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Clerk, U.S. District & Bankruptcy
Courts for the District of Columbia

UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

POM WONDERFUL LLC, a Delaware Limited
Liability Company, 1144 West Olympic
Blvd.
Plaintiff, LOS ANGELES, CA
90064

v.

THE FEDERAL TRADE COMMISSION, a
United States Agency,
Defendant.

Case: 1:10-cv-01539
Assigned To : Roberts, Richard W.
Assign. Date : 9/13/2010
Description: Admin. Agency Review

**POM WONDERFUL LLC'S COMPLAINT
FOR:**

DECLARATORY RELIEF

COMPLAINT FOR DECLARATORY RELIEF

Plaintiff POM Wonderful LLC ("POM" or "Plaintiff") alleges as follows:

I. NATURE OF ACTION

1. The Federal Trade Commission ("FTC") is a powerful federal agency.
2. The FTC is empowered, among other things, to regulate health related claims in food advertising pursuant to its statutory authority to prohibit deceptive practices under Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45, 52. The Agency's powers to regulate food advertising are derived solely from that statute.
3. While the FTC may focus the weight of its vast resources against companies that are arguably engaged in the manufacture of unsafe products, the FTC may also target companies that provide admittedly safe, and even healthy products to market. The FTC's focus on POM, for example, is based entirely upon POM's promotion of pomegranate products.
4. The FTC's powers, however, are not unlimited. The FTC may not enact new rules that exceed the powers granted to it by Congress or by statute or do so in a manner that

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violates the FTC's own rulemaking procedures, or the First and Fifth Amendments. The FTC may not encroach upon the jurisdiction reserved for the Food and Drug Administration ("FDA") or attempt to enforce the Federal Food, Drug, and Cosmetic Act ("FDCA"). Nor can the FTC impose an undue hardship on individuals or companies by suddenly changing direction in the criteria it uses to evaluate deceptive advertising (that are completely opposite and contrary to its previous rules and policies) to the detriment of those who have reasonably relied on past policy. Yet this is precisely what the FTC has done.

5. The FTC has now both (1) represented to POM and (2) announced to the food industry through two recently published consent orders against Nestle U.S.A. and Iovate Health Sciences, Inc. (the "Nestle and Iovate Consent Orders") that the FTC has adopted a "new standard" and set of requirements that it is universally applying against food and dietary supplement companies to determine whether an individual or company is engaged in deceptive advertising. However, the new measures of "deceptive" advertising now invoked by the FTC are directly contrary to over twenty (20) years of FTC food advertising rules and regulations, and contrary to law, including the First and Fifth Amendments.

6. The new requirements now adopted by the FTC directly contravene its prior focus on "deceptive" advertising and significantly alter the criteria that advertisers may use to establish the truth of their advertising. Specifically, (1) the FTC now requires advertisers to obtain prior FDA approval before making certain types of health related claims about food, beverages, and dietary supplements, specifically, "disease claims," which represent that a product treats, mitigates, or prevents disease – ***and the FTC is requiring prior FDA approval regardless of whether or not the claims are true or supported by competent, reliable scientific evidence***; and (2) the FTC is also now requiring two "well controlled" clinical studies for non-disease claims, which also represents a dramatic change in the level of substantiation required to establish the truth of these types of claims.

7. Until now, the FTC had regulated only “deceptive” speech or advertising, in accordance with its given scope of authority under the FTC Act. The FTC never before required prior approval of advertising statements by any agency or the FDA. As admitted by the FTC in its previously published comments submitted to the FDA, invoking such a requirement, in effect, constitutes a ban on both deceptive speech and non-deceptive speech, the latter of which is protected by the First Amendment.

8. Specifically, the FTC has engaged and is engaging in the following unlawful and unauthorized conduct in violation of POM’s rights and resulting in immediate injury to POM:

- (a) The FTC has promulgated new rules that garner for itself greater jurisdictional authority and power than permitted by Congress and its own published rules—*i.e.* the FTC, by now requiring that certain categories of health benefit advertising, *even if not deceptive*, require prior FDA approval, is exceeding its authority under Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 47, 52, which authorize the FTC to regulate and prevent “deceptive” acts or practices in food advertising. The FTC is also encroaching upon the exclusive authority reserved for the FDA;
- (b) The FTC has promulgated rules that create an outright ban on non-deceptive, protected speech, which by the FTC’s own admission (in published comments the FTC submitted to the FDA) violate the First Amendment rights of advertisers; and
- (c) The FTC has promulgated rules, without adhering to its own rulemaking procedures, that substantially change the legal definition of deceptive advertising in food before the FTC. Before implementing such rules that effectively redefine “deceptive” advertising, the FTC was required to engage in formal rulemaking procedures under Section 18 of the FTC Act,

15 U.S.C. § 57(a), and 5 U.S.C. § 553, which it failed to do.

9. The FTC's conduct above has resulted in immediate and significant injury to POM, and disrupted POM's present and ongoing business. POM, to its detriment, has relied on the FTC's long-standing policies and rules that used a "substantiation" standard to evaluate advertising and speech. POM invested tens of millions of dollars in funding independent research and in establishing a research program to better understand and promote the nutritional qualities and health benefits of pomegranates. The new FTC rules essentially bar POM from discussing or disclosing the results of its research and the benefits of its products.

10. The FTC's actions above have detrimentally impacted POM's freedom of speech now, the value of its research program now, and are violating its First and Fifth Amendments rights.

11. In depending on well-settled FTC rules, POM methodically and incrementally developed a science strategy predicated on the expectation that this science could and would be used to benefit consumers and the public through the dissemination of this truthful information in advertising. The FTC's abrupt change in the rules depreciated POM's investments in its science program and marketing strategy that reasonably relied upon a clear line of demarcation between the FDA and FTC, and that did not assume prior restraints on truthful speech. In addition, POM has spent millions establishing a brand identity that is synonymous with good health. The FTC, by its acts, is injuring POM's goodwill and brand identification with consumers as the juice company that focuses on science and good health.

12. Accordingly, POM herein seeks a declaratory judgment by the Court that: (a) the FTC's new standards are invalid; (b) the FTC exceeded its statutory jurisdiction under Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45, 52; (c) the FTC violated the First and Fifth Amendments; (d) the FTC's implementation of these rules violated the FTC's own rulemaking procedures under Section 18 of the FTC Act, 15 U.S.C. § 57(a), and 5 U.S.C. § 553; and (e) the

FTC's actions are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

II. PARTIES

13. Plaintiff POM is a Delaware limited liability company with its principal place of business in Los Angeles, California.

14. POM is the largest processor and distributor of pomegranates and pomegranate products in the United States.

15. POM produces, markets and sells POM WONDERFUL® brand bottled pomegranate juice, and various other pomegranate products. POM has been bottling, selling and marketing its juice products since 2002. POM has invested millions of dollars to research and promote the nutritional qualities and health benefits associated with pomegranate juice, including emphasizing the high level of antioxidants contained in POM WONDERFUL® brand juices.

16. Defendant FTC is an independent administrative agency of the United States Government, organized pursuant to the Federal Trade Commission Act, 15 U.S.C. §§ 41, *et seq.* The principal office of the FTC is in Washington, D.C.

III. JURISDICTION AND VENUE

17. This action seeks declaratory relief under the Federal Declaratory Judgment Act, 28 U.S.C. § 2201.

18. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1346 because all causes of action arise under the Constitution and laws of the United States.

19. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(e).

20. There exists currently an actual and justiciable controversy between the parties regarding the constitutionality of the FTC's conduct, the scope of the FTC's authority and the

meaning of United States statutes and FTC regulations.

21. Declaratory relief will resolve this controversy and is necessary to eliminate the immediate effect that the FTC's pronouncements have had on POM's current operations, including its research and advertising programs. Declaratory relief is also necessary to eliminate the chill that the FTC's new standards have had and continue to have on POM's First and Fifth Amendment rights.

IV. GENERAL ALLEGATIONS

22. Under Section 5 of the Federal Trade Commission Act (15 U.S.C. §§ 41-58) ("FTC Act"), the FTC has broad authority to, among other things, investigate and prosecute individuals and organizations for engaging in deceptive advertising under the FTC Act. The FTC may also use the threat of litigation before its own agency to leverage "consent agreements." The FTC may also promulgate rules defining deceptive acts or practices under Section 18 of the FTC Act (15 U.S.C. § 57a) and 5 U.S.C. § 553. This legislation was adopted to ensure that the FTC adheres to adequate rulemaking and notice procedures to provide affected parties with their requisite due process rights.

23. The FTC specifically advised POM that it is now applying a "new standard" of review for deceptive advertising to POM and to the food and dietary supplement industry as a whole. The FTC specifically referred POM to the Nestle and Iovate Consent Orders and represented to POM that the requirements in these Consent Orders constitute the "new standard" that the FTC is now applying universally with legal force and effect. The FTC provided POM with the recently published Consent Orders to make its point that these standards have the force and effect of law, that they delineate the new definition of deception, and that the new requirements are enforceable against POM and the industry as a whole.

24. These published Consent Orders in fact served as vehicles to communicate the

universal application of these new policies and compel the entire food and dietary supplement industries to follow these policies. The FTC's enforcement mechanism through the Nestle and Iovate Consent Orders was no less effective and coercive than direct enforcement through a formal regulation. Without more, these published consent agreements provided a significant chilling effect on speech and conduct by third parties, though their conduct may in all respects be proper and lawful. The FTC's specific referral to POM of these Consent Orders, further confirmed the legal effect of these pronouncements.

25. The new standards reflected in the Nestle and Iovate Consent Orders are not merely interpretive of present standards or rules. Instead, they are directly contrary to over twenty (20) years of FTC food advertising rules and regulations and contrary to law, including the First and Fifth Amendments. Furthermore, the FTC was required to engage in formal rulemaking before implementing these new rules.

25. The FTC is now requiring advertisers to (1) obtain prior FDA approval before making certain types of health related claims about food, beverages, and dietary supplements, specifically, "disease claims" which represent that a product treats, mitigates, or prevents disease – *and the FTC is requiring prior FDA approval regardless of whether or not the claims are true or supported by competent, reliable scientific evidence*; and (2) conduct two "well controlled" clinical studies for non-disease claims, which also represents a dramatic turn in the level of substantiation required to establish the truth of these types of claims.

26. Until now, the FTC had regulated only "deceptive" speech or advertising, in accordance with their given scope of authority under the FTC Act. The FTC never before required prior approval of advertising statements by any agency or the FDA. The FTC has admitted in its own previously published comments that this requirement constitutes a ban on both deceptive speech and non-deceptive speech, the latter of which is protected by the First Amendment.

27. Specifically, the new measures of “deceptive” advertising now invoked by the FTC directly contravene its prior focus on “deceptive” advertising and significantly alter the criteria that advertisers and POM may use to establish the truth of their advertising. The FTC previously determined whether a health related claim was deceptive by evaluating whether, at the time of making the representation, the advertiser possessed and relied upon “competent, reliable scientific evidence” to substantiate the representation. This has now changed. In now requiring a prior determination by the FDA for “disease claims,” the FTC has unlawfully substituted the long-held FTC rules that appropriately allowed advertisers and POM to substantiate the truth of all of their claims, with a complete bar (and prior restraint) on speech that includes non-deceptive speech protected by the First Amendment. The FTC is now violating POM’s (and other third parties’) First Amendment rights.

28. As also reflected in the Iovate Consent Order specifically, the FTC now prohibits an advertiser from making certain health benefit claims even if it has satisfied traditional substantiation standards, unless the advertiser also has two “well-controlled” clinical studies. This also reflects a significant departure from the FTC’s prior rules defining the level of substantiation required to establish the truth of these types of health related claims.

29. The FTC’s promulgation of new rules garner for itself greater jurisdictional authority and power than permitted by Congress and its own published rules. The FTC, by now requiring that certain categories of health benefit advertising require prior FDA approval, *even if not deceptive*, is exceeding its authority under Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45, 52, which authorize the FTC to regulate and prevent “deceptive” acts or practices in food advertising. In doing so, the FTC is now seeking to sanction parties solely for making claims that have not been expressly approved by the FDA and is usurping the exclusive authority of the FDA to enforce the FDCA. But, Congress has made it clear that neither the FTC, nor any federal agency other than the FDA, has authority to enforce the FDCA.

30. The FTC has also violated its own rulemaking procedures, as these new standards substantially change the legal definition of deceptive advertising in food before the FTC. The FTC was required to engage in a formal rulemaking process under Section 18 of the FTC Act, 15 U.S.C. § 57a, and The Administrative Procedure Act, 5 U.S.C. § 553, but failed to do so.

31. The new requirements impose significant new burdens and risks on advertisers, including POM, by requiring a pre-approval process that is highly discretionary and contingent in nature, burdensome and which could take years for the advertisers and the FDA to consider and complete. The FTC's sudden promulgation of its "new standards" has depreciated POM's investment in its science program as well as its marketing strategy, which did not assume prior restraints on truthful speech. The FTC's actions have also damaged POM's goodwill and brand identification as the juice company that focuses on science and good health. The FTC's actions above are affecting POM's advertising now, the value of its research program now, and violating its First and Fifth Amendments rights.

FIRST CAUSE OF ACTION

**[For Declaratory Judgment that the FTC Is Acting Beyond
Its Jurisdiction and Powers]**

32. POM repeats and realleges paragraphs 1 through 31 of this complaint as though fully set forth therein.

33. Pursuant to 5 U.S.C. § 706(2)(C), a reviewing court shall hold unlawful and set aside agency action found to be "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right."

34. The FTC has exceeded its statutory jurisdiction under Sections 5 and 12 of the FTC Act by: (i) requiring advertisers to obtain prior FDA approval before making certain types of health related claims, regardless of whether or not the claims are true; and (ii) imposing new substantive rules on POM and other advertisers without using the necessary rulemaking

procedures that require notice and comment. By doing so, the FTC is attempting to enforce the FDCA, which role Congress expressly and solely assigned to the FDA.

35. The FTC's newly adopted standards constitute a final agency action within meaning of 5 U.S.C. § 704.

36. An actual and justiciable controversy exists between the parties, for which there exists no adequate remedy other than that requested herein.

SECOND CAUSE OF ACTION

[For Declaratory Judgment that the FTC's New Standard Violates POM's Constitutional Rights under First and Fifth Amendments]

37. POM repeats and realleges paragraphs 1 through 36 of this complaint as though fully set forth therein.

38. Pursuant to 5 U.S.C. § 706(2)(B), a reviewing court must hold unlawful and set aside agency action found to be "contrary to constitutional right, power, privilege, or immunity."

39. The First Amendment protects POM's truthful, non-misleading speech concerning its pomegranate products.

40. The FTC's newly adopted standard requiring prior FDA approval of certain categories of health related claims represents an improper prior restraint on protected speech in violation of the First Amendment, and prevents POM and other members of the regulated community from truthfully advertising the health benefit attributes of its products that are based on competent, reliable scientific data.

41. The FTC's newly adopted requirements, as expressed by the FTC to POM, have legal force and effect and are being applied against POM as well as the industry as a whole as reflected in the Nestle and Iovate Consent Orders. These new standards have deprived POM of due process of law in violation of the Fifth Amendment. POM has a substantial property interest in the scientific research it has funded. POM has also invested significantly in its advertising and

marketing for its pomegranate products. By adopting the new requirements without affording POM any due process under law or adhering to the FTC's own rulemaking procedures, the FTC diminished the value of POM's research program and strategy.

42. The FTC's newly adopted standards constitute a final agency action within meaning of 5 U.S.C. § 704.

43. An actual and justiciable controversy exists between the parties, for which there exists no adequate remedy other than that requested herein.

THIRD CAUSE OF ACTION

[For Declaratory Judgment that the FTC Has Violated Its Own Rulemaking Procedures and the Administrative Procedure Act]

44. POM repeats and realleges paragraphs 1 through 43 of this complaint as though fully set forth herein.

45. Pursuant to 5 U.S.C. § 706(2)(D), a reviewing court shall hold unlawful and set aside agency action found to have been taken "without observance of procedure required by law." The procedures required for promulgating a rule are set forth in 5 U.S.C. § 553. They include the publication of notice of a proposed rule and the opportunity for public comment.

46. The FTC has failed to adhere to the rulemaking procedures under Section 18 of the FTC Act, 15 U.S.C. § 57(a), and the requirements set forth in 5 U.S.C. § 553. The FTC has in fact adopted entirely new substantive rules with universal application and has advised POM of the same. These new rules are a complete turnabout from the FTC's previous "substantiation" requirements and/or depart significantly from the FTC's previously established food advertising standards. These standards have substantially redefined with specificity the definition of "deceptive" advertising within the meaning of 15 U.S.C. § 45(a)(1).

47. POM has been and continues to be prejudiced by the FTC's imposition of the FTC's new rules that were implemented without the FTC's compliance with its own rulemaking

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requirements, or any other adequate form of notice of the change in enforcement standards.

48. The FTC's newly adopted standards constitute a final agency action within meaning of 5 U.S.C. § 704.

49. An actual and justiciable controversy exists between the parties, for which there exists no adequate remedy other than that requested herein.

FOURTH CAUSE OF ACTION

[For Declaratory Judgment that the FTC's Action Is Arbitrary, Capricious, and an Abuse of Discretion Under 5 U.S.C. § 706(2)(A)]

50. POM repeats and realleges paragraphs 1 through 49 of this complaint as though fully set forth herein.

51. Pursuant to 5 U.S.C. § 706(2)(A), a reviewing court must hold unlawful and set aside agency action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

52. The FTC has acted arbitrarily, capriciously, and contrary to law. The FTC has ignored its own rulemaking procedures and there does not exist any reasonable relationship between preventing deceptive advertising and barring outright any statements making disease claims in advertising unless the FDA has given its prior approval.

53. Because application of the FTC's new standard to POM, and other members of the regulated food and dietary supplement community, is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, it must be set aside.

54. The FTC's newly adopted standards constitute a final agency action within meaning of 5 U.S.C. § 704.

55. An actual and justiciable controversy exists between the parties, for which there exists no adequate remedy other than that requested herein.

PRAYER FOR RELIEF

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WHEREFORE, POM respectfully requests that this Court:

- (a) Declare invalid the new requirements imposed by the FTC against POM;
- (b) Declare that the FTC has exceeded its statutory jurisdiction under Sections 5 and 12 of the FTC Act;
- (c) Declare that the FTC's newly adopted standard requiring prior FDA approval of certain categories of health benefit claims:
 - (i) represents an improper prior restraint on protected speech in violation of the First Amendment; and
 - (ii) deprives POM of due process of law in violation of the Fifth Amendment;
- (d) Declare that the FTC has failed to adhere to the rulemaking procedures under Section 18 of the FTC Act, 15 U.S.C. § 57(a), and the requirements set forth in 5 U.S.C. § 553;
- (e) Declare that the FTC has acted arbitrarily, capriciously, and contrary to law;
- (f) Award POM its costs; and
- (g) Award POM such other and further relief which the Court deems just and proper.

Respectfully Submitted,

DATED: September 13, 2010

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