IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INDIVIOR INC., INDIVIOR UK LIMITED, and AQUESTIVE THERAPEUTICS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 18-497 (RGA)
ACTAVIS LABORATORIES UT, INC.,	)	
Defendant.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) ("Indivior"), Indivior UK Limited (formerly known as RB Pharmaceuticals Limited) ("Indivior UK"), and Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx LLC) ("Aquestive") (collectively, "Plaintiffs") file this Complaint against Defendant Actavis Laboratories UT, Inc. ("Actavis") 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 Abbreviated New Drug Applications ("ANDAs") 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 Nos. 9,931,305 ("the '305 patent") and 9,855,221 ("the '221 patent") (collectively, "the patents-in-suit").

THE PARTIES

2. Plaintiff Indivior is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, North Chesterfield, VA 23235.

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

4. Plaintiff Aquestive is a Delaware corporation having a principal place of business at 30 Technology Drive, Warren, New Jersey 07059.

5. 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

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

7. 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 Delaware and throughout the United States.

8. This Court has personal jurisdiction over Actavis because of, *inter alia*, Actavis's incorporation in Delaware; Actavis's continuous and systematic contacts within this judicial district; its previous submission to the jurisdiction of this judicial district; 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.

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

THE PATENTS-IN-SUIT

10. Plaintiff Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx LLC) is the lawful owner of the '305 patent, and Plaintiff Indivior is an exclusive licensee of the '305 patent and holds the exclusionary rights to market and sell Suboxone® sublingual film in the United States. The '305 patent, entitled "Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions," was duly and legally issued on April 3, 2018, naming Robert Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the '305 patent is attached hereto as Exhibit A.

11. Plaintiff Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx LLC) is the lawful owner of the '221 patent, and Plaintiff Indivior is an exclusive licensee of the '221 patent. The '221 patent, entitled "Uniform Films for Rapid-Dissolve Dosage Form Incorporating Anti-Tacking Compositions," was duly and legally issued on January 2, 2018, naming Garry L. Myers, Pradeep Sanghvi, Andrew Philip Verrall, Vimala Francis, and Laura Brooks as inventors. A true copy of the '221 patent is attached hereto as Exhibit B.

SUBOXONE® SUBLINGUAL FILM

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

13. 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.

14. The '305 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as covering Suboxone® sublingual film.

15. The '221 patent is listed in the Orange Book as covering Suboxone® sublingual film.

ACTAVIS'S INFRINGING GENERIC PRODUCT

16. Actavis submitted ANDA Nos. 204383 and 207087 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of Actavis's generic product before expiration of the patents-in-suit.

17. ANDA Nos. 204383 and 207087 refer to and rely on Plaintiffs' NDA for Suboxone® sublingual film and purports to contain data showing bioequivalence of Actavis's generic product with Suboxone® sublingual film.

ACTAVIS'S PARAGRAPH IV NOTICE

18. Plaintiffs received Notification Letters from Actavis dated March 8, 2018, stating that ANDA Nos. 204383 and 207087 contain Paragraph IV certifications alleging that the '221 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

19. The Notification Letters further state that Actavis submitted ANDA Nos. 204383 and 207087 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of Actavis's generic product before expiration of the '221 patent. On information and belief, ANDA Nos. 204383 and 207087 concern dosages of Actavis's generic product and refer to and rely on Plaintiff Indivior's NDA for Suboxone® sublingual film and purport to contain data showing bioequivalence of Actavis's generic product with Suboxone® sublingual film.

COUNT 1
INFRINGEMENT OF THE '305 PATENT UNDER 35 U.S.C. § 271(E)(2)

20. On information and belief, Actavis's generic product is covered by one or more claims, including at least claim 26, of the '305 patent.

21. By filing ANDA Nos. 204383 and 207087 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, and/or sale of Actavis's generic product prior to the expiration of the '305 patent, Actavis has committed acts of infringement of the '305 patent under 35 U.S.C. § 271(e)(2).

22. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA Nos. 204383 and 207087 to be a date which is not any earlier than the expiration date of the '305 patent, including any extensions of that date.

COUNT 2
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '305 PATENT UNDER 35 U.S.C. § 271

23. On information and belief, unless enjoined by this Court, Actavis plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Actavis's generic product immediately following approval of ANDA Nos. 204383 and 207087.

24. On information and belief, Actavis's manufacture, use, offer to sell, or sale within the United States, or importation into the United States of Actavis's generic product before the expiration of the '305 patent would infringe one or more claims, including at least claim 26, of the '305 patent under 35 U.S.C. § 271.

25. The acts of infringement by Actavis set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

COUNT 3
INFRINGEMENT OF THE '221 PATENT UNDER 35 U.S.C. § 271(E)(2)

26. On information and belief, Actavis's generic product is covered by one or more claims, including at least claims 1 and 8, of the '221 patent.

27. By filing ANDA Nos. 204383 and 207087 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, and/or sale of Actavis's generic product prior to the expiration of the '221 patent, Actavis has committed acts of infringement of the '221 patent under 35 U.S.C. § 271(e)(2).

28. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA Nos. 204383 and 207087 to be a date which is not any earlier than the expiration date of the '221 patent, including any extensions of that date.

COUNT 4
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '221 PATENT UNDER 35 U.S.C. § 271

29. On information and belief, unless enjoined by this Court, Actavis plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Actavis's generic product immediately following approval of ANDA Nos. 204383 and 207087.

30. On information and belief, Actavis's manufacture, use, offer to sell, or sale within the United States, or importation into the United States of Actavis's generic product before the expiration of the '221 patent would infringe one or more claims, including at least claims 1 and 8, of the '221 patent under 35 U.S.C. § 271.

31. The acts of infringement by Actavis set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter:

A. A judgment that Actavis has infringed the '305 patent under 35 U.S.C. § 271(e)(2) by submitting and maintaining ANDA Nos. 204383 and 207087;

B. A declaratory judgment that Actavis's manufacture, use, offer to sell, or sale within the United States, or importation into the United States of Actavis's generic product would infringe the '305 patent under 35 U.S.C. § 271;

C. A judgment that Actavis has infringed the '221 patent under 35 U.S.C. § 271(e)(2) by submitting and maintaining ANDA Nos. 204383 and 207087;

D. A declaratory judgment that Actavis's manufacture, use, offer to sell, or sale within the United States, or importation into the United States of Actavis's generic product would infringe the '221 patent under 35 U.S.C. § 271;

E. Preliminary and permanent injunctions, restraining and enjoining Actavis, its officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in, causing, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs and formulations, or from inducing and/or encouraging the use of methods, claimed in the patents-in-suit;

F. An order that the effective date of any approval of ANDA Nos. 204383 and 207087 be a date that is not earlier than the expiration of the patents-in-suit, including any extensions thereof and any later expiration of exclusivity associated with the '305 patent and/or

'221 patent;

G. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys' fees;

H. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Actavis commercially manufactures, uses, offers to sell, or sells in the United States, or imports into the United States, Actavis's generic product before the expiration of the patents-in-suit, including any extensions; and

I. Any and all other relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
jtigan@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Daniel A. Ladow
James M. Bollinger
Timothy P. Heaton
J. Magnus Essunger
Sujatha Vathyam
TROUTMAN SANDERS LLP
875 Third Avenue
New York, NY 10022
(212) 704-6000

Charanjit Brahma
TROUTMAN SANDERS LLP
580 California Street, Suite 1100
San Francisco, CA 94104
(415) 477-5700

Erica N. Andersen
Jeffrey B. Elikan
Jeffrey H. Lerner
Ashley M. Kwon
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, D.C. 20001
(202) 662-6000

Attorneys for Indivior Inc. & Indivior UK Limited

Cassandra A. Adams
STEPTOE & JOHNSON LLP
1114 Avenue of the Americas
New York, NY 10036
(212) 506-3900

James F. Hibey
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, NW
Washington, DC 20036
(212) 429-3000

Jamie Lucia
STEPTOE & JOHNSON LLP
1 Market Street
Steuart Tower, Suite 1800
San Francisco, CA 94105
(415) 365-6711

Attorneys for Aquestive Therapeutics, Inc.

April 30, 2018
11857404