

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

|                       |   |                    |
|-----------------------|---|--------------------|
| -----                 | : | X                  |
|                       | : |                    |
| BAYER HEALTHCARE LLC, | : |                    |
|                       | : |                    |
| Plaintiff,            | : | No. 22 Civ. 5931   |
|                       | : |                    |
| v.                    | : | <b>JURY DEMAND</b> |
|                       | : |                    |
| PERRIGO COMPANY PLC,  | : |                    |
|                       | : |                    |
| Defendant.            | : |                    |
|                       | : |                    |
| -----                 | : | X                  |

**COMPLAINT**

Plaintiff Bayer Healthcare LLC (“Bayer”), by its attorneys Simpson Thacher & Bartlett LLP for its Complaint against Defendant Perrigo Company plc (“Perrigo”), respectfully alleges as follows:

**NATURE OF THE ACTION**

1. This is a case about false advertising in the over-the-counter (“OTC”) allergy relief market. Defendant Perrigo is the maker of Nasonex 24HR Allergy (“Nasonex”), which obtained Food and Drug Administration (“FDA”) approval for sale in the highly competitive OTC market in March 2022. Plaintiff Bayer brings suit to stop Perrigo from misleading consumers about the length of time it takes for Nasonex to relieve allergy symptoms, both independently and relative to competitor products, such as those offered by Bayer. Bayer is the maker of Claritin and Claritin-D, which are antihistamine pills, and has recently launched Astepro, the first-ever antihistamine nasal spray to be in offered over-the-counter in the United States.

2. Perrigo's false advertising campaign is wrongly claiming that Nasonex works 2x faster than other OTC allergy sprays and that antihistamine pills and antihistamine sprays do not. The truth is that Nasonex is part of a class of steroid nasal sprays that take much longer to work than antihistamine medicines. Steroid nasal sprays take half a day to a full day to start to work, or longer. Antihistamines start to work much faster, some at 30 minutes, some at 60 minutes, some at 75 to 180 minutes after the first dose. Given the significant lag time for steroid allergy sprays to start working on the first dose, steroid-based sprays such as Nasonex have significantly longer onset times than antihistamine medicines and are not considered "fast" within the allergy relief market. Perrigo is egregiously misstating these facts to American consumers.

3. Perrigo's advertising campaign makes the untrue and unsupported claims that (1) Nasonex provides relief twice as fast as other OTC allergy sprays; (2) Nasonex "works" at 12 hours or 2x faster than leading nasal allergy sprays; (3) Nasonex provides "fast" relief; and (4) antihistamine pills and antihistamine sprays cannot be compared with respect to onset of action to other OTC steroid nasal sprays (collectively, the "False Onset Claims").

4. The False Onset Claims are false and misleading on their face and cannot be substantiated by clinical results.

5. *First*, Perrigo's claim that Nasonex provides allergy relief twice as fast as other OTC allergy sprays is false and misleading. Studies conducted to determine the onset speed of Nasonex have concluded that Nasonex begins to take effect, at the earliest, at 11 hours after use. In comparison, clinical studies show that other nasal allergy sprays, such as the leading competitor Flonase begin to relieve symptoms, at the earliest, at 12 hours after treatment.

6. *Second*, Perrigo’s claim that Nasonex “works” in 12 hours or 2x faster than leading nasal allergy sprays is misleading. In contrast to the advertisements, the Nasonex label states that consumers “*may* start to feel relief within 12 hours.” (emphasis added). Nasonex users can expect to experience “full effect [only] after several days of regular, once-a-day use.” Perrigo has glibly converted the FDA-required message that Nasonex “*may*” start to provide relief within 12 hours into a slick consumer promise that the products *will* provide relief at 12 hours or less – that is, two times faster than Flonase based on Perrigo’s misleading interpretation.

7. *Third*, Perrigo’s claim that Nasonex offers “fast” relief is incompatible both with clinical results and with industry standards. Industry standards require symptom relief versus placebo at one hour or less in order to qualify as “fast” relief. Nasonex’s onset time of 11 hours, at the earliest, does not meet this standard.

8. *Fourth*, Perrigo’s claim that, “*unlike allergy pills,*” Nasonex works “2X faster” than leading allergy steroid nasal sprays is flatly contradicted by clinical studies. Indeed, Bayer’s Claritin starts working in the range of 75 to 180 minutes, and Bayer’s Claritin-D starts working on allergies with nasal congestion in as little as 30 minutes. Thus, both Claritin and Claritin-D (collectively, the “Claritin Products”), which are “allergy pills,” have significantly earlier onset times than does Nasonex. In addition, Perrigo makes the demonstrably false claim that antihistamine pills and antihistamine nasal sprays cannot be compared with respect to onset of action with “other steroid nasal sprays,” by denoting both antihistamine pills and antihistamine sprays with an “N/A” in a chart showing which medicines work “2x faster” than steroid nasal sprays. Claritin-D, an antihistamine pill, and Astepro, an antihistamine spray, both start to work in as little as 30 minutes, *over twenty times faster* than both Nasonex and Flonase,

steroid nasal sprays. Even under a conservative calculation, Claritin starts to work *four times* faster than Nasonex and Flonase.

9. Bayer therefore brings this action to enjoin Perrigo's efforts to advertise false and misleading claims about the time within which Nasonex offers allergy symptom relief, and how Nasonex compares to competitor treatments with respect to symptom relief onset. The Court should immediately enjoin Perrigo from further dissemination of the False Onset Claims.

### **JURISDICTION AND VENUE**

10. This Court has subject matter jurisdiction over Bayer's claim for violation of Section 43(a) of the Lanham Act pursuant to Section 39 of the Lanham Act, 15 U.S.C. § 1121(a), and 28 U.S.C. §§ 1331, 1332 and 1338(a). This Court has supplemental jurisdiction over Bayer's claims for violation of New York's General Business statutes and common law pursuant to 28 U.S.C. §§ 1338(b) and 1367(a).

11. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) because Perrigo transacts business in this district, markets and sells its Nasonex product in this district, and, upon information and belief, maintains a manufacturing facility in the Bronx, New York.

### **PARTIES**

12. Plaintiff Bayer is a limited liability corporation organized under the laws of the state of Delaware and with its principal place of business in Whippany, New Jersey. Bayer is engaged in the business, among other things, of manufacturing and selling nonprescription, or OTC, medicines and other health and personal care products. Bayer's products include the Claritin Products, which are well-known OTC allergy treatments, as well as the recently launched OTC allergy nasal spray Astepro.

13. Upon information and belief, Defendant Perrigo is a corporation organized under the laws of the Republic of Ireland with its international headquarters in Dublin, Ireland. Perrigo's U.S. headquarters and principal place of business are located in Allegan, Michigan. Perrigo manufactures and sells a variety of OTC medicines in the U.S. market. Perrigo markets and sells its OTC nasal spray Nasonex in the U.S. market.

## **FACTUAL BACKGROUND**

### **The Products**

14. Bayer's Claritin Products and Astepro compete in the OTC allergy relief market with Perrigo's Nasonex. Allergy relief medicines treat the symptoms of an allergic reaction to indoor, outdoor, seasonal, and perennial (or year-round) allergens such as pollen and dust. Typical symptoms include nasal and sinus congestion, sneezing, runny nose, and an itchy throat or nose.

15. Allergy relief medicines rely on one or more of several mechanisms to counteract the symptoms of an allergic reaction. Antihistamines, like Astepro and the Claritin Products, relieve symptoms by blocking the absorption of the chemical histamine, which is released by the immune system during an allergic reaction and causes the symptoms. Decongestants, like the one in Claritin-D, relieve nasal and sinus congestion. Corticosteroids, like Nasonex and Flonase, counteract inflammation caused by one or more substances, including cytokines, that the body produces during an allergic reaction.

16. Allergy relief medicines are delivered via various application methods. Some medicines, like the Claritin Products, are taken orally in capsule, tablet, or oral solution form. Others, like Astepro and Nasonex, are taken via a nasal spray.

17. Bayer's Claritin is an oral antihistamine containing the active ingredient loratadine. Claritin offers temporary relief for allergy symptoms including runny nose, sneezing,

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