

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

RECKITT BENCKISER)	
PHARMACEUTICALS INC., RB)	
PHARMACEUTICALS LIMITED, and)	
MONOSOL RX, LLC,)	
)	
Plaintiffs,)	CA. No. 14-1451-RGA
v.)	
TEVA PHARMACEUTICALS USA, INC.,)	
)	
Defendant.)	

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Reckitt Benckiser Pharmaceuticals Inc. (“RBP”), RB Pharmaceuticals Limited (“RBP UK”), and MonoSol Rx, LLC (“MonoSol”) (collectively, “Plaintiffs”) file this Complaint against Defendant Teva Pharmaceuticals USA, Inc. (“Teva” or “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 Abbreviated New Drug Applications (“ANDAs”) to the Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of Plaintiff RBP's Suboxone® sublingual film prior to the expiration of the patents asserted herein.

THE PARTIES

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

3. Plaintiff RBP 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 Teva is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, 19454.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 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 Teva because of, *inter alia*, Teva'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, 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 RBP UK is the lawful owner of the '832 patent, and Plaintiff RBP 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 RBP 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 RBP 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 RBP 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 RBP 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 Joseph M. Fuisz as inventors. A true copy of the '277 patent is attached hereto as Exhibit E.

SUBOXONE® SUBLINGUAL FILM

15. Plaintiff RBP is the holder of New Drug Application (“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 RBP 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 its Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the “Orange Book.”

20. 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.

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” (“Paragraph IV” certifications).

23. 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 a Paragraph IV certification, the Hatch-Waxman Act requires the ANDA applicant to give notice (“notice of 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).

25. The patent owner can file an infringement action within 45 days of receiving the notice of 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 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).

DEFENDANT’S ANDAs

27. Plaintiffs received letters from Defendant dated October 17, 2014 (the “Notification Letters”), stating that Abbreviated New Drug Application (“ANDA”) Nos. 205299 and 205806 were submitted to the United States Food and Drug Administration (“FDA”) and contain certifications pursuant to 21 U.S.C. § 355(j)(2)(B)(vii)(IV) (a “Paragraph IV certification”) alleging that the ‘832, ‘150 and ‘514 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the

ANDAs.

28. The 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 patents-in-suit. On information and belief, ANDA Nos. 205299 and 205806 concern respective dosages of Defendant’s generic product and refer to and rely on Plaintiff RBP’s NDA for Suboxone® sublingual film and purport to contain data showing bioequivalence of Defendant’s generic product with Suboxone® sublingual film.

29. Plaintiffs commenced this action on December 2, 2014, within 45 days of receiving the Notification Letters.

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

30. Plaintiffs reallege paragraphs 1-29 above as if fully set forth herein.

31. On information and belief, Defendant’s generic product is covered by one or more claims of the ‘832 patent.

32. By filing ANDA Nos. 205299 and 205806 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation 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).

33. 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. 205299 and 205806 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))

34. Plaintiffs reallege paragraphs 1-33 above as if fully set forth herein.

35. On information and belief, Defendant's generic product is covered by one or more claims of the '150 patent.

36. By filing ANDA Nos. 205299 and 205806 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation 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).

37. 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. 205299 and 205806 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))

38. Plaintiffs reallege paragraphs 1-37 above as if fully set forth herein.

39. On information and belief, Defendants' generic product is covered by one or more claims of the '514 patent.

40. ANDA Nos. 205299 and 205806 under 21 U.S.C. § 355(j) seek to obtain approval to engage in the commercial manufacture, use, sale and/or importation of Defendants' generic product prior to the expiration of the '514 patent. Therefore, Defendants' maintenance of these filings constitutes an act of infringement of the '514 patent under 35 U.S.C. § 271(e)(2).

41. 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. 205299 and 205806 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)

42. Plaintiffs reallege paragraphs 1-41 above as if fully set forth herein.

43. 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 Defendant’s generic product immediately following approval of ANDA Nos. 205299 and 205806.

44. On information and belief, Defendant’s commercial manufacture 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.

45. 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)

46. Plaintiffs reallege paragraphs 1-45 as if fully set forth herein.

47. 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 Defendant’s generic product immediately following approval of ANDA Nos. 205299 and 205806.

48. On information and belief, Defendant’s commercial manufacture 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.

49. 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 ANDA Nos. 205299 and 205806;
- B. A declaratory judgment that Defendant's commercial manufacture within the United States 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 ANDA Nos. 205299 and 205806 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, 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: May 13, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 13th day of May, 2015, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on the following counsel of record via electronic mail:

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