IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INDIVIOR INC., INDIVIOR UK LIMITED, and MONOSOL RX, LLC,	)	
	)	CA. No. _____
Plaintiffs,	)	
v.	)	
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Indivior Inc. f/k/a Reckitt Benckiser Pharmaceuticals Inc. ("Indivior"), Indivior UK Limited f/k/a RB Pharmaceuticals Limited ("Indivior UK"), and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") file this Complaint against Defendant Teva Pharmaceuticals USA, Inc. ("Defendant") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement related to United States Patent Nos. 8,475,832 ("the '832 patent"), 8,017,150 ("the '150 patent"), 8,603,514 ("the '514 patent"), 8,900,497 ("the '497 patent"), and 8,906,277 ("the '277 patent") (collectively, "the patents-in-suit") 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 Defendant's submission of a New Drug Application ("NDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a 16mg/4mg formulation of a generic version of Plaintiff Indivior's Suboxone® sublingual film prior to the expiration of the patents asserted herein.

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. Plaintiff MonoSol is a Delaware limited liability corporation having a principal place of business at 30 Technology Drive, Warren, New Jersey.

5. On information and belief, Defendant is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania.

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, Defendant 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 Defendant because of, *inter alia*, Defendant's incorporation in Delaware; its continuous and systematic contacts with corporate entities within this judicial district; its previous submission to the jurisdiction of this judicial district, including in a related, pending action (*see Reckitt Benckiser Pharmaceuticals Inc., et al. v. Teva Pharmaceuticals USA Inc.*, CA. No. 14-01451-RGA); 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 Indivior UK is the lawful owner of the ’832 patent, and Plaintiff Indivior is an exclusive licensee of the ’832 patent. The ’832 patent, entitled “Sublingual and Buccal Film Compositions,” duly and legally issued on July 2, 2013, naming Garry L. Myers, Samuel D. Hilbert, Bill J. Boone, B. Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan as inventors. A true copy of the ’832 patent is attached hereto as Exhibit A.

11. Plaintiff MonoSol is the lawful owner of the ’150 patent, and Plaintiff Indivior is an exclusive licensee of the ’150 patent. The ’150 patent, entitled “Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom,” duly and legally issued on September 13, 2011, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the ’150 patent is attached hereto as Exhibit B.

12. Plaintiff MonoSol is the lawful owner of the ’514 patent, and Plaintiff Indivior is an exclusive licensee of the ’514 patent. The ’514 patent, entitled “Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions,” duly and legally issued on December 10, 2013, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the ’514 patent is attached hereto as Exhibit C.

13. Plaintiff MonoSol is the lawful owner of the ’497 patent, and Plaintiff Indivior is an exclusive licensee of the ’497 patent. The ’497 patent, entitled “Process for Making a Film Having a Substantially Uniform Distribution of Components,” duly and legally issued on December 2, 2014, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the ’497 patent is attached hereto as Exhibit D.

14. Plaintiff MonoSol is the lawful owner of the ’277 patent, and Plaintiff Indivior is an exclusive licensee of the ’277 patent. The ’277 patent, entitled “Process for Manufacturing a Resulting Pharmaceutical Film,” duly and legally issued on December 9, 2014, naming Robert

K. Yang, Richard C. Fuisz, Garry L. Myers, and Joesph M. Fuisz as inventors. A true copy of the ’277 patent is attached hereto as Exhibit E.

SUBOXONE® SUBLINGUAL FILM

15. Plaintiff Indivior is the holder of NDA No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film.

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

17. The ’832 patent, the ’150 patent, and the ’514 patent (collectively, the “Listed Patents”) are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) as covering Suboxone® sublingual film.

THE DRUG APPROVAL PROCESS

18. 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.

19. 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.

20. In contrast, the Hatch-Waxman Act allows Abbreviated New Drug Application ("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 the 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.

21. 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.*

22. 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 ("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" ("ANDA Paragraph IV" certifications).

23. ANDA Paragraph IV certifications can allow generic manufacturers to obtain FDA approval long before expiration of the patents listed in the Orange Book.

24. If the ANDA includes an ANDA Paragraph IV certification, the Hatch-Waxman Act requires the ANDA applicant to give notice ("notice of ANDA Paragraph IV certification") 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, "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)(ii)(I).

25. The patent owner can file an infringement action within 45 days of receiving the notice of ANDA Paragraph IV certification. Such a filing by the patent owner triggers a 30-month injunction or stay of the FDA approval, beginning on the date of receipt of the notice. *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.

26. Federal regulations also govern the timing of the notice of ANDA Paragraph IV certification by directing the generic manufacturer to send such notice "when it receives from FDA an acknowledgment letter stating that its [ANDA] is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.95(b).

27. Similar to the ANDA process, Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(2) ("Section 505(b)(2)"), permits an applicant to submit a NDA "for a drug which the investigations . . . relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted . . . ." 21 U.S.C. § 355(b)(2).

28. In parallel to 21 U.S.C. § 355(j)(2)(A)(vii), a NDA submitted under Section

505(b)(2) must also include "a certification . . . with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval . . ." including: (i) that the patent information has not been filed ("505(b)(2) Paragraph I" certifications); (ii) that the patent has expired ("505(b)(2) Paragraph II" certifications); (iii) that the patent will expire on a specific date ("505(b)(2) 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" ("505(b)(2) Paragraph IV" certifications). 21 U.S.C. § 355(b)(2)(A)(i-iv).

29. If the Section 505(b)(2) NDA includes a 505(b)(2) Paragraph IV certification, the Hatch-Waxman Act requires the applicant to give notice ("notice of 505(b)(2) Paragraph IV certification") to the patent owner of the factual and legal basis for the applicant's opinion that patents listed are invalid or will not be infringed, "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(b)(3)(B).

30. The patent owner can file an infringement action within 45 days of receiving the notice of 505(b)(2) Paragraph IV certification. Such a filing by the patent owner triggers a 30-month injunction or stay of the FDA approval, beginning on the date of receipt of the notice. *See* 21 U.S.C. § 355(c)(3)(C). 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.

DEFENDANT'S ANDAs

31. Plaintiffs received two letters from Defendant dated October 17, 2014 (the "ANDA Notification Letters"), stating that ANDA Nos. 205299 and 205806 were submitted to the FDA and containing ANDA Paragraph IV certifications alleging that the Listed Patents are

invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDAs.

32. The ANDA Notification Letters further state that Defendant submitted ANDA Nos. 205299 and 205806 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and/or sale of buprenorphine hydrochloride and naloxone hydrochloride sublingual film ("Defendant's generic product") before expiration of the Listed Patents. On information and belief, ANDA Nos. 205299 and 205806 concern respective dosages of Defendant'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 Defendant's generic product with Suboxone® sublingual film.

33. On December 2, 2014, which was within 45 days of Plaintiffs' receipt of the ANDA Notification Letters, Plaintiffs commenced a patent infringement action in this Court against Defendant related to the Listed Patents arising from Defendant's ANDA Nos. 205299 and 205806 (*see Reckitt Benckiser Pharmaceuticals Inc. et al. v. Teva Pharmaceuticals USA Inc.*, CA. No. 14-01451-RGA).

DEFENDANT'S NDA

34. Plaintiffs received a letter from Defendant dated February 8, 2016 (the "NDA Notification Letter"), stating that NDA No. 208042 was submitted to the FDA and contains a 505(b)(2) Paragraph IV certification alleging that the Listed Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the NDA.

35. The NDA Notification Letter further states that Defendant submitted NDA No. 208042 to the FDA under Section 505(b)(2), seeking approval to engage in the commercial

manufacture, use, and/or sale of a 16mg/4mg formulation of Defendant's generic product before expiration of the Listed Patents. On information and belief, NDA No. 208042 refers to and relies on Plaintiff Indivior's NDA for Suboxone® sublingual film and purports to contain data showing bioequivalence of Defendant's generic product with Suboxone® sublingual film.

COUNT I
(Infringement of the '832 Patent Under 35 U.S.C. § 271(e)(2))

36. Plaintiffs reallege paragraphs 1–35 above as if fully set forth herein.

37. On information and belief, the 16mg/4mg formulation of Defendant's generic product is covered by one or more claims of the '832 patent.

38. By filing NDA No. 208042 under 21 U.S.C. § 355(b)(3)(D)(i) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of a 16mg/4mg formulation of Defendant's generic product prior to the expiration of the '832 patent, Defendant has committed an act of infringement of the '832 patent under 35 U.S.C. § 271(e)(2).

39. 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 NDA No. 208042 to be a date which is not any earlier than the expiration date of the '832 patent, including any extensions of that date.

COUNT II
(Infringement of the '150 Patent Under 35 U.S.C. § 271(e)(2))

40. Plaintiffs reallege paragraphs 1–39 above as if fully set forth herein.

41. On information and belief, the 16mg/4mg formulation of Defendant's generic product is covered by one or more claims of the '150 patent.

42. By filing NDA No. 208042 under 21 U.S.C. § 355(b)(3)(D)(i) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of a 16mg/4mg formulation of Defendant's generic product prior to the expiration of the '150 patent,

Defendant has committed an act of infringement of the ’150 patent under 35 U.S.C. § 271(e)(2).

43. 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 NDA No. 208042 to be a date which is not any earlier than the expiration date of the ’150 patent, including any extensions of that date.

COUNT III
(Infringement of the ’514 Patent Under 35 U.S.C. § 271(e)(2))

44. Plaintiffs reallege paragraphs 1–43 above as if fully set forth herein.

45. On information and belief, the16mg/4mg formulation of Defendants’ generic product is covered by one or more claims of the ’514 patent.

46. By filing NDA No. 208042 under 21 U.S.C. § 355(b)(3)(D)(i) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of a 16mg/4mg formulation of Defendant’s generic product prior to the expiration of the ’514 patent, Defendant has committed an act of infringement of the ’514 patent under 35 U.S.C. § 271(e)(2).

47. 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 NDA No. 208042 to be a date which is not any earlier than the expiration date of the ’514 patent, including any extensions of that date.

COUNT IV
(Declaratory Judgment of Infringement of the ’497 Patent Under 35 U.S.C. § 271)

48. Plaintiffs reallege paragraphs 1–47 above as if fully set forth herein.

49. On information and belief, unless enjoined by this Court, Defendant plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of a 16mg/4mg formulation of Defendant’s generic product immediately following approval of NDA No. 208042.

50. On information and belief, Defendant's commercial manufacture of a 16mg/4mg formulation of Defendant's generic product before the expiration of the '497 patent would infringe one or more claims of the '497 patent under 35 U.S.C. § 271.

51. The acts of infringement by Defendant 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 V
(Declaratory Judgment of Infringement of the '277 Patent Under 35 U.S.C. § 271)

52. Plaintiffs reallege paragraphs 1–51 as if fully set forth herein.

53. On information and belief, unless enjoined by this Court, Defendant plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of a 16mg/4mg formulation of Defendant's generic product immediately following approval of NDA No. 208042.

54. On information and belief, Defendant's commercial manufacture of a 16mg/4mg formulation of Defendant's generic product before the expiration of the '277 patent would infringe one or more claims of the '277 patent under 35 U.S.C. § 271.

55. The acts of infringement by Defendant 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 Defendant has infringed each of the Listed Patents under 35 U.S.C. § 271(e)(2) by submitting and maintaining NDA No. 208042;

B. A declaratory judgment that Defendant's commercial manufacture within the

United States of a 16mg/4mg formulation of Defendant's generic product would infringe the '497 and '277 patents under 35 U.S.C. § 271;

C. Preliminary and permanent injunctions, restraining and enjoining Defendant, its officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with it, 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;

D. An order that the effective date of any approval of NDA No. 208042 be a date that is not earlier than the expiration of the last to expire of the Listed Patents, including any extensions thereof and any later expiration of exclusivity associated with those patents;

E. 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;

F. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Defendant commercially manufactures, uses, offers to sell, or sells in the United States, or imports into the United States, a 16mg/4mg formulation of Defendant's generic product before the expiration of each patent-in-suit that Defendant is found to infringe, including any extensions; and

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

Dated: March 21, 2016

Respectfully Submitted,

/s/ Mary W. Bourke

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