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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH CENTRAL DIVISION

INDIVIOR INC. and INDIVIOR UK LIMITED, Plaintiffs, v. ACTAVIS LABORATORIES UT, INC., Defendant.	**COMPLAINT** Civil Action No. 2:17-cv-01034-DBP

Plaintiffs Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) ("Indivior") and Indivior UK Limited (formerly known as RB Pharmaceuticals Limited) ("Indivior UK") (collectively, "Plaintiffs") file this Complaint against Defendant Actavis Laboratories UT, Inc. ("Actavis" or "Defendant") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Actavis's submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture, use, and sell a generic

version of Plaintiffs' Suboxone® sublingual film prior to the expiration of United States Patent No. 9,687,454 ("the '454 patent" or "the patent-in-suit").

THE PARTIES

2. Plaintiff Indivior is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

3. Plaintiff Indivior UK is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.

4. On information and belief, Actavis is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 577 Chipeta Way, Salt Lake City, UT 84108.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. On information and belief, Actavis is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products in Utah and throughout the United States.

7. This Court has personal jurisdiction over Actavis because of, *inter alia*, Actavis's principal place of business in Utah; Actavis's continuous and systematic contacts with the State of Utah; Actavis's registration to do business in Utah; and its marketing and sales activities in this judicial district, including, but not limited to, the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

8. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400.

THE PATENT-IN-SUIT

9. Plaintiff Indivior UK is the lawful owner of the '454 patent, and Plaintiff Indivior is an exclusive licensee of the '454 patent. The '454 patent, entitled "Sublingual and Buccal Film Compositions," was duly and legally issued on June 27, 2017, naming Garry L. Myers, Samuel D. Hilbert, Bill J. Boone, Beuford Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan as inventors. A true copy of the '454 patent is attached hereto as Exhibit A.

SUBOXONE ® SUBLINGUAL FILM

10. Plaintiff Indivior is the holder of New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film.

11. On August 30, 2010, the FDA approved NDA No. 22-410 for the manufacture, marketing, and sale of Suboxone® sublingual film for the treatment of opioid dependence. Plaintiff Indivior has sold Suboxone® sublingual film under NDA No. 22-410 since its approval.

12. The '454 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as covering Suboxone® sublingual film.

THE DRUG APPROVAL PROCESS

13. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act" and codified at 21 U.S.C. § 355. The Hatch-Waxman Act was intended to balance two important public policy goals. First, Congress wanted to ensure that innovator drug manufacturers would have meaningful patent protection and a period of marketing exclusivity to enable them to recoup their investments in the development of valuable new drugs. Second, Congress sought to ensure that, once the patent

protection and marketing exclusivity for these drugs expire, consumers would benefit from the availability of lower priced generic versions of approved drugs.

14. Under 21 U.S.C. § 355(b)(1), the innovator drug manufacturer and NDA applicant is required to submit extensive testing and safety information concerning the drug. In addition, the NDA applicant must submit information on "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted." Once the NDA is approved, the FDA lists this patent information in the Orange Book.

15. In contrast, the Hatch-Waxman Act allows ANDA applicants to obtain FDA approval for generic versions of previously-approved drugs without having to repeat the extensive testing required for a new drug application. Under 21 U.S.C. § 355(j), ANDAs can rely on FDA's previous findings of safety and efficacy for an approved drug product, if they demonstrate, among other things, that the generic drug is bioequivalent to the previously-approved drug.

16. When a generic manufacturer submits an ANDA, the FDA conducts a preliminary review of the application to ensure it is sufficiently complete to permit a substantive review. *See* 21 C.F.R. § 314.101(b)(1). "Receipt of an [ANDA] means that FDA has made a threshold determination that the abbreviated application is sufficiently complete to permit a substantive review." *Id.*

17. Under 21 U.S.C. § 355(j)(2)(A)(vii), the ANDA must also include one of the following four certifications with respect to each of the patents listed in the Orange Book for the previously-approved drug product: (i) that the patent information has not been filed ("Paragraph

I" certifications); (ii) that the patent has expired ("Paragraph II" certifications); (iii) that the patent will expire on a specific date, and the generic will stay off the market until that date ("Paragraph III" certifications); or (iv) that the "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" ("Paragraph IV" certifications).

18. If the ANDA includes a Paragraph IV certification, the Hatch-Waxman Act requires the ANDA applicant to give notice to the patent owner of the factual and legal basis for the applicant's opinion that patents listed in the Orange Book are invalid or will not be infringed ("Notification Letter"), "not later than 20 days after the date of the postmark on the notice with which the [FDA] informs the applicant that the application has been filed." 21 U.S.C. § 355(j)(2)(B).

19. If the patent owner files an infringement action within 45 days of receiving the Notification Letter, a 30-month injunction or stay of the FDA approval is triggered, calculated from the date of receipt of the Notification Letter. *See* 21 U.S.C. § 355(j)(5)(B)(iii). This 30-month period is intended to allow time for judicial resolution on the merits of any patent infringement, validity, and/or enforceability claims, before the competitor is allowed entry into the market.

ACTAVIS'S PARAGRAPH IV NOTICE

20. Plaintiffs received Notification Letters from Actavis dated August 2, 2017 and August 24, 2017, stating that ANDA Nos. 204383 and 207087 contain Paragraph IV certifications alleging that the '454 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

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