inadequately substantiated.

NAD sided with the challenger, concluding that a consumer viewing the advertiser's Web site could reasonably believe that the challenged advertising statements applied to all of the Zicam products, including the oral products. NAD also noted that, even though Zicam is a homeopathic remedy, the specific performance claims about Zicam's efficacy must be supported by competent and reliable scientific evidence. NAD concluded that Matrixx had offered no evidence to suggest that the Zicam oral products work in the same manner, or are as effectively, as the products sprayed or dabbed in the consumer's nose, and, thus, the prior studies did not support Matrixx's new claims. NAD made several recommendations to change the advertising: First, that when making claims about the ability of oral Zicam to reduce the severity of cold symptoms, Matrixx should add the qualifier "may"; second, that in making any claims in reliance on clinical studies, Matrixx should make clear to which product – oral or nasal – it is referring; and, third, that the advertiser's truthful claim that numerous physicians have supported the products was not equivalent to a "Doctors Recommend" claim and, therefore, did not have to meet the substantiation standards for such a claim.

## Notable Lanham Act Decisions in 2009

*Schering-Plough Healthcare Products, Inc., v. Schwarz Pharma, Inc ., -- F.3d --, 2009 WL 3460808 (7th Cir. 2009) (Posner, J.)*

Facts: Plaintiff, the manufacturer of an over-the-counter (OTC) laxative (MiraLAX), sued four defendant manufacturers of generic versions of the same laxative, which is available by prescription only. (Previously, MiraLAX also was available by prescription only.) When the FDA approved the OTC version of MiraLAX, it required that it bear the warning "use [for] no more than 7 days." The Food, Drug and Cosmetic Act (FDCA) requires generic drug labeling to be the same as the labeling of the "pioneer" drug – here MiraLAX – but also requires generic prescription drugs to bear the symbol "Rx only." In this case, MiraLAX bears the warning, but not the "Rx only" symbol; the generics bear the "Rx only" symbol, but not the warning. Therefore, the generic prescription drugs were not in compliance with the FDCA's rule requiring generic labeling to be the same as the pioneer drug, but did comply with FDCA's rule requiring the label to state that the generics were available by "prescription only" (or "Rx only").

Plaintiff brought suit under the Lanham Act, alleging that the statements "by prescription only" (or "Rx only") on defendants' generic version of the laxative were literally false because plaintiff's version of the laxative was available OTC without a prescription.

When plaintiff brought suit, the FDA was considering whether (1) the generic products were misbranded in stating "Rx only" in light of MiraLAX's availability OTC, and (2) the pioneer and generic drugs were "really the same," such that they would violate an FDCA rule prohibiting the sale of the same drug both OTC and by prescription.

After defendants moved to dismiss, the district court dismissed the complaint without prejudice, finding that the suit was premature in light of the proceedings before the FDA. Plaintiff appealed, arguing that the district court should have found the labeling "literally false" in violation of the Lanham Act without regard to whatever might happen in the FDCA proceedings. Defendants cross-appealed, arguing that dismissal should have been with prejudice because plaintiff could not state a claim under the Lanham Act regardless of the FDA's ultimate decision.

Issue: Is plaintiff's suit premature in light of the FDA proceedings?

Holding: Yes, plaintiff's suit is premature.

After noting that the FDA had not yet made a final agency action regarding the labeling issues, and recognizing that there may be a conflict between the Lanham Act and the requirements of the FDCA, the court, in an opinion by Judge Posner, agreed with the district court that plaintiff's suit was premature.

Judge Posner's opinion went on to conclude, in what clearly was dicta, that "there is force" to defendants' argument that, on the merits, the district court properly denied plaintiff's motion for summary judgment on its Lanham Act claim. That portion of the Seventh Circuit's opinion has created controversy in the blogosphere.

Plaintiff argued that, because they could prove defendants' "Rx only" statement is "literally false," they were entitled to summary judgment even without evidence that anyone was misled by that statement. Judge Posner disagreed, and chastised plaintiff for what he thought to be plaintiff's simplistic application of the principles of "literal falsity."

Judge Posner began his analysis by stating that the purpose of the Lanham Act's false advertising provisions "is to protect sellers from having their customers lured away from them by deceptive ads," and noted that "many literally false statements are not deceptive." Therefore, if "no one is deceived," there is no injury, and there can be no suit. Appearing to fault plaintiff for not attempting to prove that anyone was actually misled by defendants' labeling, Judge Posner stated that "obviously" the generic version of the laxative sold by defendants is available by prescription only, "but it is not obvious, as [plaintiff] contends, . . . from the labels . . . that every other product containing [the active ingredient in all the laxative products at issue] is prescription only." Thus, Judge Posner concluded that plaintiff "cannot just intone 'literal falsity' and by doing so prove a violation of the Lanham Act."

In this analysis, the Seventh Circuit appears to suggest that the doctrine of literal falsity is both more narrow and more capacious than traditionally applied. For example, the court stated that, on the one hand, even if a statement is literally false, "if no one is or could be fooled, no one is or could be hurt," and there can be no viable claim. On the other hand, the court opined that, even if a statement is not literally false, but is "so obviously misleading," there should be "no need to gather evidence that anyone was confused." According to the court, a "literal" falsehood is "bald-faced, egregious, undeniable, over the top." Thus, opined the Court, "[t]he proper domain of 'literal falsity' as a doctrine that dispenses with proof that anyone was misled . . . is the patently false statement that means what it says to any linguistically competent person."

Commentary: The main holding of this case – that judicial deference to FDA's decision making process regarding label requirements to avoid a potential conflict between the FDA and a Lanham Act court on a matter that clearly falls under FDA's regulatory authority – is no doubt correct. But the dicta is provocative. How and whether Judge Posner's dicta will impact future decisions in the Seventh Circuit and elsewhere remains to be seen.

### *Pom Wonderful v. Ocean Spray Cranberries, -- F. Supp. 2d --, 2009 WL 2151355 (C.D. Cal. 2009)*

Facts: Plaintiff pomegranate juice maker sued defendant juice maker alleging defendant's pomegranate juice drinks contained false and misleading representations under the Lanham Act and California state law claims regarding the primary ingredients and the level of antioxidants in its beverages. Plaintiff claimed this "tricked" consumers into purchasing defendant's product, which is sold at a lower price, because they believe it is similar to plaintiff's product. Defendant moved to dismiss, arguing that the case was barred by the FDCA and FDA regulations, usurped the FDA's primary jurisdiction, and did not meet Rule 9(b) pleading standards.

Issue: (1) Are plaintiff's claims precluded or preempted by the FDCA or FDA regulations? (2) Does the FDA have primary jurisdiction over plaintiff's claims? (3) Has Plaintiff adequately pled with particularity?

Holding: (1) No, neither plaintiff's Lanham Act claims nor its state law claims are precluded or preempted by the FDCA or FDA regulations. (2) No, the FDA does not have primary jurisdiction over plaintiff's claims. (3) Yes, plaintiff has adequately pled with particularity.

The court first held that plaintiff's allegations did not rely on a determination of the FDA or an interpretation of its regulations. Instead, because the truth of defendant's marketing representation (the primary ingredients of the juice) is "readily verifiable," whether the defendant's representations are misleading is not contingent on a decision by the FDA or enforcement of its regulations. Indeed, the FDA regulations do not define what constitutes a "false or misleading" label. While the court recognized that the FDA regulations contain a number of requirements for labels of multiple-juice beverages like the beverages in question, plaintiff's allegations did not reference, contest or attempt to enforce those requirements. Although some of plaintiff's claims might actually conflict with FDA regulations, the court declined to limit plaintiff's allegations until the factual record was further developed.

The court further held that plaintiff's state law claims are neither expressly nor impliedly preempted. Although the FDCA contains an express preemption provision applicable to the labeling of the products at issue, the court held that plaintiff's false advertising and unfair competition claims are unrelated to the FDA regulations. Under the FDCA preemption clause in question, plaintiff's claims are not preempted because they do not appear to impose "different requirements" than FDCA or FDA regulations. In rejecting defendant's implied preemption argument, the court held that Congress did not intend for the FDCA to occupy the field of food labeling and advertising.

The court also rejected defendant's primary jurisdiction argument, finding that the instant case does not require any special expertise and that the FDA is not in the midst of investigating, and had not expressed any interest in investigating, the challenged claims.

Finally, although the court agreed that the Rule 9(b) pleading standard applied to plaintiff's claims because they were grounded in fraud, the court held that the allegations of the complaint were pleaded with sufficient particularity.

*Schering-Plough Healthcare Products, Inc., v. Neutrogena Corp., -- F. Supp. 2d --, 2009 WL 2407207 (D. Del. 2009)*

Facts: Plaintiff, the manufacturer of Coppertone sunscreen products, sued rival sunscreen manufacturer Neutrogena, alleging false advertising under the Lanham Act and state law arising out of defendant's in-store displays, pamphlets and print ads.

Plaintiff moved for a preliminary injunction enjoining defendant's use of (1) an illustration that allegedly falsely conveyed that sunscreens without defendant's patented Helioplex® ingredient do not provide adequate UVA protection, and (2) a bar graph comparing plaintiff's and defendant's products because it falsely communicated that plaintiff's products provided only half the sunburn protection of defendant's product.

Issue: Whether plaintiff demonstrated a likelihood of success on the merits sufficient to support a preliminary injunction.

Holding: Plaintiff could not demonstrate a likelihood of success on the merits that defendant's representations were literally false. Therefore, the court denied the motion for preliminary injunction and did not consider the issue of irreparable harm.

The court found that defendant's Helioplex® illustrations on defendant's in-store displays and pamphlets were not unambiguous, which is a prerequisite to a finding of literal falsity. They did not contain an express comparison of products, nor were the representations

made false on their face. While the court concluded that consumers could interpret the illustrations in a way that rendered them false, a preliminary injunction was not warranted because at the preliminary injunction phase plaintiff argued only literal falsity.

The court then addressed the challenged bar graph illustrations and effectiveness claims in defendant's print advertisements. With respect to the bar graph's direct comparison of the products' UVA protection, the court held that the graph did not impart a clear or unambiguous message to ground a finding of literal falsity because there was conflicting expert testimony regarding what message SPF information communicates to consumers about UVA protection (as opposed to UVB protection). Regarding the effectiveness claims, the court held that Defendant's representation of 100 percent more combined UVA/SPF protection was not literally false. The court relied on the fact that plaintiff offered a range of products from SPF 15 to 70+, while defendant's range was only 55 to 70+ – therefore, there was an average 40 percent difference in the SPF product lines. For UVA protection, there was a 100 percent difference between the average PFA scores of defendant's and plaintiff's product lines. Finally, the court relied on evidence that plaintiff itself compares products on its Web site by raw SPF and PFA (UVA) score to reject plaintiff's claim that comparison by raw score rather than percentage of UV rays blocked amounted to a literal falsehood.

Commentary: This decision illustrates the conundrum Lanham Act plaintiffs often face when considering whether to seek preliminary injunctive relief. Often, either because of fear of marketplace harm or fear of being found by a court to have engaged in undue delay, there is no time to field a consumer survey before seeking an expedited injunction. As a result, plaintiffs commonly rely only on allegations of literal falsity at the preliminary injunction stage. As this case demonstrates, that strategy can be risky.

### *Baden Sports, Inc. v. Molten USA, Inc., 556 F.3d 1300 (Fed. Cir. 2009)*

Facts: The parties manufacture competing basketballs and plaintiff holds a patent for a basketball incorporating a "layer of padding underneath the outer covering." Plaintiff brought a false advertising claim against defendant based on defendant advertising its own basketball with an inner padded layer as "innovative," "proprietary" and "exclusive." The District Court granted defendant's summary judgment motion regarding the "proprietary" and "exclusive" claims and held that such statements were precluded from Lanham Act liability by the Supreme Court's decision in Dastar Corp. v. Twentieth Century Fox Film Corp., 539 U.S. 23 (2003), because such terms merely convey that defendant was the inventor and owner of the relevant basketball technology. *See id.* at 1303. However, the District Court denied defendant's summary judgment motion regarding the term "innovative" and held that the term does not necessarily connote the inventor of the technology, but rather can describe the "nature, characteristics, or qualities" of the basketballs, and such claims could be challenged following Dastar. Following a jury trial, defendant was found liable for intentional false advertising and approximately $8 million in damages. Defendant appealed the district court's summary judgment decision regarding the "innovation" claim.

Issue: Does *Dastar* preclude a Lanham Act challenge to an advertisement of product "innovation"?

Holding: Yes – District Court reversed and damages vacated. The Federal Circuit explained that Dastar held that the limited wording in section 43(a) of the Lanham Act only applies to certain unfair trade practices, and does not encompass defendant's claim

of product "innovation" because this claim does not concern the "origin of goods," to which section 43(a)(1)(A) applies (the "unfair competition" prong of section 43(a)), and does not concern the "nature, characteristics, [or] qualities" of defendant's basketballs, to which section 43(a)(1)(B) applies (the "false advertising" prong of section 43(a)). *See id.* at 1305.

Regarding the "origin of goods" language, the court explained that Dastar held that this phrase refers to the producer of the goods, and not the author of any idea embodied in those goods. Applied to the Baden case, the court held that "it is apparent that *Dastar* does not permit Baden to claim false advertising under section 43(a)(1)(A). Baden has not argued that someone other than Molten produces the infringing basketballs, and nothing in the record indicates that Molten is not in fact the producer of the balls. Thus, Baden's claims . . . do not cause confusion as to the origin of the basketballs." *See id.* at 1306.

As for section 43(a)(1)(B), which prohibits advertising that "misrepresents the nature, characteristics, qualities, or geographic origin" of goods, the Federal Circuit held that this provision did not apply to defendant's claim of product "innovation" because such a claim did not concern the "nature, characteristics, or qualities" of defendant's basketballs, but rather only the inventor of defendant's basketball technology. *See id.* at 1307. The Federal Circuit cited a prior Ninth Circuit decision regarding karaoke machines that held that the "nature, characteristics, and qualities" phrase did not refer to the licensing status of those machines, but rather such things as the quality of its audio and visual effects. *See id.* (citing Sybersound Records, Inc. v. UAV Corp., 517 F.3d 1137 (9th Cir. 2008)). Similarly here, defendant's claim of "innovation" did not refer to any physical or functional attributes of the basketballs, but rather "only indicates, at most, that its manufacturer created something new, or that the product is new, irrespective of who created it," and thus was not actionable under section 43(a)(1)(B). *See id.*

The Federal Circuit clarified that while its holding was compelled by the Ninth Circuit's prior interpretation of Dastar in Sybersound, "under the law of a different circuit, this case may well have a different result." *See id.* at 1308 n.4 (citing First Circuit and Southern District of New York decisions holding that some "false authorship" claims could fall within Section 43(a)(1)(B)).

Commentary: The Federal Circuit's holding in Baden Sports is questionable, if only because the innovativeness of a product can fairly be characterized as a "quality" of that product. One can well understand the Appellate Court's reluctance to affirm a high seven-figure damage award resulting from advertising characterizing a basketball as "innovative," but there likely were better ways to justify reversal, such as holding that such a claim was puffery or not material, or concluding that the damage award was not supported by the evidence.

### *Surefire, LLC v. Advanced Armament Corp., No. SA CV 08-1405 DOC (RNBx), 2009 U.S. Dist. LEXIS 124098 (C.D. Cal. April 13, 2009)*

Facts: Plaintiff and defendant were competitors in the market for "firearm suppressors," the thin silencing tubes that muffle the sound produced by firearms. Defendant published a print advertisement promoting a new silencer that pictured plaintiff's product alongside a "competitor brand" silencer. The advertisement featured "cutaway" views of the silencers revealing the hidden inner cores, and included statements and images that indicated that defendant's silencer was more durable and less likely to malfunction than

the "competitor brand." Plaintiff's product was *not* explicitly mentioned in the advertisement. However, plaintiff filed suit for false advertising and moved for a preliminary injunction, alleging that the "competitor brand" was "distinctly identifiable" as plaintiff's product, and that the advertisement was literally false and misleading because plaintiff's product is neither unreliable nor likely to fail during ordinary use.

Issue: Could defendant's print advertisement – which did not explicitly mention plaintiff or plaintiff's product – be enjoined on the basis of literal falsity?

Holding: No. The court held that "[plaintiff's] assertion that the advertisement disparages [plaintiff's] suppressors rests on the notion that the suppressor can be positively identified as [plaintiff's]. However, because the advertisement at issue makes *no* specific mention that the inferior suppressor is in fact [plaintiff's] suppressor, the Court finds that the statements at issue are not literally false on their face." *See id.* at *10 (emphasis in original). With respect to the possibility that the advertisement was literally false by necessary implication, the court held that "[plaintiff] is unlikely to succeed in proving that the statements are false by necessary implication because it is unclear on the face of the advertisement whether the defunct suppressor at issue was manufactured by [plaintiff]." *See id.* at *11. The court rejected plaintiff's argument that the defective silencer was easily identifiable as plaintiff's product because "the suppressor core pictured is similar to other suppressor cores from other manufacturers. . . . While it is possible that the metal casing might be identifiable as [plaintiff's] product, the revealed suppressor core looks similar to cores of manufacturers other than [plaintiff]." *See id.*

The court rejected plaintiff's follow-up argument that the advertisement was misleading, because although the advertisement prompted discussion in an online trade forum regarding whether plaintiff's product was the "competing brand" in the advertisement, "the online discussion does not indicate whether forum posters were in fact misled as to the quality of defendant's suppressors as a result of the advertisement." *See id.* at *14.

Finally, the court held that irreparable harm could not be presumed for similar reasons, namely, because there was no explicit comparison between plaintiff's and defendant's products in the advertisement, and it was not sufficient to have a side-by-side comparison of defendant's product and an unnamed and unidentifiable defective suppressor. *See id.* at *16.

*Commentary*: Apparently, plaintiff did not conduct a consumer survey to establish that prospective purchasers identified the allegedly inferior product depicted in the advertising as plaintiff's product. Given the nature of the products at issue, one could surmise that finding likely purchasers of the parties' products at shopping malls or anywhere else for that matter would have presented insurmountable difficulties. The court's decision is troublesome, to the extent it can be read as suggesting that the mere fact that plaintiff's product was not identified by name in defendant's advertising precludes a finding of literal falsity. Such a holding would be dead wrong: it is often the case that record evidence of various sorts will permit a finding that an unnamed competitive product is sufficiently identifiable as to permit a finding that a comparison of that product with the advertiser's product is literally false.

*Rainbow Play Systems, Inc. v. Backyard Adventure, Inc., No. Civ 06-4166, 2009 WL 3150984 (D.S.D. Sept. 28, 2009)*

Facts: Plaintiff, a manufacturer of wooden play sets for children, sued defendants, competitors in the same market, for injuries arising out of the defendants' allegedly misleading use of the term "cedar" to market play sets made from lumber commonly referred to as, among other things, "China cedar." Plaintiff contended that the defendants' use of the term "cedar" to market their products violated the Lanham Act, in that China cedar was scientifically classified as a cypress rather than true cedar. In response, the defendants produced evidence that the plaintiff had marketed its own play sets as "cedar" notwithstanding the fact that they were made out of "western red cedar" and "incense cedar," both of which were also properly classified as cypress. Defendants moved for summary judgment based on the defense of unclean hands.

Issue: Whether the plaintiff's allegedly misleading use of the term "cedar" in marketing its own product required its Lanham Act claim to be barred by the defense of unclean hands.

Holding: Yes. The court agreed with the defendants that the plaintiff's advertisements were "just as false" as the defendants' advertisements, and granted the defendants' motion for summary judgment based on the unclean hands defense.

The court noted that the unclean hands defense was available as an affirmative defense in a Lanham Act case where the plaintiff has engaged in inequitable conduct or bad faith that has a material relation to the equitable relief that the plaintiff seeks. In this regard, the court found that "if Defendants have engaged in inequitable conduct by referring to lumber from a tree that is not classified as cedar in a scientific or botanical classification, [plaintiff] has also engaged in inequitable conduct," and the plaintiff's conduct was materially related to the equitable relief that the plaintiff sought. In granting summary judgment, the court rejected the plaintiff's argument that the defendants were required to show they were injured by the plaintiff's conduct in order to invoke the unclean hands defense. The court declined to follow dicta from a Minnesota case plaintiff cited, and instead relied on "better-reasoned cases" to hold that the defendants' failure to show that they were injured by the plaintiff's inequitable conduct did not preclude them from successfully asserting the unclean hands defense.

*Irwin Industrial Tool Co. v. Worthington Cylinders Wisconsin, LLC, No. 3:08-cv-291, 2009 WL 606218 (W.D.N.C. Mar. 9, 2009)*

Facts: Plaintiffs are the manufacturers and trademark owners of the Bernzomatic one-pound hand torch, the market leader in consumer hand torch and hand torch cylinders since the 1950s. For over 20 years, Western Industries supplied Bernzomatic with hand torch cylinders, which Bernzomatic then sold under the Bernzomatic brand pursuant to an agreement between the parties. In 2004, Worthington, the defendant in this action, acquired Western Industries and then entered into a new supply agreement that gave Bernzomatic the exclusive right to sell certain Worthington cylinders to distributors and retailers under the Bernzomatic brand.

In 2007, Worthington terminated the supply agreement and began manufacturing and selling its own hand torch cylinders to Bernzomatic's competitors, which were substantially similar to the cylinders Worthington previously sold to Bernzomatic. Worthington began running an advertisement that depicted a hand tearing away a Bernzomatic label on its hand torch cylinder, revealing a Worthington label underneath. The advertisement states, "Uncover the name you've trusted all along," and "All the quality you've come to expect in hand torch cylinders is now available direct from the source."

Issue: Whether the plaintiff stated a claim under the Lanham Act based on allegations that the advertisement (1) falsely stated or implied that consumers have not trusted and should not trust Bernzomatic, (2) falsely stated or implied that consumers have actually been purchasing a Worthington product when they thought they were purchasing a Bernzomatic product, and (3) violated Section 43(a)(1)(A) of the Lanham Act, which prohibits advertising that "is likely to cause confusion, or to cause mistake, or to deceive," as to the origin of goods.

Holding: (1) No. The court held that the plaintiff failed to state a claim for false advertising to the extent it claimed that the advertisement stated or implied that consumers should have not trusted or should not trust the Bernzomatic brand. The court observed that the advertisement in fact implied the opposite; that Bernzomatic is a trusted brand, and that because Worthington is the "source" of Bernzomatic cylinders Worthington should be trusted as well.

(2) Yes. The court rejected Worthington's argument that the advertisement was literally true because Worthington or its predecessor supplied Bernzomatic with the hand torch cylinders it sold under the Bernzomatic brand for over 20 years. The court observed that Worthington's advertisement reasonably could be understood to imply that Worthington was the sole source of Bernzomatic hand torch cylinders for the entire time that Bernzomatic has sold hand torch cylinders, when in fact Western Industries supplied the cylinders prior to 2004. At most, Worthington was the source for Bernzomatic cylinders for three years, not "all along" as the advertisement claimed.

(3) Yes. For the same reasons, the court denied Worthington's motion to dismiss the false designation of origin claim. The court found that Worthington's representations that it has been the source for Bernzomatic hand torch cylinders "all along" implied an association between Worthington and Bernzomatic that was likely to confuse or deceive consumers.

*LG Electronics U.S.A., Inc. v Whirpool Corp., No. 08 C 242, 2009 WL 3113246 (N.D. Ill. Sept. 28, 2009)*

Facts: LG sued Whirlpool for false advertising arising out of Whirlpool's marketing of "steam" clothes dryers that LG claimed did not actually employ steam.

Steam washers and dryers are recent innovations that are designed to reduce wrinkles and odors in clothes by replicating the experience of dry cleaning at home. LG's steam dryer uses a boiler unit outside the dryer drum to create steam that is sprayed into the dryer drum as a vapor. LG claims that the steam combines with the air in the dryer drum and condenses into "hot white billowy steam." In contrast, Whirlpool's steam dryers introduce a spray of cool or cold water into a hot, spinning dryer drum. Whirlpool's advertisements claim, among other things, that the dryers "naturally steam out wrinkles" using the "pure power of steam" that was "a whole new way to care for your clothes . . .; [j]ust another laundry innovation from Whirlpool."

LG sued Whirlpool for false advertising, claiming that the advertisements were literally and impliedly false in that they conveyed the message that Whirlpool's dryers use actual steam in drying clothes. Whirlpool moved for summary judgment on LG's claims.

Issue: Whether Whirlpool was entitled to summary judgment dismissing LG's claims of literal and implied falsity.

Holding: No. With regard to literal falsity, Whirlpool argued that it was entitled to summary judgment because the dryers met the definition of steam used by *Consumer Reports* and other competitors and various dictionaries and by LG in its patent for the steam dryer. The court rejected Whirlpool's argument, noting first that the *Consumer Reports* evidence was inadmissible hearsay, and that the behavior of competitors was irrelevant. Second, the court noted that there was conflicting testimony with regard to the proper definition of steam, observing that Whirlpool's own engineer testified that steam occurs whenever wet clothes were placed in a dryer, which meant, in theory, that any dryer could be called a steam dryer. Third, LG's patent was irrelevant because, to the extent it described steam, it did not address Whirlpool's method of spraying water into a dryer drum.

The court also found that Whirlpool failed to address LG's claim that the advertisements were literally false in that they necessarily implied that Whirlpool's dryers used steam, whereas conventional dryers do not. In light of the advertisements' assertion that the dryers were "a whole new way to care for clothes" with the "pure power of steam," the court found that a jury could reasonably conclude that the advertisements implied that Whirlpool's dryers employed a process not previously available in conventional dryers, which was inconsistent with testimony by Whirlpool's engineers that the steam created by Whirlpool's dryers might not differ substantially from evaporation that occurs in conventional dryers.

In support of its implied falsity claim, LG relied on a mall-intercept survey that purported to analyze the message that the Whirlpool commercials conveyed to consumers. Respondents were shown two Whirlpool steam dryer commercials, a control commercial and a commercial that made the steam claims, and then asked a series of open-ended questions and, depending on their responses, a final closed-ended question. Whirlpool argued that it was entitled to summary judgment on LG's implied falsity claim because the survey (1) ignored the responses to open-ended questions and gave too much weight to responses to closed-ended questions; and (2) selected a control commercial that was not sufficiently similar to Whirlpool's actual commercial. First, the court rejected Whirlpool's argument that open-ended questions are always more probative, and recognized that closed-ended questions "may provide relevant information beyond what first pops into the minds of respondents," given that consumers "do[] not necessarily make appliance purchasing decisions impetuously." Second, the court found that, although the control commercial used different imagery than the steam claim commercials, it was not so different as to warrant exclusion of the survey. The court ultimately held that Whirlpool's criticisms went to the weight, not admissibility, of the survey, and denied Whirlpool's motion for summary judgment.

## Important Consumer Class Action Decisions in 2009

**Preemption, Standing and Other Motion to Dismiss Decisions**

**Drug and Device Preemption**

*Wyeth v. Levine, 129 S. Ct. 1187 (2009)*

**Note: This is a personal injury case, not a false advertising case. However, since the claims arise from the defendant's "failure to warn" of certain risks, plaintiffs in certain drug and medical device false advertising cases that do not involve any**

**claims of physical injury have contended, albeit misguidedly, that Wyeth is relevant to cases in which a drug or medical device label is alleged to be false or deceptive.**

Facts: Plaintiff patient sued Wyeth, the manufacturer of the anti-nausea drug Phenergan, for personal injuries allegedly caused by Wyeth's alleged failure to adequately warn of the risk of intra-arterial puncture when administering the drug intravenously (the IV push method). Wyeth moved for summary judgment on the ground that plaintiff's failure to warn claims were impliedly preempted by the FDCA.

Issue: Are plaintiff's state law claims alleging that defendant's drug labels failed to adequately warn of the dangers associated with administering the drug by the IV push method preempted by the FDCA?

Holding: No; plaintiff's claims are not impliedly preempted because the defendant did not show that it was impossible to comply with both the state and federal laws at issue, or that enforcing the state law claims would create an obstacle to accomplishing the goals of Congress under the FDCA.

The court rejected Wyeth's argument that an actual conflict with federal law existed because the FDA's pre-market approval process, to which Phenergan was subject, did not allow Wyeth to alter the label unilaterally. On the contrary, the court found that FDA regulations clearly charge manufacturers with both crafting an adequate warning label and revising it once it becomes aware that the drug is associated with a serious health hazard.

In rejecting Wyeth's argument that laintiff's state law claims created an obstacle to the goals of Congress, the court gave no deference to the FDA's statement (relied on by Wyeth) that the FDCA "establishes 'both a floor and a ceiling' so that 'FDA approval of labeling…preempts conflicting or contrary State law." The court found that the statement, which appeared in the preamble to a 2006 regulation regarding the content of prescription drug labels, did not merit deference because (1) it did not appear in the prior proposed rule, and so did not give interested parties notice of, or a chance to comment on, the rule's potential preemptive effect and (2) it represented a dramatic change in the FDA's position regarding the preemption of state laws.

Commentary: Plaintiffs in Wyeth were seeking monetary damages as a result of alleged personal injury caused by Wyeth's drug, not an injunction requiring Wyeth to alter the drug labeling in a manner contrary to FDA requirements, or precluding Wyeth from marketing its product for its intended use. There is reason to anticipate that even in false advertising cases involving FDA-regulated drugs, Wyeth will have only limited impact. Moreover, Wyeth addressed only implied preemption because the FDCA does not contain an express preemption provision relevant to the approval and labeling of drugs. By contrast, there is an express preemption provision applicable to the FDCA's regulation of medical devices (see discussion of Medtronic case immediately below) which, of course, the Supreme Court in Wyeth had no cause to consider.

### *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig., 592 F. Supp. 2d 1147 (D. Minn. 2009)*

Facts: Plaintiffs in a multidistrict litigation brought a master complaint against defendant Medtronic for personal injuries arising from Medtronic's allegedly defective Sprint Fidelis defibrillator leads. Among the 21 claims asserted against Medtronic were claims for

violation of (1) the Minnesota False Statements in Advertising Act; (2) the Minnesota Deceptive Trade Practices Act; and (3) the Minnesota Consumer Fraud Act (the Consumer Fraud claims). The Consumer Fraud claims stemmed from Medtronic's failure to provide adequate warnings after it became aware of certain defects in the (already FDA-approved) leads. Medtronic moved to dismiss each of the claims on the ground that they were preempted by the FDCA.

Issue: Are plaintiffs' state law claims preempted by the FDCA?

Holding: Yes; the court granted Medtronic's motion to dismiss all 21 claims, finding they were preempted by the FDCA.

Relying on the Supreme Court's decision in Riegel v. Medtronic, Inc., 552 U.S. 312, 128 S. Ct. 999 (2008), Medtronic had argued that plaintiffs' claims were expressly preempted by 21 U.S.C. §360k(a), the express preemption provision of the Medical Device Amendments to the FDCA ("MDA"). In response, plaintiffs argued that: 1) the preemption defense was not available to Medtronic, because the company's recall of the defective leads invalidated the device's PMA; and 2) in any event, plaintiffs' claims are "parallel" claims, which, per Riegel, are not preempted by the MDA's preemption provision.

Turning to plaintiffs' first argument, the court stated that plaintiffs' assumption that the recall invalidated the device's PMA was faulty, since the FDA itself distinguishes between the recall of a device and the revocation of the device's PMA. More importantly, however, plaintiffs' legal theories hinged on whether the leads were in compliance with federal requirements at the time of the alleged tort (i.e., at the time the leads at issue were implanted in the patients), and thus the issue was whether the PMA for the leads was in effect at that time (it was), not whether it was later invalidated. To hold otherwise would "in essence, result in *retroactive* second-guessing of the FDA's decision-making" (emphasis in original).

With regard to plaintiffs' second argument, the court noted that some of plaintiffs' alleged "parallel" claims raised the specter of Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), in that they failed to provide enough factual detail to alert Medtronic to the basis for plaintiffs' assertion that the leads failed to comply with certain manufacturing standards. As for the claims arising from plaintiffs' allegations that Medtronic failed to provide adequate warnings, the court found that it was not a "parallel" claim because there was no federal requirement that Medtronic give any warnings other than those required by its PMA. Further, to the extent that plaintiffs' claim arose from Medtronic's alleged failure to comply with the FDA's post-sale reporting requirements, the court held that it was impliedly preempted by §337(a) of the FDCA, which reserves the exclusive power to enforce or restrain violations of the FDCA to the federal government, and not private litigants.

The court did not separately address the Consumer Fraud claims, it merely found them to be derivative of plaintiffs' other claims, and thus dismissed them on the same grounds.

**Preemption and State "Safe Harbor" Statutes**

*Aspinall v. Phillip Morris, Inc., 902 N.E.2d 421 (Mass. 2009)*

Facts:Plaintiffs brought a class action against cigarette manufacturers, arguing that their use of the descriptors "light" and "low tar" on cigarette labels and in cigarette advertising

falsely conveyed the idea that "light" cigarettes were less harmful than regular cigarettes, in violation of the Massachusetts Consumer Practices Act (MCPA). Defendants moved for summary judgment on the ground that plaintiffs' claim was barred by the MCPA's safe harbor provision or, alternatively, was preempted by federal law; the motion was denied. Defendants appealed.

The Supreme Judicial Court of Massachusetts issued a stay pending the decision of the U.S. Supreme Court in Altria Group, Inc. v. Good, which dealt with essentially the same issues in this case. After the Supreme Court's decision in Altria, 129 S. Ct. 538 (2008), which found that claims for false or misleading advertising of "light" cigarettes were not preempted by the Federal Cigarette Labeling and Advertising Act, the sole issue left on appeal was whether plaintiffs' claims were barred by the MCPA's safe harbor provision.

Issue: Does the MCPA's safe harbor provision, which states that the act shall not apply to transactions or actions otherwise permitted by a federal regulatory authority, bar plaintiffs' claim that defendants' use of the allegedly false and misleading descriptors "light" and "low tar" violated the MCPA's prohibition on unfair and deceptive practices?

Holding: No. Defendants' advertising and labeling does not fall within the safe harbor of the MCPA because defendants failed to show that the FTC *affirmatively* permitted the use of the descriptors in its labeling and advertising. The court noted that the FTC has previously stated that it had "no official position" on descriptors on cigarette packages, and that the mere failure of the FTC to take any formal action to stop defendants from using the descriptors was insufficient to satisfy the defendants' burden.

### *DePriest v. AstraZeneca Pharm., LP, 2009 Ark. 547 (Ark. 2009)*

Facts: Plaintiffs sued the defendant drug manufacturer, AstraZeneca, in state court, alleging that the defendant had fraudulently marketed its drug Nexium as being "new" and superior to its prior drug, Prilosec, at treating various conditions related to gastro-esophageal reflux disease, when the two drugs allegedly had similar therapeutic results. Plaintiffs asserted numerous common law and statutory claims, including common-law fraud and violation of the Arkansas Deceptive Trade Practices Act (ADTPA).

Plaintiffs amended their complaint several times, eventually filing a Fifth Amended Complaint, which defendant moved to dismiss on the ground that the complaint failed to state a claim and, in addition, on the ground that plaintiffs' claims were preempted. The court granted the motion, finding plaintiffs' false advertising claims to be barred by the ADTPA's "safe harbor" provision; also, as an independent reason for dismissal, the court found that all of plaintiffs' claims were preempted by federal law. Plaintiffs appealed.

Issue: Was the trial court correct to dismiss plaintiffs' claims?

Holding: Yes. The allegedly false and misleading advertising at issue was consistent with, and supported by, the labeling approved by the FDA. Thus, the defendant's allegedly false advertising fell within the ADTPA's safe harbor provision, which expressly provides that the Act does not apply to advertising or practices which are subject to, permitted by, or comply with the rule, order or laws administered by the FTC or other regulatory body.

The court also affirmed dismissal of the common law claims for fraud and unjust enrichment that were predicated on the allegedly false advertising, holding that because

the defendant's advertisements were in accordance with the FDA-approved labeling, they were not false or misleading as a matter of law.

The court rejected plaintiffs' request that it adopt the reasoning of the California trial court in *Ledwick v. AstraZeneca Pharm. LP*, Case No. BC 324 519, which denied AstraZeneca's motion for demurrer on the basis of preemption in a similar case regarding advertising for Nexium. In declining to follow the unpublished decision in *Ledwick*, the court pointed out that the state statute at issue in that case, California's Unfair Competition Law, does not contain a safe harbor provision.

Since the court dismissed plaintiffs' claims on the above grounds, it declined to review the lower court's finding that the claims were also preempted by federal law.

**Preemption, Primary Jurisdiction and Natural/Organic Advertising Claims**

*Holk v. Snapple Beverage Corp., 575 F.3d 329 (3d Cir. 2009)*

Facts: Plaintiff brought a putative class action suit in New Jersey state court, alleging inter alia that Snapple violated the New Jersey Consumer Fraud Act (the CFA) by engaging in false and deceptive marketing and advertising of its beverages. Plaintiff's claims were predicated on the statement made on the beverage labels, and elsewhere, that the drinks were "All Natural," which Plaintiffs' claimed was misleading because the drinks contained high fructose corn syrup (HFCS), a synthetic sweetener. Snapple removed the case to the District Court for the District of New Jersey, pursuant to the Class Action Fairness Act, 28 U.S.C. 1453(b), and then moved to dismiss. The District Court granted Snapple's motion to dismiss, holding that the claims were impliedly preempted by the FDCA. Plaintiff appealed the District Court's dismissal.

Issue:Are plaintiff's state law claims arising from the allegedly false and misleading statement that Snapple beverages are "All Natural" preempted by the FDA and FDCA's extensive federal regulatory scheme governing the beverage industry?

Holding: No. Defendants did demonstrate that it was the "clear and manifest" intent of Congress to occupy the field of beverage regulation, and there was no applicable law regarding the definition of the word "natural" with which plaintiff's state law claims could be said to conflict.

First, the court refused to consider Snapple's argument that plaintiff's claims were expressly preempted by the Nutrition Labeling and Education Act, 21 U.S.C. §343 *et seq.* (NLEA), on the ground that Snapple had waived that argument with regard to the "All Natural" claim (Snapple had only raised that argument below with regard to a juice-content claim that was withdrawn prior to the District Court's ruling).

Next, the court found that "field preemption" did not apply because: (1) the NLEA states that courts should not construe the Act to preempt state law unless the law is expressly preempted under 21 U.S.C. §343-1 of the FDCA; (2) the NLEA preserves state warning laws by stating that the express preemption provision does not apply to them; (3) the FDA has stated that it does not intend to occupy the field of food and beverage labeling; and (4) the existence of a federal regulatory scheme is not enough to imply Congressional intent to occupy a legislative field.

Last, the court found that there was no implied "conflict" preemption because there was no federal "law" with regard to the use of the word "natural." Although Snapple submitted

evidence that the FDA had instituted and enforced an informal policy with regard to the use and definition of the term "natural," the policy was not entitled to preemptive effect because it had not undergone the formal rulemaking process, and therefore lacked the force of law.

*All One God Faith, Inc. v. Hain Celestial Group, Inc., No. C 09-03517 JF (HRL), 2009 WL 4907433 (N.D. Cal. Dec. 14, 2009)*

Facts: Plaintiff was a manufacturer and distributor of personal care and cosmetic products, which are certified as "organic" or "made with organic" ingredients, in compliance with the applicable USDA standards -- the National Organic Program (NOP) standards. The NOP standards were promulgated pursuant to the Organic Foods Products Act of 1990, 7 U.S.C. §6501 *et seq.* (the Organic Foods Act), however, the USDA did not require that personal care products comply with them. Plaintiff sued several competitors under the Lanham Act, claiming that they falsely and misleadingly used the word "organic" on their products' labels despite the fact that they did not comply with the NOP standards, as consumers would allegedly expect of products labeled as "organic." Defendants moved to dismiss; the court granted the motion.

Issues: (1) Was plaintiff required to pursue an administrative remedy before bringing suit; (2) was plaintiff's claim barred by the doctrine of primary jurisdiction; and (3) was plaintiff's claim precluded by the federal NOP standards?

Holding: (1) Yes, the Organic Foods Act states that a district court has subject matter jurisdiction only upon the appeal of a final decision of the Secretary of the USDA. While the court acknowledged that the USDA has declined to impose NOP standards on personal care products, the court held that fact did not excuse plaintiff from first pursuing its remedies under the Organic Foods Act. As an adversely affected person under the act, plaintiff may file an administrative complaint challenging the USDA's decision not to impose NOP standards on personal care products.

(2) Yes, the court held that it would be inappropriate for it to assume the USDA's regulatory role by interpreting the NOP and imposing standards with regard to the labeling of personal care products as "organic" that the USDA has refused to impose on defendants. While agreeing that plaintiff could theoretically assert a Lanham Act claim for misrepresentation based on consumer expectations which did not implicate the primary jurisdiction doctrine, the court found that the complaint was not currently pleaded that way.

(3) Yes. The court found that the labeling and marketing of "organic" products falls within the exclusive jurisdiction of the USDA, which has not required manufacturers of personal care products to comply with NOP standards. Plaintiffs' complaint urges that the court enjoin defendants from using the term "organic" unless they comply with these standards, which would require that the court override the USDA's decision not to impose those standards on personal care products. Thus, the court held that plaintiffs' injunctive relief claim would violate the act's bar on private enforcement actions. However, the court did not dismiss the complaint with prejudice, stating that it was not persuaded that plaintiff could not amend the complaint to state a valid Lanham Act claim that was not predicated on the NOP standards.

*Lockwood v. ConAgra Foods, Inc., No. C 08-04151 (CRB), 2009 U.S. Dist. LEXIS 10064 (N.D. Cal. Feb. 3, 2009)*

Facts: Plaintiffs brought a putative class action suit under California's Unfair Competition Law (UCL), alleging inter alia that defendant engaged in false and deceptive advertising of its Healthy Choice pasta sauce by claiming the sauce was "All Natural" when it contained the synthetic sweetener High Fructose Corn Syrup (HFCS). Defendant moved to dismiss on the ground that Plaintiffs' claim is expressly preempted by the Nutrition Labeling and Education Act, 21 U.S.C. §343 *et seq.* (NLEA), and impliedly preempted by the FDA's extensive regulatory scheme promulgated under the Food, Drug and Cosmetic Act (FDCA), or, alternatively, that plaintiffs' claim was barred by the doctrine of primary jurisdiction.

Issue:Are plaintiffs' UCL claims, which arise from the allegedly false and misleading statement that Healthy Choice pasta sauce is "All Natural," preempted by the NLEA and/or the FDA's extensive federal regulatory scheme governing food labeling?

Holding: No; plaintiffs' claims are neither expressly nor impliedly preempted by federal law, and the doctrine of primary jurisdiction does not apply.

First, the court concluded that the express preemption provision of the NLEA did not apply, since plaintiffs had not alleged that defendant's sauce contained any artificial flavoring, color, or preservative, nor had they alleged that the sauce was an "imitation" of another food product.

Next, the court found that "field preemption" did not apply because Congress has indicated that it does not intend to occupy the field of food and beverage labeling by permitting states to regulate matters covered by the NLEA and its regulations (provided the state law does not fall within the scope of the NLEA's express preemption provision). In addition, the fact that the FDA only has an informal "policy" and not a "legal requirement" with regard to the use of the word "natural" on food labels also indicates an intent not to occupy the field.

Further, the court found that there was no implied "conflict" preemption because defendant had not shown it was impossible to comply with both federal and state law, nor that the state law stood as an obstacle to the objectives of the FDA. For instance, the court noted, there was no evidence in the record that the FDA had considered a more restrictive definition of "natural" but that, after balancing policy objectives, it had decided to retain its current policy.

Last, the court held that the application of the primary jurisdiction doctrine was inappropriate in this matter. The record indicates that the FDA has been asked repeatedly to adopt a formal rule with regard to the definition of "natural," and that it has declined to do so because it has "limited resources" and doing so was not a priority. Furthermore, the court found that, even if the FDA were to formally define the term, it would not dispose of plaintiffs' state law claims.

### *DeBouse v. Bayer*

DeBouse v. Bayer, 2009 WL 4843362 (Ill. Dec. 17, 2009), illustrates the difficulties facing a putative plaintiff claiming to have suffered economic harm by paying elevated prices for a drug due to the manufacturer's failure to disclose known side effects, where the drug was prescribed by a doctor and the manufacturer did not directly advertise or market to the plaintiff as an end consumer.

In DeBouse, plaintiff filed a class action against Bayer AG, the manufacturer of Baycol, a cholesterol-lowering drug that was subsequently associated with rhabdomyolysis, a serious condition affecting a patient's muscle tissue and causing varying degrees of kidney damage. Plaintiff DeBouse began taking Baycol on the recommendation of her doctor, and had not seen advertisements or had any exposure to the drug before her doctor prescribed it. Prior to August 2001, when Baycol was withdrawn from the market, DeBouse had purchased three prescriptions containing 30 tablets each. DeBouse discontinued her use of Baycol without having suffered physical harm; she claimed, however, to have been harmed economically by having paid inflated prices for Baycol as a result of Bayer's deceptive omission that the drug's use had been linked to rhabdomyolysis. She represented a certified class of Baycol consumers who had allegedly suffered the same economic harm.

The trial court certified three questions for interlocutory review. Bayer appealed the appellate decision, and on its second appeal, the Illinois Supreme Court addressed the certified questions, restated as follows: (1) whether a consumer who purchased an unsafe product has an action under the Illinois Consumer Fraud Act (ICFA) when the manufacturer did not advertise to the consumer, but rather to third parties, and no information about the product reached the consumer; (2) whether the mere offering of a prescription drug to consumers was a representation that the drug was "reasonably safe" under the ICFA; and (3) whether Bayer's advertising statements and omissions to doctors, with the intent that they reach and influence consumers' decisions to purchase its product, could support an "indirect deception" consumer claim under the ICFA. *Id.* at *1-2.

Addressing the first question, the court concluded that the requirement that actual damage occurred as "a result of" defendant's deception meant that a plaintiff must prove she had been "actually deceived," which DeBouse concededly could not do, having had no knowledge of Baycol through advertising or other means prior to her doctor's prescription. "If there has been no communication with the plaintiff, there have been no statements or omissions." *Id.* at *5. Conversely, the court answered the third question in the affirmative, continuing to hypothetically "recognize" a "theory of indirect deception" although finding "DeBouse cannot prove such a theory in this case." *Id.* at *6. What circumstances might support such a theory it did not say. Finally, the court held that because of the inherent uncertainty that any prescription drug will be safe for all patients and not cause harmful side effects in some, "the mere sale of a prescription drug cannot be a representation which serves as a basis for a consumer fraud claim." *Id.* at *7. Armed with these answers, the court took the unusual step on a certified question of granting summary judgment for Bayer without remand.

While DeBouse did not shut the door on an "indirect deception" claim, the Illinois Supreme Court left it open no more than a crack. This case is a definitive victory for pharmaceutical defendants that market to the medical or health care insurance communities rather than to the public at large.

### *In re Tobacco II and its progeny*

At first glance, the California Supreme Court's decision in In re Tobacco II, 46 Cal.4th 298 (Cal. 2009), appeared to offer plaintiffs some relief from the heightened standing requirements imposed with Proposition 64, the passage of the California voter initiative. Prop. 64 amended the enforcement provisions applicable to California's Unfair Competition Law (UCL) and False Advertising Law (FAL) to provide that a representative

plaintiff must have suffered "injury in fact and [have] lost money or property as a result of such unfair competition." *See* Cal. Bus. & Prof. Code § 75000 *et seq. In re Tobacco II* relieved plaintiffs from the onerous burden of pleading these requirements as to each member of a putative class. But Plaintiffs' victory appears to have been ephemeral. As the following cases reveal, federal courts and even California state courts soon narrowed *In re Tobacco II*'s reach, indicating a continued trend in 2009 toward heightened scrutiny of plaintiffs' standing to bring class claims.

### *In re Tobacco II*

The passage of Proposition 64 created open questions as to whether new standing requirements under California's UCL and FAL applied to each member of a plaintiff class or solely to each class representative, and what showing would suffice to meet these requirements. The California Supreme Court attempted to resolve these issues in *In re Tobacco II*.

Plaintiffs brought suit under the UCL, FAL and Consumer Legal Remedies Act (CLRA) against the American Tobacco Company; Philip Morris USA Inc.; R.J. Reynolds Tobacco Company; Brown & Williamson Tobacco Corporation; British American Tobacco Co., Ltd.; Liggett & Myers, Inc.; Hill and Knowlton, Inc.; the Council for Tobacco Research-U.S.A., Inc.; the Tobacco Institute, Inc.; United States Tobacco Company; and Lorillard Tobacco Company, based on harms allegedly incurred as a result of defendants' fraudulent and deceptive advertising campaigns, which plaintiffs claimed had concealed known facts about the addictive properties of nicotine.[3] Prior to the 2004 passage of Proposition 64, the California trial court had certified a plaintiff class, defined as "[a]ll people who at the time they were residents of California, smoked in California one or more cigarettes between June 10, 1993 to April 23, 2001, and who were exposed to Defendants' marketing and advertising activities in California." *Id*. at 306. After the amendments, defendants moved to decertify the class for failing to meet the new standing requirements. The trial court granted defendants' motion and the appellate court affirmed.

The California Supreme Court identified two questions of statutory interpretation for de novo review: First, it considered "who must meet the standing requirement in a UCL class action," and second, "what [wa]s required to establish standing under the UCL" as amended. *Id.* at 314, 324. Turning to Question One, the court found that the plain language of the amendment referred to an individual plaintiff; i.e., a representative plaintiff, not to multiple plaintiffs. In addition, Proposition 64 ballot materials did not indicate that the initiative was intended to fundamentally alter well-established class action rules that required only the class representative to show standing. The court also noted that such an interpretation conflicted with the statute's broad restitution provisions that had been read to grant relief without individualized proof of deception, reliance and injury. *Id.* at 320. Thus, it held that only class representatives, not the absent class members, must meet the standing requirement imposed by the passage of Proposition 64.

With regard to the second question, however, the court determined that the "as a result of" language of the amendment imposed an "actual reliance" requirement on plaintiffs prosecuting a private enforcement action under the UCL. *Id.* at 326. However, the court

[3] Plaintiffs withdrew their CLRA claim after class certification on this claim was denied.

qualified this holding by stating that it was not necessary "that [the plaintiff's] reliance upon the truth of the fraudulent misrepresentation be the sole or even the predominant or decisive factor influencing his conduct.... It is enough that the representation has played a substantial part, and so had been a substantial factor, in influencing his decision.'" *Id*. This left putative plaintiffs on solid ground; they did not need to make the near-impossible showing that each class member had suffered harm, and although actual reliance was required, proof of an extensive advertising campaign could in some circumstances suffice to meet this element. But in federal courts, decisions applying the pleading standards of Fed. R. Civ. P. 9(b) quickly made clear that In re Tobacco II would not have the plaintiff-friendly impact some had foreseen, and even in California state courts, the impact of Tobacco II has been distinctly muted.

### *Brownfield v. Bayer Corp.*

In Brownfield v. Bayer Corp., 2009 U.S. Dist. LEXIS 63057 (E.D. Cal. July 2, 2009), a federal district court attempted to define the CLRA, FAL, and UCL requirements of actual reliance and injury-in-fact, and held that plaintiffs were required to show exposure to defendants' allegedly deceptive advertising campaign and that they were within the discrete category of persons for whom the product was unapproved.

Putative plaintiffs were consumers of YAZ®, an oral contraceptive professed to treat symptoms of premenstrual dysphoric disorder (PMDD) and moderate acne in women who use oral contraceptives. Plaintiffs brought claims against Bayer, the contraceptive's manufacturer and marketer, under the CLRA, FAL, and UCL, based on alleged misrepresentations made in defendant's advertising campaign that "cause[d] women to believe that YAZ is approved to treat women with any degree of severity of the symptoms presented." *Id.* at *3. Plaintiffs claimed that the combination of auditory statements, visuals, and images in defendant's ads failed to express the limitations of the drug, and that by contrast to the implications of defendant's ads, YAZ® was not FDA-approved for women who suffered from PMS that did not rise to the level of PMDD, or for severe acne.

The court dismissed the CLRA, FAL and UCL claims under Fed. R. Civ. P. 12(b)(6) and 12(b)(9) for lack of standing and failure to plead fraud with particularity. The court first determined that actual reliance was required for each of plaintiffs' statutory claims pursuant to the specific standing requirement in the UCL and FAL, and by California law interpreting similar language in the CLRA. *Id.* at *10. Plaintiffs' allegations were insufficient as they failed to allege "what Plaintiffs saw, heard and relied upon in making their purchases." *Id*. "Plaintiffs have not alleged any facts showing they viewed either of the ads at issue prior to purchasing YAZ® or that they purchased YAZ® in reliance on the challenged aspects of the ads and were injured as a result." *Id.* at *11.

The court further concluded that the allegations of injury based on plaintiffs' own purchases were implausible under Ashcroft v. Iqbal, 129 S. Ct. 1937 (2009), and Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), as plaintiffs did not claim to be in the class of persons that fell outside of the FDA-approved uses of YAZ®. *See id.* at 12. "If, for example, Plaintiffs purchased YAZ® for use as an oral contraceptive, as a treatment for symptoms of PMDD in women who use oral contraceptives, then Plaintiffs have presumably suffered no injury, as YAZ® is approved for those uses." As an alternative ground for dismissal, the court held that all of plaintiffs' statutory claims were grounded in fraud and thus plaintiffs were required, and failed, to meet Fed. R. Civ. P. 9(b)'s specific pleading requirements. *Id*. at *15.

### *In re Actimmune Marketing Litigation*

The Actimmune litigation offered the most extensive analysis of the juxtaposition of the pleading standards of Fed. R. Civ. P. Rule 9(b) with the amended standing requirements of California's UCL, FAL, and CLRA. After In re Actimmune Marketing Litigation, 2009 U.S. LEXIS 103408 (N.D. Cal. Nov. 6, 2009), plaintiff consumers of a prescribed pharmaceutical must not only show actual reliance by their doctor on a defendant's fraudulent representations, but they must specifically allege what representations their doctors received, when they received them, and how the doctors relied on these representations when prescribing the pharmaceutical to plaintiffs, and show that such representations were directly attributable to defendants.

Putative plaintiffs, consumers and a third-party-payor (TPP) health association, brought claims against defendant biotech companies under California's UCL, FAL and CLRA, based on defendants' allegedly fraudulent marketing representations professing that studies showed that the drug Actimmune produced a "significant survival benefit" to patients with mild to moderate symptoms of idiopathic pulmonary fibrosis (IFP), although defendants purportedly knew that Actimmune was not effective to treat IFP and had not been approved by the FDA. Plaintiffs proceeded under the theory that they were prescribed Actimmune by their doctors, who in turn prescribed the drug in reliance on defendant's fraudulent statements, causing plaintiffs to purchase an expensive drug that provided them with no benefit. *Id.* at *15.

The court addressed the causation and reliance elements of plaintiffs' claims under the federal pleading standards, holding that In re Tobacco II "did not relieve class representatives from the burden of satisfying Rule 9(b)." "[W]hile under certain circumstances *Tobacco II* may absolve plaintiffs in California courts from pleading the exact content, location, and timing of a representation that was part of a long-term fraudulent advertising campaign, *Rule 9(b)* mandates the causation elements announced in Tobacco II be pled with specificity." *Id.* at *39.

Under this standard, the court determined that plaintiffs' pleadings were inadequate. It found that consumer plaintiffs' allegations that "their doctors were exposed generally to the marketing of Actimmune because of their membership in various medical organizations and because they routinely received or had access to publications in which Actimmune was discussed" were insufficient where "plaintiffs fail to allege that the defendants were responsible for the information about Actimmune that the doctors received," nor did they "explain that the doctors relied upon the information" in prescribing the drug. *Id.* at *34. "Neither [consumer] plaintiff alleges … that they or their doctors ever were actually the recipient of any of defendants' fraudulent representations…. Plaintiffs do not identify any particular article, symposium, meeting, drug representation visit or any other vehicle for conveying information about pharmaceuticals from which they learned that Actimmune was an effective treatment for IPF." *Id.* Nor did the TPP plaintiff sufficiently plead a UCL or FAL violation. Although the TPP alleged that many of its members worked directly with defendants and relied on information received from them in prescribing the drug, the court found that it failed to specify "the content of the representations conveyed … to the prescribing doctors" or that "the doctors believed that Actimmune was an effective treatment for IPF," or whether "any … employees who ultimately decided whether or not to approve payment for … prescriptions were ever exposed to or relied upon any of defendants' misrepresentations." *Id.* at *38.

Secondly, the court found that plaintiffs had failed to allege "exposure to a long-term advertising campaign" under the In re Tobacco II presumption, noting that defendants' "seven-year effort to market Actimmune to approximately 7,000 pulmonologists and 200,000 individuals suffering from IPF pales in comparison to the decades-long, national, ubiquitous advertising campaigns embarked upon by cigarette manufacturers." *Id.* at *41. Because all of plaintiff's CLRA claims sounded in fraud, those too were dismissed for failure to adequately allege reliance under Rule 9. *Id.* at *48.

### *Birdsong v. Apple, Inc.*

In Birdsong v. Apple, Inc., 2009 WL 5125776 (9th Cir. Dec. 30, 2009), the 9th Circuit confirmed that the amended UCL required that putative plaintiffs themselves must suffer "injury in fact," and that potential harm to others was not sufficient.

Putative plaintiffs, purchasers of iPod digital audio players, brought claims under the UCL against Apple, Inc., iPods' manufacturer. The iPods purchased came with Apple earbud headphones but could be used with third-party headphones, and had the capability of producing sound as loud as 115 decibels. Apple packaged the iPods with a warning instructing consumers that using earphones or headphones at high volumes could lead to hearing damage, and the company provided similar warnings on its Web site. Plaintiffs claimed that they were injured by Apple's sale of a product that had the capability to produce unsafe levels of sound and the ability to expose consumers to these unsafe levels for long periods of time. They also maintained that these features amounted to a defect which caused the iPods to be worth less than what plaintiffs paid for them.

The court rejected both of these theories. It noted that plaintiffs did not claim that "they suffered or imminently will suffer hearing loss from their iPod use," nor did they claim that hearing loss was "substantially certain." "[A]t most, they plead a potential risk of hearing loss to those who might *choose* to use their iPods in an unsafe manner." The court further rejected the theory that this alleged defect had deprived plaintiffs of the benefit of their bargain in purchasing the iPods, as plaintiffs did not have to listen at high volumes, nor did Apple represent that they could listen to music at high volumes for extended periods of time. "The plaintiffs' alleged injury in fact is premised on the loss of a 'safety' benefit that was not theirs to begin with."

### *Princess Cruise Lines, Ltd. v. Superior Court of Los Angeles County*

Princess Cruise Lines, Ltd. v. Superior Court of Los Angeles County, 179 Cal. App.4th 36, 101 Cal. Rptr.3d 323 (Cal. App. 2d Dist. Nov. 10, 2009), marks another failed attempt, this time in California state court, for plaintiffs proceeding with state statutory consumer deception claims under the In re Tobacco II presumption or on a theory of indirect reliance.

Plaintiffs, passengers on defendant's cruise ship who purchased shore excursions that were offered as part of a cruise package, brought claims against the cruise line owner and operator, alleging violations of the UCL, CLRA and FAL. They alleged that through defendant's control of the third parties that independently provided the island excursions, defendant was able to inflate the cost of the excursions above the third-party rates, damaging plaintiffs and those similarly situated. *Id.* at 325. The California Court of Appeal, on a petition for mandate, granted summary judgment in favor of the petitioner cruise line on plaintiffs' UCL, CLRA and FAL claims, concluding, as did the federal courts in Brownfield, that actual reliance was required for claims based on a theory of fraud

under all three statutes, and that plaintiffs' failure to show any exposure to defendant's advertising was fatal to their claims.

Plaintiffs proposed two theories of reliance. First, they maintained that the presumption of actual reliance recognized in In re Tobacco II for "an extensive and long-term advertising campaign" should apply, and alternatively, that they had heard about defendant's advertising representations from former cruise passengers. Rejecting both of plaintiffs' bases, the court found that regardless of whether defendant had engaged in a prolonged advertising campaign, plaintiffs' theories were fundamentally flawed because they had no actual contact with the cruise line and had otherwise expressed their willingness to participate in third party-operated island excursions regardless of the price. *Id.* at 329. As plaintiffs "would have gone on the excursions whatever the price was and without reference to anything petitioner said or did in connection with the excursions," it was "immaterial how [plaintiffs] heard about the excursions and what, if anything, petitioner said or wrote about them." *Id.*Class Certification Decisions

### *In Lee v. Carter-Reed Co.*

In Lee v. Carter-Reed Co., 2009 WL 2475314 (N.J. Super. Ct. App. Div. Aug. 14, 2009), the Superior Court of New Jersey, Appellate Division, affirmed the trial court's denial of plaintiff's motion for class certification in a "mass media false advertising case" brought against the manufacturers and distributors of the dietary supplement Relacore. Specifically, the trial court held, and the Appellate Division agreed, that "a common core of facts and law d[id] not predominate to allow class treatment." *Id.* at *7.

Relacore was marketed in a variety of campaigns "through magazines, television, radio stations, Internet Web sites, and promotional materials sent to retailers." *Id.* at *1. The claims emphasized in the various campaigns varied over the years but, according to the plaintiff, one consistent message was that use of the product would result in a reduction in belly fat. *Id.* The plaintiff alleged that she purchased Relacore based on this claim and used the product as directed for 90 days but did not lose any belly fat. *Id.* She then commenced an action in New Jersey state court alleging violations of New Jersey's Consumer Fraud Act (CFA), as well as common-law fraud. *Id.* After limited discovery, the plaintiff moved to certify a class of all persons who bought Relacore since the product was introduced to the market in 2002. *Id.*

The trial court's opinion denying class certification found that "questions of law or fact common to the class did not predominate over the questions affecting only its individual members and that a class action was not superior to other methods of adjudication." *Id.* Specifically, the trial judge identified 14 different "insurmountable" issues that would require evidentiary hearings as to each putative class member. These issues included questions relating to reliance, causation and damages, among others.

In affirming the decision, the appellate court noted the problems relating to predominance that were inherent in this particular case. For instance, the court pointed out that the Relacore marketing campaign was mutlifaceted: "In some ads, it is touted as a belly fat retardant; in others, a mood elevator; in others, a stress reducer. We have no idea the reason any putative class members purchased the product, assuming they heard or saw any advertising." *Id.* at *5. Denial of class certification was affirmed because, according to the court, it was very possible that "plaintiff and the putative class members suffered losses from a variety of sources not common to all." *Id.* at *6.

### *Hodes v. Van's International Foods*

The Central District of California reached a similar result in Hodes v. Van's International Foods, 2009 WL 2424214 (C.D. Cal. July 23, 2009). There, plaintiffs brought suit against Van's International Foods, the manufacturer, marketer and distributor of frozen waffles in a variety of product lines. *Id.* at *1. Van's waffles are marketed as healthy and "all natural" and "listed nutritional values on its packaging labels showing lower quantities of calories, fat, and sugar than its competitors." *Id.* "Plaintiffs alleged that these nutritional values were false, and that, in fact, Van's waffles contained significantly more calories, fat, and sugar than the labels represented." *Id.* In denying plaintiffs' class certification motion for failure to satisfy the requirements of Rule 23(b)(3), the court stated that "common questions of law and fact do not predominate over individualized issues . . . ." *Id.* at *4. Specifically, the court voiced a number of "concerns about how Plaintiffs will identify each class member and prove which brand of Van's frozen waffles each member purchased, in what quantity, and for what purpose." Further, the plaintiffs did not present the court "with any indication of how to determine the amount of damages suffered by each class member." The court stated that it would not "engage in its own investigation as to which of Van's 19 frozen waffle varieties class members purchased, how much each class member spent, and whether those particular varieties contained nutritional inaccuracies." *Id.* The court found that "[t]he common questions presented by Plaintiffs in this matter do not outweigh the individual issues regarding class size, damages, and proof" and that plaintiffs did not establish "that a class action is the most superior method of adjudication." *Id.* at *5.

### *Jermyn v. Best Buy Stores, L.P.*

Conversely, in Jermyn v. Best Buy Stores, L.P., 256 F.R.D. 418 (S.D.N.Y. 2009), the Southern District of New York granted plaintiff's motion for class certification in a consumer class action brought against Best Buy. The plaintiff's lawsuit centered around Best Buy's "price match guarantee" policy, whereby Best Buy advertises to "the consuming public that it will match a competitor's lower price on any item purchased in the store." *Id.* at 423. According to the plaintiff, this policy is used "as a ploy, to lure unsuspecting consumers into its stores and to induce them to purchase its merchandise, while allegedly having an undisclosed 'Anti-Price Matching Policy,' pursuant to which employees aggressively deny customers' legitimate price match requests." *Id.* Plaintiff sued on behalf of himself and a putative class of thousands of similarly situated New York consumers for, inter alia, false and deceptive practice under Minnesota's Consumer Fraud Act, false and deceptive acts and practices under New York General Business Laws §§ 349 and 350, and unjust enrichment.

In arguing against class certification, Best Buy contended that each putative class member's claims "are dependent upon each class member's individual conversations with a Best Buy employee" (in rejecting their price match request) and that "there are three different versions of the price match policy during the proposed seven year time period." *Id.* The court found that these differences related solely to damages and would not defeat class certification. The court found that there were a number of common questions of law and fact that sufficiently formed a "unifying thread" through each of the class members, including "whether Best Buy has an 'internal' policy or practice of refusing to honor its price match guarantee," whether this policy was "in conflict with its 'public' price match guarantee policy" and whether this was a "deceptive act or practice" or "false and misleading . . . ." *Id.* at 430. The court went on to state that it mattered not

*how* the class members' price match requests were rejected, only that they *were* rejected. *Id.*

### *In re Tobacco II Cases*

The Supreme Court of California addressed the standing requirements plaintiffs must satisfy in Unfair Competition Law (UCL) class actions in In re Tobacco II Cases, 46 Cal. 4th 298 (2009). That case involved, *i*nter alia, alleged violations of the UCL by the tobacco industry through "a decades-long campaign of deceptive advertising and misleading statements about the addictive nature of nicotine and the relationship between tobacco use and disease." *Id.* at 306. The trial court initially certified the case as a class action, defining the class to include "'All people who at the time they were residents of California, smoked in California one or more cigarettes between June 10, 1993 to April 23, 2001, and who were exposed to Defendants' marketing and advertising activities in California.'" *Id.* Subsequently, California voters passed Proposition 64, which requires a private person bringing a UCL claim to show that he or she "has suffered injury in fact and has lost money or property as a result of such unfair competition." *Id.* at 314. The tobacco industry defendants then moved to have the class decertified, arguing that this "new standing requirement imposed on plaintiffs bringing a UCL action by Proposition 64 – that such persons must have suffered injury in fact and lost money or property as a result of the alleged UCL violation – applied to every class member." *Id.* at 310. The trial court granted decertification, stating that the new standing requirements resulted in individual issues predominating, making class treatment unmanageable and inefficient. *Id.* at 311. The intermediate appellate court affirmed. *Id.*

The Supreme Court of California reversed the decertification and remanded the case to the trial court, holding that only the *named plaintiffs*, and not all class members, must establish injury, reliance and causation for purposes of standing. *Id.* at 328-29. However, the Supreme Court's decision also makes clear that the issues of injury, reliance and causation remain relevant to the class certification determination of whether individual or common issues predominate. *Id.* at 312-13 (reiterating the requirements for maintenance of a class action, including (1) an ascertainable class and (2) a "community of interests" shared by the class members).

### *Cohen v. DirecTV, Inc.*

This latter point was clarified further in Cohen v. DirecTV, Inc., 178 Cal.App.4th 966 (Cal. Ct. App. 2009). There, a DIRECTV subscriber brought a class action complaint against the satellite television company alleging violations of the UCL and the California Consumer Remedies Act (CLRA). *Id.* at 968. These allegations centered on DIRECTV's national advertising and marketing of its "HD Package" and plaintiff's contention that DIRECTV was not, in fact, transmitting its television signal at a true HD resolution, but rather at a lower resolution. *Id.* at 969-70. Plaintiff moved for class certification, which was denied by the trial court. *Id.* at 970-71. The California Court of Appeal, Second District, affirmed, finding that "common issues of fact do not predominate over [plaintiff's] proposed class because the members of the class stand in a myriad of different positions insofar as the essential allegation in the complaint is concerned, namely, that DIRECTV violated the CLRA and the UCL by inducing subscribers to purchase HD services with false advertising." *Id.* at 979. Further, the court found the In re Tobacco II decision irrelevant:

> because the issue of "standing" simply is not the same thing as the issue of "commonality." Standing, generally speaking, is a matter addressed to the trial court's jurisdiction because a plaintiff who lacks standing cannot state a valid cause of action. Commonality, on the other hand, and in the context of the class certification issue, is a matter addressed to the practicalities and issues of litigating a class action in the trial court. We see no language in *Tobacco II* which suggests to us that the Supreme Court intended our state's trial courts to dispatch with an examination of commonality when addressing a motion for class certification.

*Id.* at 981 (internal citations omitted). The Appellate Court found the trial court's determination that there would be individual questions associated with each class member's reliance on DIRECTV's alleged false representations to be proper grounds for the denial of plaintiff's motion. *Id.*

### *Wiener v. Dannon Co.*

In Wiener v. Dannon Co., 255 F.R.D. 658 (C.D. Cal. 2009), the Central District of California denied plaintiff's motion for class certification in a putative class action filed against The Dannon Company for allegedly misrepresenting the health benefits of Activia and Activia Light yogurt, as well as DanActive.

Activia and Activia Light – yogurt products containing the probiotic bacteria *Bifidus Regularis* – were both marketed by Dannon through television commercials, print media, in-store displays, and product promotions as "'scientifically proven' to naturally regulate digestion when eaten daily for two weeks." *Id.* at 663. Similarly, DanActive – a drinkable dairy product containing the probiotic bacteria Casei Immunitas – was marketed through the same channels as "'clinically proven' to strengthen the immune system." *Id.* According to Dannon, both of these claims were supported by clinical studies. *Id.* Plaintiff Weiner filed a class action complaint "alleging that Dannon violated both the [CLRA and the UCL], and breached express warranties to its consumers." *Id.* Weiner had purchased Activia, but had never purchased Activia Light or DanActive. *Id.* Weiner moved for class certification and to be appointed class representative of a class of "[a]ll persons who purchased in California at any time up to August 1, 2008, DanActive, Activia or Activia Light." *Id.*

In opposing Weiner's motion for class certification, Dannon argued that the plaintiff's "claims are not typical of the claims of DanActive purchasers, as the products, which were advertised separately, involve different health benefits that are supported by different studies." *Id.* at 665. Weiner countered that typicality *was* satisfied "because her legal theories are identical to those advanced on behalf of all potential class members and Dannon's course of conduct, its advertising suggesting that the products have clinically proven benefits, is identical for both Activia and DanActive purchasers." *Id.* The court agreed with Dannon's argument, noting that the different products claim different health benefits and target consumers with different health issues. *Id.* at 666. Further, these health benefits were allegedly substantiated by different studies, and the advertising and marketing of the products were separate. *Id.* According to the court, this all led to a substantial divergence in the evidence required to prove the claims with regard to Activia and DanActive, therefore making plaintiff's claims atypical compared to the rest of the class. *Id.* As such, plaintiff's motion for class certification was denied with leave to substitute an appropriate class representative. *Id.* at 673.

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