# In victory for Bayer, court rules that class failed to show vitamin claims are false or deceptive

Class Action Alert

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Bayer won a major victory last week in the Southern District of California when Judge Anthony Battaglia granted Bayer's motion for summary judgment, dismissing the plaintiffs' California class action in a comprehensive and well-reasoned 83-page opinion.

In its opinion, the court also granted Bayer's *Daubert* motion excluding the testimony of the plaintiffs' marketing expert.

DLA Piper has served as National Counsel to Bayer in the One-A-Day consumer class actions.

**The plaintiff's allegations**

In 2009, plaintiffs David Johns and Marc Bordman filed a class action against Bayer on behalf of a California class who purchased Bayer's One-A-Day Men's Health Formula and One-A-Day Men's 50+ Advantage (the products) between 2002 and 2009. They claimed that Bayer violated the California Legal Remedies Act and Unfair Competition Law, alleging false and deceptive advertising of prostate health benefits associated with the products.

The plaintiffs asserted there was no credible scientific evidence supporting Bayer's prostate health statements and that scientific evidence indicated the contrary. Specifically, plaintiffs challenged two statements made by Bayer: 1) the structure function claim on both products that the products "support prostate health;" and 2) the qualified health claim and related statements on One-A-Day Men's Health Formula packaging stating that emerging research suggests selenium may reduce the risk of prostate cancer (together, the "prostate statements").

**Bayer moved for summary judgment**

Bayer moved for summary judgment on three grounds, arguing that: 1) claims based on the qualified health claim were preempted by a 2003 FDA Letter approving a selenium qualified health claim; 2) the plaintiffs' claims were in fact "lack of substantiation" claims that inappropriately attempted to shift the burden of proof to Bayer; and 3) the plaintiffs had failed to proffer a viable measure of damages or restitution under the UCL and CLRA.

The court granted summary judgment based on the "lack of substantiation" argument. The court denied preemption and did not rule on the damages or restitution arguments, finding them moot.

**The lack of substantiation theory**

Bayer argued that the plaintiffs' evidence failed to raise a triable issue of fact that successfully demonstrated the prostate statements were false or deceptive. Rather, the court said, the plaintiffs had relied on a "lack of substantiation" theory – one that may be pursued only by regulatory agency enforcement, not by private parties. The plaintiffs contended that the prostate statements were unsubstantiated but also contended that the prostate statements were provably false or likely to deceive reasonable consumers.

***Falsity***. In its opinion, the court first addressed the plaintiffs' falsity argument. Bayer argued, and the court agreed, that based on the expert testimony, the plaintiffs had not raised a triable issue that the nutrients *did not* support prostate health and that selenium *did not* reduce the risk of prostate cancer. The court found that plaintiffs had attempted to shift the burden of proving the truth of the prostate statements to Bayer, and the court determined this attempt was inappropriate.

***Likely to deceive.*** The plaintiffs argued that whether or not the prostate statements were provably false, the plaintiffs could prevail by showing the prostate statements were likely to deceive a reasonable consumer, a question they argued was best left to a jury. The court disagreed, stating that the plaintiffs had not articulated how the prostate statements were deceptive, nor had they presented any proof of actual deception. Therefore, there was no evidence to put before a jury on the issue of deception.

The court explained that the plaintiffs' arguments based on alleged deception were circular, in that they were based on a lack of substantiation theory. In other words, in order to avoid the lack of substantiation barrier, the plaintiffs attempted to argue that Bayer's statements were deceptive, but even that claim depended on their contention that the statements were unsubstantiated. The court ruled that the plaintiffs had failed to raise a triable issue that the prostate statements were misleading or likely to deceive reasonable consumers.

**Preemption**

Bayer also argued an alternative ground for summary judgment that the plaintiffs' allegations based on Bayer's qualified health claim about selenium, along with introductory language Bayer used immediately preceding the qualified health claim, were preempted by the FDA's approval in 2003 of a specific qualified health claim about the benefits of selenium. [i]

The plaintiffs argued that they were not challenging the portion of the package labeling specifically approved by the FDA, but rather the introductory "emerging research" language preceding the FDA-approved statement. Bayer contended that the introductory language identifying prostate cancer and emerging research added precision, but did not expand the FDA-approved language. In other words, Bayer argued that its reference to the 2003 FDA Letter showed that "prostate cancer" is a more specific reference than "forms of cancer," and referring to "emerging research" essentially was the same as referring to "some scientific evidence."

The court ruled that the plaintiffs' claims would be preempted if the claims were based solely on the FDA-approved language. It also affirmed that federal agency action "short of formal notice and comment rulemaking" can preempt state law. However, the court denied preemption, based on its view that the language at issue exceeded the bounds of the language authorized by the FDA.

The court did not address the summary judgment arguments regarding damages as moot.

**Exclusion of plaintiffs' expert**

The plaintiffs and Bayer each filed extensive motions to exclude each other's science, marketing and damages experts under *Daubert*. Once the court ruled in favor of Bayer on its motion for summary judgment based on its determination that the plaintiffs' claims were based on "lack of substantiation," the respective motions to exclude the damages experts became moot. The court denied the parties' respective motions to exclude each other's science experts, Dr. Harry Milman (for the plaintiffs) and Dr. Jeffrey Blumberg (for Bayer) and in fact referenced their respective testimony extensively in analyzing the motion for summary judgment.

However, the court granted Bayer's motion to exclude the testimony of the plaintiffs' marketing expert, Thomas J. Maronick, who had offered the following opinions in the case:

- "[T]he one constant was that at all times throughout 2002-2009 and 2007-2009, both OAD Men's Health Formula and OAD Men's 50+ Advantage, respectively, stressed that the product promoted prostate health and/or reduced the risk of prostate cancer"
- "Even when other ingredients were added, the research showed that the 'driving force' or 'Reason to Believe' (RTB) the two sub-brands was the fact that they were specially formulated for prostate health"
- "Bayer's promotion of lycopene and later selenium as added ingredients were based on the, allegedly false, proposition that these ingredients promoted prostate health and/or reduced the risk of prostate cancer"

Bayer moved to exclude Maronick's opinions on the grounds that:

- his opinions were unreliable because they were not based on any scientific principles and methodology and contradicted undisputed facts
- Maronick's report and testimony was nothing more than a narrative history of documentary evidence and improperly parroted the conclusions reached by third party market research firms and others and
- the opinions were irrelevant as they failed to address any material issues in the case, namely whether there was evidence that consumers were likely to be deceived by the prostate statements.

The court ruled that Maronick's testimony was not admissible based on the second ground, finding his report was nothing more than a synopsis of Bayer's marketing that relied heavily on quotes from internal and external documents not helpful to the trier of fact. The court then ruled that the plaintiffs' motion to exclude Bayer's marketing rebuttal expert, Dr. Ravi Dhar, was moot.

*Johns* was one of three class action cases filed in Ohio, South Carolina, and California respectively, two of which resulted in judgment in Bayer's favor and one of which was settled after pre-trial rulings. DLA Piper served as National Counsel to Bayer in all of these consumer class actions.

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[i] The FDA-approved selenium qualified health claim states: "Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive." *Selenium and Certain Cancers (Qualified Health Claim: Final Decision Letter)*, Docket No. 02P-0457 (April 28, 2003).

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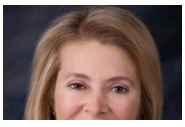

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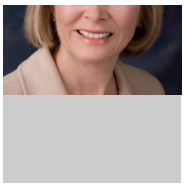

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