

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

15 CV 01866

MCNEIL-PPC, INC. and MCNEIL CONSUMER  
HEALTHCARE,

No. 15 Civ. \_\_\_\_

Plaintiffs,

Complaint

- against -

Plaintiff Demands Trial By Jury

JUDGE SWAIN

GLAXOSMITHKLINE CONSUMER  
HEALTHCARE L.P.,

Defendant.

RECEIVED  
MAR 12 2015  
U.S.D.C. S.D. N.Y.  
CASHIERS

Plaintiffs McNeil-PPC, Inc. and McNeil Consumer Healthcare (together  
“McNeil”), by their attorneys Kramer Levin Naftalis & Frankel LLP, for their complaint against  
defendant GlaxoSmithKline Consumer Healthcare L.P. (“GSK”), allege as follows:

Introduction

1. This is an action for false advertising under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and deceptive acts and practices and false advertising under N.Y. Gen. Bus. Law §§ 349 and 350.

2. McNeil distributes and markets Zyrtec<sup>®</sup>, an over-the-counter (“OTC”) antihistamine that is the best-selling single-ingredient allergy pill on the market by dollar sales. McNeil also distributes and markets Benadryl<sup>®</sup>, an OTC antihistamine that is the best-selling single-ingredient allergy pill on the market by unit sales.

3. At the outset of the Spring allergy season, GSK has recently launched a competing OTC allergy relief product, Flonase<sup>®</sup> Allergy Relief (“Flonase”), and has saturated the

market with advertising that falsely and misleadingly targets Zyrtec and Benadryl in an effort to acquire a customer base at the expense of McNeil's hard-earned reputation and market share. McNeil seeks to halt Flonase's advertising before more damage is done at the end of March through May, the prime season for sales of OTC allergy pills.

4. GSK's campaign uses the prominent tagline that Flonase "OUTPERFORMS THE #1 ALLERGY PILL," expressly basing this claim, in some advertising, on "a head-to-head trial" in which Flonase supposedly "outperformed the #1 allergy pill in providing nasal symptom relief" and, more extensively, on a comparison of "Total nasal symptoms vs. leading allergy pill." Apparently on the theory that a comparison to a single-ingredient product was appropriate, the GSK study or studies referred to tested Flonase against the single-ingredient allergy pill, Claritin<sup>®</sup>. But Claritin is not the best-selling single-ingredient allergy pill and there is no testing that demonstrates superiority for Flonase over either Zyrtec or Benadryl. Indeed, a separate GSK clinical study shows that there is no statistically significant difference between Flonase and Zyrtec in providing nasal symptom relief and that any numerical differences between the products that were observed are "unlikely to be clinically relevant."

5. In correspondence between the parties beginning in January, 2015, McNeil demanded that GSK either discontinue or modify the "OUTPERFORMS THE #1 ALLERGY PILL" claim by specifically referring to Claritin. GSK refused and instead began in mid-February, 2015 to air a television commercial making yet another false claim. In addition to repeating the claim that Flonase "OUTPERFORMS THE #1 ALLERGY PILL," GSK's commercial falsely and misleadingly communicates that Flonase controls 6 allergy symptoms while the "leading allergy pill only controls 1." In fact, Zyrtec and Benadryl do not treat just one

allergy symptom; rather both are each indicated for sneezing, itchy watery eyes, runny nose, and itchy throat or nose.

6. With the prime allergy sales season quickly approaching, McNeil will be irreparably harmed if GSK is allowed to continue its false and misleading comparative claims. That harm is exacerbated by the timing of GSK's advertising just as the prime allergy season is beginning and by the fact that GSK is investing heavily in promoting its new product launch with these claims.

7. GSK's false claims are also detrimental to consumers. Medications such as Zyrtec and Benadryl are critically important to the millions of allergy sufferers who experience symptoms that are often debilitating. During allergy season, these consumers may be particularly susceptible to the kinds of claims GSK is making and may be deceived into falsely believing that Flonase provides better allergy relief than Zyrtec and Benadryl, and therefore unnecessarily change allergy medications.

8. By this action, McNeil seeks to (i) enjoin GSK from continuing to make false and misleading claims that its product "OUTPERFORMS THE #1 ALLERGY PILL"; (ii) enjoin GSK from continuing to make false and misleading claims that its product provides "greater" symptom relief than Zyrtec or Benadryl and that these pills treat only one allergy symptom; (iii) require GSK to disseminate corrective advertising; and (iv) recover damages for the substantial harm caused by GSK's false and misleading advertising.

The Parties, Jurisdiction and Venue

9. Plaintiff McNeil-PPC., Inc., is a New Jersey corporation with its principal place of business at 199 Grandview Road, Skillman, New Jersey 08558. Plaintiff McNeil Consumer Healthcare is a Division of McNeill-PPC, Inc. and has a principal place of business at 7050 Camp Hill Road, Fort Washington, Pennsylvania 19034. McNeil develops, distributes and markets a broad range of well-known, trusted and high-quality consumer healthcare products, including allergy products that are sold under the Zyrtec and Benadryl brand names.

10. GSK is a Pennsylvania limited partnership with its principal place of business at 100 GSK Drive, Moon Township, Pennsylvania 15108. GSK also distributes and markets consumer healthcare products, including its allergy product Flonase. Flonase is sold throughout the United States, including the State of New York.

11. This action is based on Section 43(a) of the Lanham Act, 15 U.S.C. § 1125, and Sections 349 and 350 of the New York General Business Law. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 for the claim arising under the Lanham Act, and 28 U.S.C. §§ 1332 and 1367 for the claims arising under New York statutory law.

12. Venue is properly laid in this district pursuant to 28 U.S.C. § 1391.

The Products at Issue in the OTC Allergy Market

13. Zyrtec and Benadryl are single active ingredient allergy pills, known as single-ingredient pills, containing the active ingredients Cetirizine and Diphenhydramine, respectively, which are clinically proven antihistamines that provide relief from allergy symptoms.

14. Zyrtec is indicated for the temporary relief of the following symptoms due to hay fever or upper respiratory allergies: sneezing, itchy watery eyes, runny nose, and itchy throat and nose. Benadryl is indicated to treat the same symptoms.

15. Since the launch of Zyrtec in 2008 and McNeil's acquisition of the Benadryl brand in 2006, McNeil has made significant expenditures on promotion and advertising to inform retailers and consumers about the efficacy of its OTC allergy pills. To date, McNeil has spent nearly a billion dollars on marketing and advertising of Zyrtec, and millions of dollars on marketing and advertising for Benadryl. Among other things, McNeil has promoted Zyrtec to retailers as the leading single-ingredient allergy medication.

16. Since their launch, retail sales of Zyrtec and Benadryl have been strong and to date amount to billions of dollars for Zyrtec, and approximately one billion dollars for Benadryl. Millions of allergy sufferers have controlled their allergy symptoms by regular use of Zyrtec or Benadryl.

17. A major competitor of McNeil in the OTC allergy relief space is Bayer, which distributes and markets the single-ingredient allergy pill Claritin<sup>®</sup>. The active ingredient in Claritin is Loratadine. Like Zyrtec and Benadryl, Claritin is indicated for the temporary relief

of the following allergy symptoms: runny nose, sneezing, itchy watery eyes, and itchy nose and throat.

18. Zyrtec is the #1 single-ingredient allergy pill in dollar sales for calendar year 2015 to date, and for the 52 week period ending February 14, 2015. Zyrtec was also the #1 selling single-ingredient allergy pill in dollars for all of calendar year 2014.

19. Benadryl is the #1 single-ingredient allergy pill in unit sales for calendar year 2015 to date and for the 52 week period ending February 14, 2015. Benadryl also was the #1 selling single-ingredient allergy pill in units for all of calendar year 2014. If unit sales are equalized across the category to account for doses and pill count in a package or bottle, Zyrtec would be the #1 single-ingredient allergy pill in unit sales for the calendar year 2014, year-to-date 2015, and the 52 week period ending February 14, 2015.

20. In addition to Zyrtec, McNeil distributes and markets a product called Zyrtec-D. Unlike the single-ingredient allergy pill Zyrtec, Zyrtec-D is a combination product containing both the active ingredient Cetirizine, and a nasal decongestant, Pseudoephedrine Hydrochloride. In addition to temporarily relieving sneezing, itchy watery eyes, runny nose, and itchy throat or nose, Zyrtec-D has an indication for nasal decongestion.

21. Bayer also distributes and markets a combination product containing a decongestant. Called Claritin-D, Bayer's combination product contains the active ingredients Loratadine and Pseudoephedrine Sulfate, and bears an additional indication for nasal congestion.

22. GSK's Flonase is an OTC nasal spray, previously available only in prescription form, which was first launched in retail outlets in late January, 2015. The active ingredient in Flonase is Fluticasone Propionate. Flonase is indicated for the temporary relief of nasal congestion, runny nose, sneezing, itchy nose and itchy, watery eyes.

GSK's False and Misleading Advertising

The "OUTPERFORMS THE #1 ALLERGY PILL" Tagline

23. The centerpiece of GSK's launch advertising for its OTC Flonase allergy medicine is that Flonase "OUTPERFORMS THE #1 ALLERGY PILL." The following image from the homepage on the Flonase website is illustrative of GSK's prominent use of this claim:



<https://www.flonase.com/about/> (last visited March 12, 2015).

24. In addition to the Flonase website, GSK makes the "THE #1 ALLERGY PILL" claim in numerous advertising media, including television advertising, a handout distributed in retail stores such as Sam's Club, signage in the allergy relief aisle in stores such as Walmart, and on the Flonase product listing page on the Walmart website.

25. GSK expressly bases its claim that Flonase “OUTPERFORMS THE #1 ALLERGY PILL” on one or more comparative clinical trials. For example in its Walmart advertising, GSK claims that “[i]n a head-to-head trial, FLONASE® Allergy Relief outperformed the #1 allergy pill in providing nasal symptom relief.” (see <http://www.walmart.com/ip/Flonase-Allergy-Relief-0.54-fl-oz-120-metered-sprays/39456749>) (last visited March 12, 2015). In all of its advertising, GSK also ties the claim to this or other head-to-head studies by disclosing that it is based on a comparison of “Total nasal symptoms vs leading allergy pill.” See, e.g., *supra* ¶ 23 (<https://www.flonase.com/about/>)

26. The study or studies referenced by GSK do not show that Flonase outperforms Zyrtec or Benadryl. Rather, they compare Flonase and Claritin’s single-ingredient pill. GSK’s use of the phrase “allergy pill” in this context apparently reflects its belief that it is appropriate to compare its product, which contains a nasal decongestant, to a single-ingredient allergy pill rather than to a combination product with a decongestant such as Zyrtec-D or Claritin-D. But in the single-ingredient allergy medication product category, Claritin is not the “#1 allergy pill” whether measured by dollars, units or units equalized for dosage and pill count.

27. GSK’s claim that its studies demonstrate that it “Outperforms the #1 allergy pill” is literally false. Flonase does not outperform Zyrtec. To the contrary, a separate study conducted by GSK comparing Flonase and Zyrtec found that Flonase “administered once daily did not demonstrate statistically significant differences compared with cetirizine [Zyrtec] administered once daily for two weeks in the treatment of nasal symptoms of seasonal allergic rhinitis (SAR) in adults.” That study went on to note that “[t]he observed margin of difference was small in favor of [Flonase] but unlikely to be clinically relevant.” The claim is also false

with respect to Benadryl because the study or studies GSK refers to in its advertising do not establish that Flonase outperforms Benadryl.

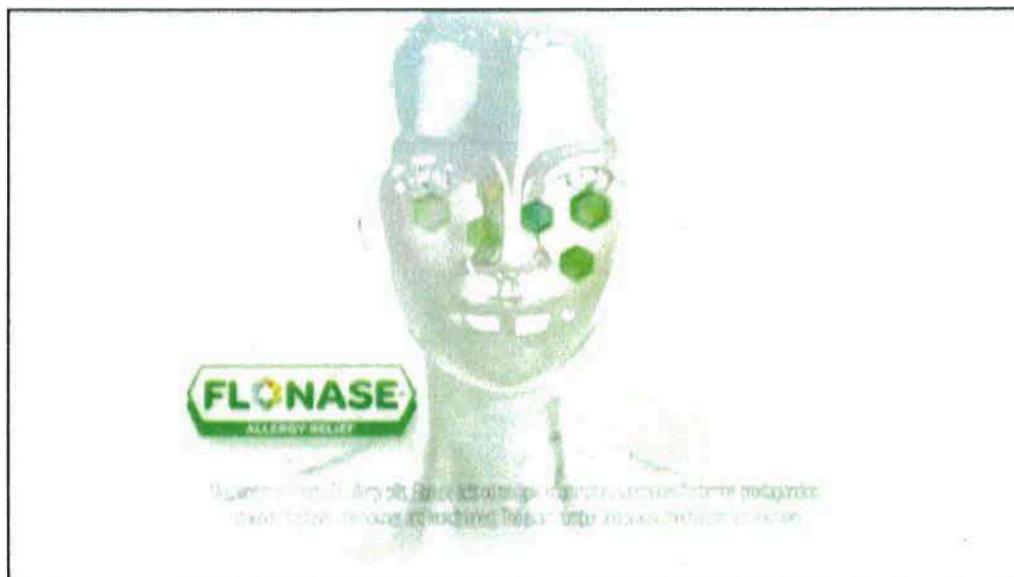
The “6 is greater than 1” Television Commercial

28. GSK’s television advertising for Flonase makes the false and misleading “#1 ALLERGY PILL” claim in conjunction with another false and misleading superiority claim. In a commercial expressly aimed at “introducing Flonase Allergy Relief Nasal Spray” to consumers as “now available over the counter in full prescription strength,” GSK states:

*When we breathe in allergens, our bodies react by overproducing 6 key inflammatory substances that cause our symptoms. The leading allergy pill only controls 1.*



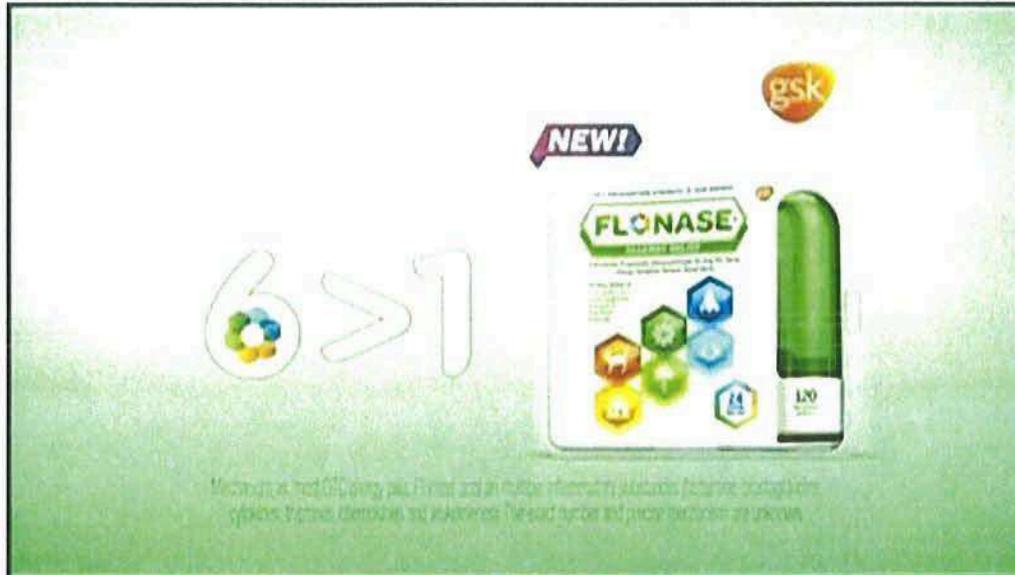
*Flonase controls 6 and 6 is greater than 1.*



*Flonase, the 24-hour relief...that outperforms the #1 allergy pill.*



*So go ahead, inhale life. New Flonase. 6 is greater than 1.  
This changes everything.*



29. GSK’s “6 is greater than 1” claim is either literally false or false by necessary implication. By linking the control of inflammatory substances to symptoms, GSK is unambiguously conveying that it controls six symptoms of allergies, while the “leading allergy pill only controls one.” As set forth above, Zyrtec and Benadryl — and Claritin for that matter — treat more than one allergy symptom, including sneezing, itchy watery eyes, runny nose, and itchy throat or nose. The commercial also unambiguously communicates that because Flonase controls six inflammatory substances, it provides better total symptom relief than the “leading allergy pill” and also (as the super states) “most OTC allergy pills,” which is false for the reasons explained above.

#### The Harm to McNeil and to the Public

30. GSK’s false and misleading advertising has caused and will continue to cause McNeil irreparable injury. The launch advertising for any new product, particularly during the peak selling period for a seasonal product such as allergy medicine, represents a unique and critical opportunity to gain market share and customer acceptance and loyalty for the product.

Advertising for a new product drives more focus from consumers, who have never heard of the product before.

31. The Spring allergy season lasts roughly from late March through the middle of May. A significant percentage of the annual retail sales for Zyrtec and Benadryl occur during allergy season, resulting in roughly \$10 million dollars a week in retail sales for Zyrtec and \$3.2 million dollars a week in retail sales for Benadryl.

32. By disseminating false comparative claims on the cusp of the Spring allergy season, GSK's actions threaten to harm McNeil's reputation and that of Zyrtec and Benadryl, thus jeopardizing McNeil's hard-earned standing and market share. Unless and until GSK is ordered to cease making its false and misleading claims and issue corrective advertising, McNeil stands to suffer a loss of its hard-earned sales, goodwill, and retailer and consumer confidence that would be incalculable and might never be recouped.

33. This injury is likely to be accelerated because GSK is pouring enormous resources into disseminating its advertising, which includes website ads, in-store materials and a television commercial that is being extensively aired on network television nationwide.

34. GSK's false and misleading advertising also poses a risk to consumers. If GSK's false advertising is not stopped, consumers will continue to take away the false message that Flonase outperforms Zyrtec and Benadryl, and that these pills only treat one allergy symptom. Consumers who are using Zyrtec or Benadryl to effectively control their allergy symptoms, which during prime allergy season can be severe, may be deceived into unnecessarily changing medications based on the false and misleading message that Flonase has been proven to outperform Zyrtec or Benadryl.

First Claim for Relief

35. McNeil repeats and realleges the allegations contained in paragraphs 1 through 34 of the complaint.

36. The claims and comparisons made by GSK in promoting Flonase are false and misleading and violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

37. The foregoing acts have occurred in, or in a manner affecting, interstate commerce.

38. Unless GSK is enjoined by this Court from continuing to make these claims and ordered to retract and correct them, GSK's false and misleading advertising will continue to cause McNeil to suffer a loss of consumer confidence, sales, profits, and goodwill which will irreparably injure McNeil.

39. McNeil has no adequate remedy at law.

Second Claim for Relief

40. McNeil repeats and realleges the allegations contained in paragraphs 1 through 34 and 38 of the complaint.

41. The above described acts constitute a deceptive act and practice, in violation of Section 349 of the New York General Business Law.

Third Claim for Relief

42. McNeil repeats and realleges the allegations contained in paragraphs 1 through 34 and 38 of the complaint.

43. The above described acts constitute false advertising in violation of Section 350 of the New York General Business Law.

Wherefore, McNeil respectfully requests that the Court:

(i) issue a preliminary and permanent injunction ordering that GSK, its agents, servants, employees, representatives, subsidiaries and affiliates refrain from directly or indirectly using in commerce or causing to be published or otherwise disseminated any promotional materials or activities stating or implying that Flonase “OUTPERFORMS THE #1 ALLERGY PILL”;

(ii) issue a preliminary and permanent injunction ordering that GSK, its agents, servants, employees, representatives, subsidiaries and affiliates refrain from directly or indirectly using in commerce or causing to be published or otherwise disseminated any promotional materials or activities stating or implying that Flonase treats six allergy symptoms whereas Zyrtec and Benadryl treat only one;

(iii) issue a preliminary and permanent injunction ordering that GSK, its agents, servants, employees, representatives, subsidiaries and affiliates refrain from

directly or indirectly using in commerce or causing to be published or otherwise disseminated any promotional materials or activities stating or implying that Flonase is “greater,” “better,” or otherwise outperforms Zyrtec or Benadryl;

(iv) issue a preliminary and permanent injunction ordering GSK to issue appropriate corrective advertisements, reasonably designed to reach all people to whom its false and misleading advertising was disseminated, retracting the false and misleading claims contained in the advertising; and

(v) award McNeil:

(a) GSK’s profits, gains and advantages derived from GSK’s unlawful conduct, such damages to be trebled pursuant to 15 U.S.C. § 1117;

(b) all damages sustained by McNeil by reason of GSK’s unlawful conduct, including all expenditures required to correct the false, misleading, unfair, and disparaging descriptions and representations alleged herein, such damages to be trebled pursuant to 15 U.S.C. § 1117;

(c) exemplary and punitive damages as the Court finds appropriate to deter any future willful conduct; and

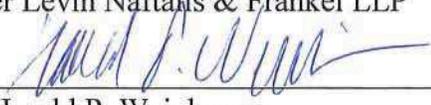
(d) interest on the foregoing sums;

(vi) award McNeil attorneys' fees and costs and disbursements of this action;  
and

(vii) grant such other and further relief as the Court deems just and proper.

Dated: New York, New York  
March 12, 2015

Kramer Levin Naftalis & Frankel LLP

By: 

Harold P. Weinberger

Norman C. Simon

Eileen M. Patt

Kurt M. Denk

1177 Avenue of the Americas

New York, New York 10036

(212) 715-9100

Attorneys for Plaintiffs

McNeil-PPC, Inc. and McNeil Consumer

Healthcare