IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON

FEDERAL TRADE COMMISSION,
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Plaintiff,

v.

RECKITT BENCKISER GROUP PLC,
103-105 Bath Road
Slough, Berkshire, SL1 3UH, England

Defendant.

Case Number: 1:19CV00028

COMPLAINT

Complaint for Injunctive and Other Equitable Relief

Plaintiff, the Federal Trade Commission ("FTC"), by its designated attorneys, petitions this Court, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), for a permanent injunction and other equitable relief against Defendant Reckitt Benckiser Group PLC ("RB Group") to undo and prevent its unfair methods of competition in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

I. Nature of the Case

1. This case challenges anticompetitive conduct by RB Group, with and through its former subsidiary, Reckitt Benckiser Pharmaceuticals, now known as Indivior, Inc. ("Indivior"), to impede lower-cost generic competition to its lucrative opioid replacement therapy Suboxone. Until December 23, 2014, Indivior was a wholly owned subsidiary of RB Group.

2. Suboxone was originally sold in tablet form. By 2009, annual sales of Suboxone Tablets were more than $700 million. With no patent or regulatory exclusivity, however, RB

Group and Indivior expected competition from lower-cost generic versions of Suboxone Tablets would soon erode these substantial sales.

3. RB Group, through Indivior, promoted the sale or use of Suboxone Film using false and misleading claims that Suboxone Film was less susceptible to accidental pediatric exposure than Suboxone Tablets. These misrepresentations coerced a majority of consumers to switch to the more expensive Suboxone Film before the entry of lower-cost generic Suboxone Tablets, thereby preserving the lucrative Suboxone monopoly and harming consumers.

4. RB Group, through its subsidiary Indivior, also knowingly submitted a petition to the Food and Drug Administration on September 25, 2012, fraudulently claiming that Suboxone Tablets had been discontinued due to safety concerns about the tablet formulation of the drug, and took other steps to fraudulently delay the entry of generic competition for Suboxone in order to maintain higher prices for Suboxone.

II. Jurisdiction and Venue

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345.

6. This Court has personal jurisdiction over the Defendant pursuant to 15 U.S.C. § 53(b) and because Defendant has the requisite constitutional contacts with the United States of America.

7. Venue in this District is proper under 15 U.S.C. § 22, 28 U.S.C. § 1391(b) and (c), and 15 U.S.C. § 53(b). Defendant transacts business in, and committed an illegal act in, this District.

8. Defendant's general business practices and the unfair methods of competition alleged herein are "in or affecting commerce" within the meaning of Section 5 of the FTC Act, 15 U.S.C. § 45.

9. Defendant is, and at all times relevant herein has been, a corporation, as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

III. The Parties

10. Plaintiff Federal Trade Commission ("FTC") is an independent administrative agency of the United States Government, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. § 41 *et seq.*, with its principal offices in Washington, D.C. The FTC is vested with authority and responsibility for enforcing, *inter alia*, Section 5 of the FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to enjoin violations of any law the FTC enforces and to seek equitable monetary remedies.

11. Defendant Reckitt Benckiser Group PLC is a British corporation with a registered office at Turner House, 13-105 Bath Road, Slough, Berkshire, SLI 3UH, England. Defendant manufactures and markets numerous consumer products worldwide, including in the United States. Prior to 2013, Defendant was engaged in the business of selling prescription pharmaceutical products in the United States through its subsidiary, Indivior. Defendant participated in the anticompetitive conduct described in this complaint.

IV. Background

A. Generic drugs and substitution

12. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 355(b)(2) and 355(j) and 35 U.S.C. § 271(e), establishes procedures designed to facilitate competition from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.

13. A company seeking to market a new pharmaceutical product must file a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") demonstrating the safety and efficacy of the new product. These NDA-based products generally are referred to as "brand-name drugs" or "branded drugs."

14. A company seeking to market a generic version of a branded drug may file an Abbreviated New Drug Application ("ANDA") with the FDA and obtain approval without additional safety studies by showing that its generic product is therapeutically equivalent to the already-approved branded drug. 21 U.S.C. § 355(j)(2)(A)(iv). A therapeutically equivalent generic drug is "AB-rated" to the brand-drug, which means it is the same in active ingredient, dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.

15. AB-rated generic drugs can be substituted at the pharmacy to fill a prescription for the branded product. All 50 states and the District of Columbia have drug substitution laws that encourage and facilitate this type of substitution. When a pharmacist fills a prescription written for a branded drug, these laws allow or require the pharmacist to dispense an AB-rated generic version of the drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise.

16. State substitution laws were enacted in part because the pharmaceutical market does not function well. In a well-functioning market, a consumer selects and pays for a product after evaluating the product's price and quality. In the prescription drug market, however, a patient can obtain a prescription drug only if the doctor writes a prescription for that particular drug. The doctor who selects the drug does not pay for it, and therefore generally has little incentive to consider price. State substitution laws are designed to correct this market

imperfection by shifting the drug selection choice from physicians to pharmacists and patients who have greater financial incentives to make price comparisons.

17. The Hatch-Waxman Act and state substitution laws have succeeded in facilitating lower-cost generic competition: generic drugs typically capture over 80% of a branded drug's sales within six months. Generic drug products are usually far cheaper than the branded version—with discounts often reaching 85% or more off the brand price. Thus, generic competition has generated large savings for patients, health care plans, and federal and state governments. The Generic Pharmaceutical Association has reported that use of generic versions of brand-name drugs saved the U.S. healthcare system $265 billion in 2017 alone.

B. Suboxone

18. Suboxone is a prescription pharmaceutical product approved for the treatment of opioid addiction. It is a combination of the opioid buprenorphine and the opioid antagonist naloxone. Buprenorphine is the only opioid approved for the treatment of opioid addiction outside of a clinic. It binds to opioid receptors and reduces withdrawal symptoms. Naloxone has no therapeutic role but instead functions as an abuse deterrent; if Suboxone is crushed and injected, the naloxone triggers immediate withdrawal symptoms. When Suboxone is taken orally, as intended, the naloxone has no effect.

19. Indivior obtained FDA approval for Suboxone Tablets in 2002. Suboxone Tablets are an oral tablet form of Suboxone intended to be dissolved under the tongue.

20. The FDA designated Suboxone Tablets as an orphan drug under 21 C.F.R. § 316 because it was the first buprenorphine drug approved for the treatment of opioid addiction and the FDA believed that Indivior would not recover the cost of developing the product. Indivior thus received seven years of exclusivity, during which time no generic Suboxone Tablets could be approved. Suboxone proved far more successful than the FDA anticipated. By 2009,

Suboxone annual sales had grown to more than $700 million. Suboxone Tablets lost all exclusivity in 2009, making them subject to possible generic competition.

21. On October 20, 2008, Indivior filed an NDA for Suboxone Film. The FDA approved the NDA on August 30, 2010, and Indivior launched the product in September 2010.

22. Suboxone Film contains the same active ingredients and is clinically interchangeable with Suboxone Tablets. Any differences between the two formulations are clinically insignificant. For example, Suboxone Film strips are packaged in individual, sealed, single-dosage foil pouches that are torn open by the user. Suboxone Tablets are packaged in child-resistant bottles.

V. Anticompetitive Conduct

23. By 2010, multiple generic applicants had filed ANDAs seeking to sell generic Suboxone Tablets. Indivior, with RB Group's participation, executed two anticompetitive strategies to thwart generic competitors and extend its Suboxone monopoly.

24. First, Indivior coerced patients to switch from the tablet version to the recently introduced film. Generic Suboxone Tablets were not substitutable for Suboxone Film, and the impact of generic entry could thus be mitigated by switching patients to the film before generic Suboxone Tablets entered the market. RB Group and Indivior viewed switching to the film form as a business imperative to avoid generic competition.

25. To coerce patients to switch to the film, Indivior fabricated a "safety story" that the film's individual packaging made it safer than the tablets because it reduced the risk of accidental pediatric exposure. There was no data supporting this safety claim. The FDA had previously rejected this claim and informed Indivior that the film may in fact have a higher risk of pediatric exposure than the tablet. Indivior nonetheless promoted the sale or use of Suboxone Film with this false and misleading safety claim.

26. In addition to its "safety story," Indivior further coerced doctors and patients to switch from Suboxone Tablets to Suboxone Film by significantly increasing the price of the tablets. Indivior sold the film at a lower price than the tablet even though the film was significantly more expensive to produce. Indivior also announced in September 2012 that it would discontinue Suboxone Tablets in early 2013 due to its purported safety concerns. It sent letters to healthcare professionals informing them of this decision and advising them to switch patients to the film. On March 18, 2013, Indivior discontinued its Suboxone Tablet product.

27. Second, in September 2012, Indivior submitted a citizen petition requesting that the FDA reject any generic Suboxone Tablet applications or subject them to additional requirements because it knew doing so could delay approval of generics while the FDA reviewed it. The petition misrepresented a study that Indivior had commissioned and falsely claimed that there was evidence that the packaging of Suboxone Film reduced the risk of pediatric exposures.

28. On February 22, 2013, the FDA denied the citizen petition because the data did not support Indivior's claims. On the same day, the FDA approved two ANDAs for generic Suboxone Tablets, which entered the market in March 2013.

VI. Monopoly Power

29. The relevant market is no broader than branded and generic buprenorphine/naloxone products. Prior to 2013, branded Suboxone Tablets and branded Suboxone Film were the only buprenorphine/naloxone products available to consumers. Defendant had a 100% share of the relevant market.

30. Other opioid addiction treatments are not reasonably interchangeable with Suboxone. Methadone, which is also used to treat opioid addiction, is subject to more stringent regulatory controls and cannot be administered outside a clinic, requiring daily visits. Suboxone can be prescribed by a doctor and taken in the home. Generic Subutex Tablets, which contain

only buprenorphine, are also used to treat opioid addiction. However, Subutex does not contain the abuse deterrent naloxone and is therefore typically only prescribed to the small percentage of patients who cannot take naloxone.

31. The relevant market is protected by substantial barriers to entry. Potential new branded drug competitors need to conduct expensive clinical trials and obtain FDA approval. Potential sellers of generic Suboxone also face substantial barriers to entry, including the need to obtain FDA approval, and costly specialized equipment and facilities.

VII. Harm to Consumers and Competition

32. RB Group willfully maintained its monopoly power as to Suboxone through the wrongful and exclusionary conduct described above. This conduct had the purpose and effect of wrongfully impeding and suppressing lower-cost generic competition to Suboxone Tablets by eliminating the most cost-efficient means of competing.

33. The cost-efficient means of competition for a generic product is substitution at the pharmacy counter. As a practical matter, if a generic cannot be substituted at the pharmacy counter, the economically meaningful market for the generic product disappears. Generic substitution is based, in part, on the premise that generic products will not be promoted like brand drugs. While the generic theoretically can attempt to market a non-substitutable product directly to prescribing physicians, such a costly undertaking undermines the ability of generic companies to offer the lower prices that the federal and state regulatory framework was intended to foster. Additionally, this kind of marketing is impractical because the generic company promoting the product has no way to ensure that the pharmacist substitutes its product, rather than a competitor's.

34. The use of coercive and exclusionary conduct to convert patients from Suboxone Tablets to Suboxone Film largely foreclosed generic competitors from the most cost-effective

means of competing. By the time generic Suboxone Tablets were able to enter the market, 85% of Suboxone prescriptions were being written for the film version of Suboxone. This resulted in significant consumer harm by denying the majority of consumers and other purchasers of Suboxone meaningful access to lower-cost therapeutically equivalent versions of Suboxone.

Count I

Monopolization

1. Plaintiff re-alleges and incorporates by reference the allegations in all of the preceding paragraphs.

2. Defendant's willful maintenance of its monopoly through a course of anticompetitive conduct, including forcing the market to convert from Suboxone Tablets to Suboxone Film based on, *inter alia*, knowingly false claims related to patient safety, and submitting a meritless citizen petition to the FDA, constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Prayer for Relief

WHEREFORE, Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to issue a permanent injunction against violations of the FTC Act and, in the exercise of its equitable jurisdiction, to order ancillary equitable relief to remedy the injury caused by Defendant's violations; therefore, the FTC requests that this Court, as authorized by 15 U.S.C. § 53(b), 15 U.S.C. § 26, and its own equitable powers, enter final judgment against Defendant on Count I, declaring, ordering, and adjudging:

1. That Defendant's course of conduct, including forcing the market to convert from Suboxone Tablets to Suboxone Film based on, *inter alia*, knowingly false claims related to patient safety, and submitting a meritless citizen petition to the FDA, violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);

2. That Defendant is permanently enjoined from engaging in similar and related conduct in the future; and

3. That the Court grant such other equitable relief as the Court finds necessary, including restitution or disgorgement, to redress and prevent recurrence of Defendant's violations of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), as alleged herein.

Dated: July 11, 2019

D. BRUCE HOFFMAN
Director
Bureau of Competition

GAIL LEVINE
Deputy Director
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ALDEN ABBOTT
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Respectfully Submitted,

/s/ Markus H. Meier

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