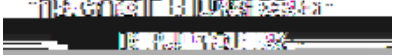


**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF VIRGINIA  
ABINGDON**

CLERKS OFFICE U.S. DIST. COURT  
AT ABINGDON, VA  
FILED  
7/11/2019  
JULIA C. DUDLEY, CLERK  


**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, SL1 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





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



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  
Bureau of Competition

ALDEN ABBOTT  
General Counsel

Respectfully Submitted,

/s/ Markus H. Meier  
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